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

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The Business of Peripheral Interventions
Disclosures

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

- Alzheimers: 5.4
- Stroke: 6.8
- Cancer: 13.7
- CHD: 15.5
- PAD: 19.8
- Diabetes: 35.5
- CVD C1-C6: 175

## 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>17</td>
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PAD ANNUAL ECONOMIC BURDEN*

$216†- $398‡ BILLION

*Total Costs Inpatient and Outpatient in 2015

†U.S. REACH population inpatient costs + outpatient medication = $10,931 X 19.8 Mil PAD in 2015
‡Margolis managed care population all-cause hospitalizations + medications + other = $20,095 x 19.8 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%
- Private: 13%
- Medicaid: 7%
- 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 $)

$216-$398  
$176  
$144  
$87  

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

2-3.4 Million
400,000-700,000 Treated w/ Revascularization or Amputation-Major & Minor
Cost $134-$248 Billion

CLI COSTS INCREASED BY:

- SEVERITY OF RUTHERFORD CATEGORY TREATED
- UNDERTREATMENT OF RISK FACTORS
- TREATMENT WITH AMPUTATION VERSUS REVASCULARIZATION
- UNPLANNED READMISSIONS

TREATMENT COSTS INCREASE WITH DISEASE SEVERITY

Mean Inpatient Treatment Costs by Rutherford Category (in Euros)

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

- INCREASES MACE & MALE

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

- ADVERSE CARDIOVASCULAR EVENTS AND LEG EVENTS INCREASE COSTS

AMPUTATION COSTS MORE THAN REVASCULARIZATION

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

- Amputation: $40,100
- Endovascular: $26,000
- Bypass: $26,900

*Including Morbidity, Mortality & Revisions

Source: THE SAGE GROUP estimates.
HIGH RATE OF CLI READMISSIONS—↑COSTS

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

- MAJORITY OF READMISSIONS UNPLANNED

- ONLY 1/3 DUE TO PRIMARY CLI-RELATED CAUSES, 2/3 DUE TO PROCEDURE COMPLICATIONS, SEPTICEMIA AND DIABETES-RELATED NON-VASCULAR PROBLEMS

- UNPLANNED READMISSIONS INCREASE MORTALITY, MALE & COSTS

CONCLUSIONS PAD

❖ PAD IS HIGHLY PREVALENT AND COMMONLY UNDERESTIMATED

❖ PAD MACROECONOMIC COST IS HIGH $216-$398B

❖ CLI COSTS ACCOUNT FOR THE MAJORITY OF TOTAL PAD COSTS—55%-65%

❖ CLI COSTS ARE INCREASED BY TREATMENT AT MORE SEVERE DISEASE STAGES, UNDERTREATMENT OF RISK FACTORS, TREATMENT WITH AMPUTATION VS REVASCULARIZATION AND HIGH HOSPITAL READMISSIONS

❖ 2015 ECONOMIC BURDEN OF PAD EXCEEDS THAT OF DIABETES, CAD AND ALL CANCERS
VENOUS DISEASE

CHRONIC VENOUS DISEASE (CVD)

VENOUS THROMBOLISM (VTE):

DEEP VEIN THROMBOSIS (DVT)
PULMONARY EMBOLISM (PE)
**U.S. PREVALENCE**

**VARICOSE VEINS (C2)**
46-57 Mill

**CHRONIC VENOUS INSUFFICIENCY-CVI (C3-C6)**
30-50 Mill

**VENOUS ULCERS (C5 & C6)**
3.4-4.8 Mill
(1.3%-2%)

**TOTAL CVD Ages 18+ (C1-C6)**
121-222 Mill

*Edema, skin changes & ulcers

VENOUS ULCERS

ANNUAL INCIDENCE
1-2 MILLION
Rate 0.4%-2.2%

INCIDENCE INCREASES W/ AGE
1.2%-2.2% in 65+
0.5% 18-64

VENOUS ULCERS (VU)

2015 TREATMENT COST
$21-46 BILL*

VU COST = 1%-3%
NATIONAL HEALTH EXPENDITURES
$30-$90 BILL

* Annual all-cause per patient costs of $17,568-$22,723 in 2015 $. 

VENOUS ULCERS

COSTS OF LOWER PRODUCTIVITY DUE TO

❖ DISABILITY
❖ MEDICALLY RELATED ABSENTEEISM
❖ UNEMPLOYMENT
❖ FORCED EARLY RETIREMENT
❖ 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 (Australia)
- Unemployment
- 12.5% VLU Workers Forced to Retire Early (Portugal)

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 PRIMARILY OUTPATIENT

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 2014.
**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

$16-$77 BILLION*

36%-57% ARE PREVENTABLE COSTS

*2015 $

Source: Mahan 2012.
VTE PREVENTABLE

❖ ADEQUATE PROPHYLAXIS REDUCES VTE
  Fatal PE ↓ 62%
  DVT ↓ 53%

❖ 60% CASES ARE HOSPITAL & NURSING HOME PTS

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

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

VTE COSTS PRIMARILY INPATIENT

Commercial

- Inpatient 75%
- Outpatient 18%
- ER 1%
- Pharmacy 6%

Medicare

- Inpatient 73%
- Outpatient 20%
- Pharmacy 7%
- ER 1%

Source: Lin 2014.
**VTE**

**RECURRENT 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 $12,000* MORE THAN PRIMARY**

*2015 $*

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.
CONCLUSIONS VENOUS

❖ AT 120+ MILL VENOUS DISEASE IS THE MOST COMMON CHRONIC DISEASE

❖ VENOUS ULCERS COST $21-$46 BILL ANNUALLY

❖ VTE HIGHLY PREVALENT & COSTLY — $16-$77 BILL

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

❖ RECURRENT VTE AND COMPLICATIONS ADD SIGNIFICANTLY TO MORBIDITY, MORTALITY & COSTS
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