THE ECONOMIC COST OF PAD, CLI & VENOUS DISEASE: HOW BIG IS THE MARKET?

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Disclosures

Honorarium:
• Cardiovascular Systems Inc.

Consultant:
• Cardiovascular Systems Inc.

Purchased Research:
• Boston Scientific India
• Medtronic
2015 U.S. PREVALENCE OF MAJOR DISEASES (Millions)

- Alzheimers: 5.4
- Stroke: 6.8
- Cancer: 13.7
- CHD: 15.4
- PAD: 19.5
- Diabetes: 29.1
- Venous: 40

Source: Alzheimer’s Assoc, ACS, AHA, ADA, Pappas Yost CLI V.I and THE SAGE GROUP estimates.
## COMPARISON OF US PAD ESTIMATES—2015

<table>
<thead>
<tr>
<th>YEAR</th>
<th>CRIQUI/ PARTNERS (Mill)</th>
<th>DIABETES METHOD (Mill)</th>
<th>NEHLER (Mill)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>11-18</td>
<td>20</td>
<td>17</td>
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PAD ANNUAL ECONOMIC BURDEN*

$213† - $392‡ BILLION

*Total Costs Inpatient and Outpatient in 2015

†U.S. REACH population inpatient costs + outpatient medication = $10,931 X 19.5 Mil PAD in 2015
‡Margolis managed care population all-cause hospitalizations + medications + other = $20,095 x 19.5 Mil PAD. Per pt. costs in 2014 $.

HOSPITAL COSTS REPRESENT MAJORITY OF PAD COSTS

NON-PAD COSTS ARE SIGNIFICANT

Cardiovascular Hospitalizations
- PAD: 57%
- CVD: 43%

All-Cause Hospitalizations
- PAD: 10%
- NON-PAD: 90%

WHO PAYS THE PAD BILL?

2013 PAD Patient Discharges by Payer

- Medicare: 75%
- Medicaid: 7%
- Private: 13%
- Other: 5%

Source: HCUP Query. Diagnosis codes for PAD.
7%-10% Medicare Patients Treated for PAD (2001-2005)

$22,179-$70,331* Expenditure per Patient
(Range reflects definition of PAD and types of treatments included, i.e. LT Care)

AK Amputation
Third Most Commonly Performed Procedure

Total Medicare PAD Bill $82-$372B*

*2014 $ X 2014 Medicare beneficiaries w/ PAD

2015 ANNUAL MEDICARE EXPENDITURES*

*Costs updated to 2014 $

2015 ANNUAL ECONOMIC BURDEN* (Billions $)

*Direct costs in the United States: PAD & CAD costs inflated to 2014 $.
CLI PREVALENCE & COST 2015

2-3 Million

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

Cost $40-$66 Billion

CLI “IDEAL” TREATMENT PATHWAY

SVS & ESVS Recommendation

- Revascularization: 70%
- Primary Amputation: 15%
- Palliative Wound Care: 15%

Source: Allie 2005 and Hallett.
25%-33% CLI patients undergo primary amputation (PA)

65,000-75,000 major amputations performed annually

CLI - PATHWAY TO AMPUTATION

- Frequently the first and only therapy for CLI
- 51%-73% No Angiogram—Despite fact that angio the odds by 90%
- 60%-71% No Revascularization

Probability of major amputation depends on who you are and where you live

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

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

MAJOR AMPUTATION ANNUAL ECONOMIC COST*

$11 BILLION

*Total Direct Inpatient and Outpatient Costs in 2014 $
TOTAL AMPUTATIONS 209,000 COST $28.2 Bill

2014 Amputation Cost by Type

- Minor Amputation: $17.6 B
- Major Amputation: $10.6 B

Source: Dillingham 2005, HCUP Queries Amputation, Medicare 5% sample. THE SAGE GROUP estimates.
Cost Estimate Does Not Include:

- **Patient Costs**
  - Inability of patient and/or family caregivers to work, lost wages—average lifetime cost of caregiving $300,000
  - Unreimbursed costs (deductibles & copayments for rehab, NH etc.)—NH costs $81,000-$91,000, only 100 days reimbursed by Medicare
  - Modifications for disabled living (handrails, wheelchair ramp, wheelchair-amenable transportation, toilet seats etc.)

