Epidemiology and Economic Impact of Peripheral Arterial Disease
• NOTHING TO DISCLOSE
Cardiovascular Disease

• PAD, CAD, CVD patients account for 50% of all morbidity and mortality in US population >50.

• Secondary prevention
• Primary prevention
  • *Primordial prevention*
“cardiovascular health”

“health thus becomes an issue for populations and not just for individuals, and health promotion and disease prevention strategies must embrace both high-risk and population strategies”

“of the 2, however, greater power resides with the population strategy when risk is widely diffused throughout the whole population, as is the case for CVD”

“By 2020, to improve the cardiovascular health of all Americans by 20% while reducing deaths from cardiovascular diseases and stroke by 20%.”
AHA 2020 impact goals

“new and expanded emphasis on prevention, control of risk, improving quality of life, and promoting health rather than solely treating disease”

“recommended that the committee broaden its scope to encompass all of CVD and stroke mortality, not just heart disease and stroke”
### 2010 AHA impact goals achieved by 2008

<table>
<thead>
<tr>
<th>CHD</th>
<th>Death rate</th>
<th>Reduction</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke</td>
<td>Death rate</td>
<td>Reduction</td>
<td>29.2%</td>
</tr>
<tr>
<td>Uncontrolled HTN</td>
<td>Prevalence</td>
<td>Reduction</td>
<td>29.4%</td>
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<tr>
<td>High cholesterol</td>
<td>Prevalence</td>
<td>Reduction</td>
<td>24.5%</td>
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<tr>
<td>Smoking</td>
<td>Prevalence</td>
<td>Reduction</td>
<td>15.8%</td>
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<tr>
<td>Non-exercisers</td>
<td>Prevalence</td>
<td>Reduction</td>
<td>2.5%</td>
</tr>
<tr>
<td>Obesity</td>
<td>Prevalence</td>
<td>INCREASE</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>Prevalence</td>
<td>INCREASE</td>
<td></td>
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</tbody>
</table>
Peripheral Arterial Disease

8 – 10 million Americans affected
  30% of 70 yr olds
  30% of 50 yr old smokers / diabetics
3-6 fold increased risk of cv morbidity or death
Asymptomatic : symptomatic  3 : 1
Increasing prevalence
  Aging population
  Ongoing tobacco abuse
  Epidemic of diabetes mellitus
  Epidemic of obesity
Critical Limb Ischemia

“End Stage” Peripheral Arterial Disease

Any patient with chronic ischemic rest pain, ulcers, or gangrene attributable to objectively proven arterial occlusive disease


Symptoms greater than 2 weeks in duration

Fontaine Stage III-IV
Rutherford Class 4-6
CLI

- 50% mortality at 5 yrs
- 70% at 10 yrs
- 5 yr mortality for cancers
  - Lung 80%
  - Ovary 55%
  - Colon 35%
  - Breast 10%
  - Prostate 0.5%
CLI is an important clinical issue in patients with PAD because of the high risk of amputation and death if optimal revascularization is not possible.

Epidemiology of Patients With Peripheral Arterial Disease (PAD) and Critical Limb Ischemia (CLI)

- Clinical course of limb and prognosis in patient with CLI are extremely poor. Approximately half these patients die or undergo major amputation within 1 year.
- Surprisingly, more than half the patients with major amputation for ischemic disease had absolutely no symptoms of leg ischemia as recently as 6 months before.

Algorithm for the Treatment of CLI

**CLI confirmed**

- Candidate for revascularization
  - Imaging (Duplex, angiography, MRA, CTA)
    - Revascularization as appropriate
  - Not candidate for revascularization
    - Stable pain and lesion
      - Medical treatment (non-operative)
    - Not-tolerable pain, spreading infection
      - Amputation


COST OF CARE

2001 Medicare expenditures for the cost of PAD related treatment

$4.37 Billion
13% of Medicare part A and B in PAD cohort
2.3% of ALL Medicare part A and B
88% for INPATIENT care

Cost of Care

• Medicare expenditures for comparison
  – $2.7B cardiac dysrhythmias
  – $3.9B CHF
  – $3.7B cerebrovascular disease
  – $4.37B PAD
Cost of Care

• 6.8% of total medicare population received treatment for PAD.
  – 4.5% 65-74
  – 7.5% 75-84
  – 11.8% >85

Cost of Care

• Cost estimates are conservative, as making the distinction between costs for atherosclerotic risk factor management and specific PAD management is semantic and artificial.

• Overall costs of the elderly medicare enrollee are double when PAD diagnosis added.
Cost of Care

• Costs are high, associated with inpatient care, and increase with age.

• PAD is treated at rates lower than known prevalence as only 1/3 of the population with known PAD had detectable related costs.

