THE COST OF MAJOR AMPUTATION

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THE SAGE GROUP LLC Research and Consulting
THE SAGE GROUP LLC is a for-profit research and consulting company specializing in vascular disease in the lower limbs including Peripheral Artery Disease (PAD), Intermittent Claudication (IC), Critical Limb Ischemia (CLI) Acute Limb Ischemia (ALI) and Diabetic Foot Ulcer (DFU) & Amputation.
Aastrom Biosciences
Abbott Vascular
ActivBiotics
Advanced Biohealing
AngioScore
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AtheroMed Inc.
Bain & Company
Bard
Baxter
Bayer (Medrad)
BioMarin Pharmaceutical
Boston Scientific
Boston Scientific India
Chemo France
Cardiovascular Systems, Inc.
CoDa Therapeutics
Cordis (Johnson & Johnson)
Cook Medical
Diffusion Pharmaceuticals LLC
Diomed Inc.
Edwards Lifesciences
Ev3
FoxHollow Technologies
GlaxoSmithKline
Grifols SA
Harvest Technologies
IDev Technologies
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DISCLOSURES

Stock Ownership (January 31, 2015)

Abbott Laboratories, Inc.
AbbVie Inc.
Angiodynamics Inc.
Derma Sciences Inc.
CRITICAL LIMB ISCHEMIA

LIMB SALVAGE CAN:

REDUCE COSTS
FOR THE ECONOMY,
THE HOSPITAL,
& THE PATIENT
CLI PREVALENCE & COST

2015

2-3 Million

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

Cost $40-$66 Billion

WHO PAYS THE CLI BILL?

2012 CLI Discharges by Payer

- Medicare 75%
- Medicaid 8%
- Private 12%
- Uninsured 3%
- Other 2%

Source: HCUP Query. Outcomes.
CLI “IDEAL” TREATMENT PATHWAY

SVS & ESVS Recommendation

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

Source: Allie 2005 and Hallett.
MAJOR AMPUTATION

- 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

AMPUTATION LOTTERY

- 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 $
COST-EFFECTIVENESS ANALYSIS (CEA)

- Model to Assess Value of a Treatment & Allocate Resources
- Compares Costs & Outcomes of Therapies
- Cost Perspective
  - Macroeconomic, Hospital, Payer, Patient

Source: Barshes 2012, Hlatky and Weintraub.
Can’t compare costs across countries

Differences in

• Clinical Practice
• Reimbursement Systems
• Prices and Costs

Source: Tenvall.
Amputation less cost-effective than either Bypass or Endovascular* (Barshes)

Amputation less cost-effective than Bypass (Brothers)

*Rutherford V-Ulcers

Source: Barshes 2012 & Brothers.
AMPUTATION NOT COST-EFFECTIVE “MARGINAL” PATIENTS

- Conventional Wisdom: Frail, Elderly Pts w Limited Mobility—Primary Amputation “Better”

- Limb Salvage w/ Endovascular “Best Option”

- PA: Lower Health Benefits & Higher Costs (Need for LT Nursing Home)

AMPUTATION NOT COST-EFFECTIVE ESRD PATIENTS

- Limb Salvage w/ Endovascular “Better” in ESRD Patients w/ Ulcers

- Wound Care Only “Better” than Endovascular: Cost $15,403 Less per year of Ambulation Endo Ambulation 0.22 Years vs Wound Care

- Wound Healing to 65%: Endovascular Better than Wound Care-New Technology?