- **Economic Cost of Death to Society**

*Source: Yost Endovascular Today 2014.*
CONCLUSIONS PAD

- PAD IS HIGHLY PREVALENT AND COMMONLY UNDERESTIMATED

- PAD MACROECONOMIC COST IS HIGH $213-$392B

- 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
VENOUS DISEASE

CHRONIC VENOUS INSUFFICIENCY (CVI)

VENOUS THROMBOLISM (VTE):

DEEP VEIN THROMBOSIS (DVT)
PULMONARY EMBOLISM (PE)
## CVI

### PREVALENCE

<table>
<thead>
<tr>
<th>Condition</th>
<th>Prevalence</th>
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<tbody>
<tr>
<td>Varicose Veins</td>
<td>25-50 Mill</td>
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<tr>
<td>More Severe Disease*</td>
<td>6-14 Mill</td>
</tr>
<tr>
<td>Venous Ulcers</td>
<td>2.4-3.8 Mill</td>
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<td>(1%-4%)</td>
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<tr>
<td>Total CVI</td>
<td>33-68 Mill</td>
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*Persistent ambulatory venous hypertension, pain, edema, skin changes & ulcers

VENOUS ULCERS

ANNUAL INCIDENCE
600,000-2 MILLION*
Rate 0.2%-2.2%

INCIDENCE INCREASES W/ AGE
(2%-4% in 65+)

*Rice study of 2007-2011 annual claims data in Medicare and private insurance database.

2015 TREATMENT COST
$10-46 BILL*

* Annual per patient costs of $17,568-$22,721 in 2015 $.

Source: Rice 2014, Olin 1999, Ma 2014 and THE SAGE GROUP.
VENOUS ULCERS

COSTS OF LOWER PRODUCTIVITY DUE TO

- DISABILITY
- MEDICALLY RELATED ABSENTEEISM
- UNEMPLOYMENT
- FORCED EARLY RETIREMENT

- 2 to 4.6 MILLION WORKDAYS LOST ANNUALLY

- VLU PATIENTS LOST 40% MORE WORKDAYS OR 14 DAYS/YEAR ON AVERAGE @ COST $2,672*

*2015$

VENOUS ULCERS

PATIENT COSTS
- Ulcer Management expense—14% Weekly Income
- Unemployment
- 12.5% VLU Workers Forced to Retire Early

REDUCED QUALITY OF LIFE
- Ulcer Treatment Burdensome & Time Consuming
- Chronic Pain: Sleep Loss
- Reduced Mobility 81%-93%: Problems Daily Living, Self Care, Inability to Work & Inability to Exercise
- Odor, Swelling, Discharge
- Negative Emotional Impact: Fear, Depression, Social Isolation

VENOUS ULCER COSTS BY TREATMENT LOCATION

- Home HC VNA + Dressings: 35%
- Outpatient: 43%
- Inpatient: 22%

Source: Ma 2014.
VENOUS ULCERS - POOR HEALING RATES

6 MO  35%-50% UNHEALED

2 YEARS  20% UNHEALED

POOR HEALING COSTS

Monthly Treatment Cost ≈ $2,900

Source: Hankin 2012 and Ma 2014.
ULCER COST*—HEALED VS NONHEALED

*Costs inflated to 2015 $.

Source: Ma 2015.
VENOUS ULCERS—FACTORS INCREASING COSTS

- LENGTH OF TIME TO HEAL
- HOSPITALIZATION
- ULCER SIZE
- ULCER DURATION
- RECURRENT ULCER

ULCER COST*—OUTPATIENT VS INPATIENT

*Costs 2011$.