Source: Barshes. JVS 2014.
ANNUAL COSTS BY TYPE

Source: Dillingham 2005 and Yost Endovascular Today. 2014.
“PATHWAY TO AMPUTATION”
IMPACT ON HOSPITAL COSTS & OUTCOMES
## HOSPITAL CHARGES

### Bypass vs Amputation Study

<table>
<thead>
<tr>
<th>Study</th>
<th>AMP</th>
<th>Procedure Charges*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mackey</td>
<td>All</td>
<td>26,142</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bypass</td>
</tr>
<tr>
<td></td>
<td></td>
<td>27,081</td>
</tr>
<tr>
<td>Complicated</td>
<td></td>
<td>40,563</td>
</tr>
<tr>
<td></td>
<td></td>
<td>40,769</td>
</tr>
<tr>
<td>Gupta</td>
<td>BKA</td>
<td>27,225</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bypass</td>
</tr>
<tr>
<td></td>
<td></td>
<td>26,194</td>
</tr>
<tr>
<td>Raviola</td>
<td>BKA</td>
<td>20,400</td>
</tr>
<tr>
<td></td>
<td></td>
<td>BP FP</td>
</tr>
<tr>
<td></td>
<td></td>
<td>20,300</td>
</tr>
<tr>
<td>Complicated</td>
<td>BKA</td>
<td>40,600</td>
</tr>
<tr>
<td></td>
<td></td>
<td>BP FP</td>
</tr>
<tr>
<td></td>
<td></td>
<td>28,700</td>
</tr>
</tbody>
</table>

HOSPITAL PROCEDURE COST
(Before Complications & Mortality)

Amputation vs Endovascular

Source: HCUP Query Outcomes.
TOTAL HOSPITAL COSTS

Procedure Cost + Costs of Perioperative:

1. Mortality
2. Morbidity
3. Revision Procedures

## PERIOPERATIVE MORTALITY

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Amputation</th>
<th>Endovascular</th>
</tr>
</thead>
<tbody>
<tr>
<td>AKA</td>
<td>5%-10%</td>
<td>1%-3%</td>
</tr>
<tr>
<td>BKA</td>
<td>15%-20%</td>
<td></td>
</tr>
</tbody>
</table>

- AKA & BKA are 2 of the top 5 procedures with the highest perioperative mortality

IN-HOSPITAL DEATH

Average Cost $18,600

(In 2010 $)

Source: Davenport & Yost.
## PERIOPERATIVE MORBIDITY INCREASES COSTS

<table>
<thead>
<tr>
<th>PROCEDURE</th>
<th>MORBIDITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amputation</td>
<td>20%-37%</td>
</tr>
<tr>
<td>General &amp; Vascular Surgery</td>
<td>16%-17%</td>
</tr>
<tr>
<td>Endovascular</td>
<td>5%-9%</td>
</tr>
</tbody>
</table>

Source: Alonso, Vogel 2011, DeRubertis, Ghaferi, Dormandy, Boltz and Schneider.
THREE MOST COMMON OPERATIVE MORBIDITIES

<table>
<thead>
<tr>
<th>AMPUTATION</th>
<th>ENDOVASCULAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wound Infection</td>
<td>Bleeding</td>
</tr>
<tr>
<td>10%-30%</td>
<td>5%-7%</td>
</tr>
<tr>
<td>DVT 13%-26%</td>
<td>Infection 1%-4%</td>
</tr>
<tr>
<td>Cardiac 9%-10%</td>
<td>Cardiac ≈ 1%</td>
</tr>
</tbody>
</table>

## IN-HOSPITAL REVISION RATES

<table>
<thead>
<tr>
<th>AMPUTATION</th>
<th>ENDOVASCULAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Above Knee</td>
<td>Endovascular</td>
</tr>
<tr>
<td>12%</td>
<td>1%</td>
</tr>
<tr>
<td>Below Knee</td>
<td>Bypass</td>
</tr>
<tr>
<td>20%</td>
<td>4%-9%</td>
</tr>
<tr>
<td></td>
<td>Amputation</td>
</tr>
<tr>
<td></td>
<td>2%-4%</td>
</tr>
</tbody>
</table>

Source: DeRubertis, Muradin, Faglia 2006, Dillingham 2005, BASIL.
TOTAL HOSPITAL COSTS
Including Morbidity, Mortality & Revisions

Amputation vs Endovascular

Source: Yost Endovascular Today 2014.
LIMB SALVAGE PROGRAM IMPACT ON HOSPITAL

- Substitute Endovascular Procedures for Amputations

- Costs

- Capture Foregone Revenues from Angiograms (51%-73% PA No Angio)

- Revenues-Attract New CLI Patients

Source: Balar, Mustapha, Bell, Sanguily and THE SAGE GROUP.
LIMB SALVAGE PROGRAM IMPACT ON HOSPITAL

- **Procedure Mix-100 Pts.**
  - Before Limb Salvage Program: 40% PA, 60% ET
  - After: 10% PA, 90% ET

- **Per Pt. Costs Reduced by $3,000 or $300,000 Total**
  - Assumes PA Total Costs $35,500 & ET $25,700

- **Capture Foregone Revenues from Angiograms—$11,600 per Pt.**
  - Assume 50% PA No Angio & Avg. Inpatient Angio DRG $5,800 X 2

- **50 New CLI Patients—Revenues by $1.3 Mil**
  - Avg. Inpatient Angio DRG $5,800 X 2 + Avg. Inpt. ET DRG $14,240

Source: Yost. THE SAGE GROUP estimates.
CLI—WHY IS EARLY DIAGNOSIS & TREATMENT IMPORTANT?

- Costs ↑ w/ Disease Severity—IC Lowest, Amp Highest
- Hospital Costs: 62%-87% of PAD Costs
- Hospitalizations ↑ w/ Disease Severity (IC 25% Amp 36%)
- 70% Have Polyvascular Disease—50% PAD + CAD
- CVD Costs Add Significantly—43% of Total Costs
- CVD Events ↑ w/ Disease Severity—AS 21% Amp 34%

PAD A RISK FACTOR EQUIVALENT TO CAD

RISK FACTOR MODIFICATION THERAPY UNDERUTILIZED

- Antihypertensive: No Rx 12%-50%
- Antiplatelet: No Rx 33%-70%
- Antilipid: No Rx 44%-60%

↑ CLI Cost Morbidity & Mortality

ENDOVASCULAR PATIENT OUTCOMES

• Discharge Status
  – 62% go home routinely 18% (NH, Rehab) 17% Home HC

• Ambulation-2 Year
  – 81% walking
  – 88% living independently

• Revascularization (18 mos.)
  – 30%-40%

• Mortality-2 Year
  – 16%-24%

AMPUTATION
PATIENT OUTCOMES

• Discharge Status
  – 18%-24% go home routinely majority (70%) go to another institution (NH, Rehab etc.)

• Ambulation
  – 60%-80% can’t walk

• Depression 35%

• Mortality - 2 Year
  – 30%-50% (frequently MI)

• Contralateral Amputation
  – 36%-50%

• Patient $ Costs
  – Lost wages, copayments & deductibles, modifications for disabled living, nursing home & home care.

AMPUTATION
MORE PATIENT OUTCOMES

• Lengthy Healing Process
  – At 100 days 45% BKA & 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%

• Skin Problems in Stump 15%-41%
  – Results in reduced prosthetic use and reduced walking time

CONCLUSIONS

- CLI: ACTUAL TREATMENT SIGNIFICANTLY DIFFERENT FROM IDEAL—↑COSTS

- AMPUTATION IS LESS COST-EFFECTIVE THAN LIMB SALVAGE—EVEN IN MARGINAL & ESRD PTS

- AMPUTATION COSTS THE HOSPITAL MORE THAN LIMB SALVAGE

- CLI EARLY DIAGNOSIS & TREATMENT: COULD REDUCE COSTS, MORBIDITY & MORTALITY

- AMPUTATION: HIGH PATIENT COSTS—NOT JUST $$$ BUT POOR QUALITY OF LIFE, PAIN, INABILITY TO AMBULATE

- MORE RESEARCH: COSTS/ECONOMICS & OC
THANK YOU—THE STAFF
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