Source: Ma 2015.
VTE

900,000-1,100,000 CASES

CLINICAL PRESENTATION:
DVT 60-70%, PE 17%-30% Both 11%-15%

MORTALITY:
30 DAY—10%-30%

20%-25% OF PE CASES PRESENT AS SUDDEN DEATH
RESULTING IN 60,000-100,000 VTE DEATHS

ECONOMIC COST
$14-$69 BILLION*
36%-57% ARE PREVENTABLE COSTS

*2011 $
ADEQUATE PROPHYLAXIS REDUCES VTE
- Fatal PE ↓ 62%
- DVT ↓ 53%

60% CASES ARE HOSPITAL & NURSING HOME PTS

52% HOSPITAL PTS AT RISK FOR VTE & 93% OF MAJOR SURGERY PTS

YET ONLY 33%-60% OF HOSPITAL PTS RECEIVE PROPHYLAXIS

VTE COSTS

Source: Lin 2014.
RECURRENCE RATES:
1 YEAR    4%-15%
10 YEAR    33%

RECURRENT VTE COSTS 2.2X-3.4X MORE DUE TO INCREASED:
Hospitalizations
LOS
ER Visits
Total Costs

RECURRENT VTE COST $11,000* MORE THAN PRIMARY

*2014 $
VTE COMPLICATIONS

- POST-THROMBOTIC SYNDROME (PTS)
  30%-50% DVT PTS

- HEPARIN INDUCED THROMBOCYTOPENIA (HIT)
  0.5%-5%

- CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH)
  1%-5%

- BLEEDING
  1% Major 1.4% Minor

COMPLICATIONS INCREASE TOTAL COSTS

- PTS COSTS ADDS $1,104-$7,800*
- HIT COSTS ADD $5,000-$7,000*
- CTEPH COSTS ADD $4,942*
- BLEEDING COSTS ADD
  Major $9,900-$22,800 & Minor $120-$3,500**

*Incremental treatment cost in 2014$.
**Average direct treatment costs in 2014$.

Source: Grosse 2015.
2015 ANNUAL COST OF CLI, VLU & VTE ($ IN BILLIONS)

Source: THE SAGE GROUP estimates.
FIVE-YEAR ALL-CAUSE MORTALITY %

*1-10 Year mortality.

CONCLUSIONS VENOUS

- AT 40+ MILL VENOUS DISEASE IS LIKELY THE MOST COMMON CHRONIC DISEASE

- VENOUS ULCERS COST $10-$46 BILL ANNUALLY

- VTE HIGHLY PREVALENT & COSTLY—$14-$69 BILL

- MAJORITY OF VTE OCCURS IN HOSPITAL & NH—BUT NOT ADEQUATELY PREVENTED

- RECURRENT VTE AND COMPLICATIONS ADD SIGNIFICANTLY TO MORBIDITY, MORTALITY & COSTS
THANK YOU!

CAT ISLAND * BEAUFORT, SC
REFERENCES

ACS American Cancer Society website.
ADA American Diabetes Association website.
AHA American Heart Association.
Alzheimer’s Association 2010 facts & figures.
Baser. Vasc Dis Mgmt 2013: 10(20); E26-36.
Bongiovanni CM. Angiology 2006; 57:139-144.
Eberhardt RT. Circulation 2014;130:333-346.
Grosse SD. Thromb Res. 2016 Jan;137:3-10.
HCUP Query. ICD-9 diagnosis codes PAD 440.20-29, 443.9 & 443.81.
HCUP Query. ICD-9 procedure codes 84.14-84.17 & 84.3.
HCUP Query. ICD-9 procedure codes 84.11-84.13.
REFERENCES

Heber OR. Health Qual Life Outcomes 2007;5:44
Sogaard KK. Circulation 2014; 130:829-36.
REFERENCES

Medicare 5% sample
Ozaki A. Venous thromboembolism. Cleveland Clinic
http://www.clevelandclinicmeded.com/medicalpubs/dISEasemanagement/cardiology/venous-
thromboembolism
REFERENCES

Smith E. Wound Practice Research 2010; 18(3):134-139.
Søgaard KK. Circulation. 2014 Sep 2;130(10):829-36.
Yost ML. The real cost of peripheral artery disease. THE SAGE GROUP. 2011.