• The potential impact of earlier detection and use of outpatient preventive strategies on total cost is unknown.
2010

• 17.6 million Americans diagnosed with PAD
  – 75% asymptomatic
• $164-290B in health care spending
• Cardiovascular events (heart attacks and strokes) and related treatments account for >40% of total cost

The SAGE group, 2010.
Initial Presentation of PAD

- 40-50% atypical leg pain
- 10-35% intermittent claudication
- 20-50% asymptomatic
- 1-2% CLI

- 5 yr f/u 2% progress to CLI
amputation

- Approximately 225,000 amputations yearly in US and Europe
- Despite advances in medical and revascularisation therapies, rates have fallen very slowly
- Mainly driven by aging population and epidemic of diabetes mellitus
amputation

- BKA  5-10% peri-op mortality
- AKA  15-20% peri-op mortality

- 1 yr mortality in CLI patients s/p amp is 45%
- Second amputation required in 30%
- Full mobility achieved in 50% BKA, 25% AKA
amputation

- 67% medicare patients with CLI underwent primary amputation
- 23% surgical revascularisation
- 10% percutaneous revascularisation
- 80% of all wound complications, strokes, and heart attacks occurred in the amp group

revascularisation

- 34% increase in 5 yr survival when CLI treated with surgical bypass vs primary amputation

- Primary amputation 3 times more costly than surgical revascularisation in both diabetic and non-diabetic patients
revascularisation

• Percutaneous therapies
  – 30-50% reduction in cost-per-leg-year-saved when compared to surgery and/or amputation

Reduction of Atherothrombosis for Continued Health

• Followed patients with established arterial disease OR presence of 3 or more risk factors
• Vascular related hospitalizations cost $21B
  – 50% PAD specific treatments
  – 50% cardiovascular related (MI and Stroke)

ReACH

- 31% symptomatic patients had at least one vascular related hospitalization
- 23% asymptomatic patients had at least one vascular related hospitalization
- Cumulative 2 yr costs
  - Claudication $7,000
  - Asymptomatic $7,445
  - Amputation $10,430
  - History of revasc $11,693
Conclusions—The economic burden of PAD is high. Recurring hospitalizations and repeat revascularization procedures suggest that neither patients, physicians, nor healthcare systems should assume that a first admission for a lower-extremity PAD procedure serves as a permanent resolution of this costly and debilitating condition.
Health care resources and costs for treating peripheral artery disease in a managed care population: results from analysis of administrative claims data. 

• MCO 6.67 million members, followed from January 1999 – August 2003.
• 30,561 pts, average age 70.7 yrs @ index
  – 67% htn
  – 57% metabolic/lipid disorders
  – 55% heart disease
  – 47% ischemic heart disease
  – 28% diabetes
• Mean post-index f/u 25.2 months
Cost of care

• Total PAD related cost $5995 PPPY (49% of the all cause cost $9149 PPPY)
  – 75% from HOSPITAL based care (36% in overall population)
  – 12% non-coronary procedures
  – 10% PAD-related drugs

• Newly Dx PAD pts, 24,075
  – 35.2% hospitalized in f/u period
  – Mean time from index 8.9 months
Medications used

- Antihypertensives 67%
- Antiplatelets 27%
- Cholesterol meds 39%
Reasons for hospitalisation

- Stroke 22.7%
- MI 11.5%
- Amputation 1.1%

Nearly 2 hospitalisations per patient over f/u
49% of cost from MI, CVA, TIA, amputation.
conclusions

- PAD is marker for systemic disease
- Overall care is expensive and driven by hospital costs
- Drug therapy (anti-hypertensives, anti-platelets, anti-lipids) is likely underutilized
Challenges in comparing surgery and endovascular therapies

- Differences in study populations
- Differences in endpoints
- Differences in length of follow-up
- Evolution of endovascular techniques
- Crossover between techniques, endo and surg
• 1996 – 2006 Medicare Part B Claims data

• Endovascular therapy increased 330%
  138 to 455 / 100,000

• Lower extremity bypass decreased 42%
  219 to 126 / 100,000

• Major amputation decreased 29%
  263 to 188 / 100,000
• Cannot jump to the simple conclusion that increase in endovascular procedures has led to decrease in major amputations
Model to Optimize Healthcare Value in Ischemic Extremities

- **BACKGROUND:**
  - The care of patients with critical limb ischemia (CLI) and tissue loss is notoriously challenging and expensive. We evaluated the cost-effectiveness of various management strategies to identify those that would optimize value to patients.

- **METHODS:**
  - A probabilistic Markov model was used to create a detailed simulation of patient-oriented outcomes, including clinical events, wound healing, functional outcomes, and quality-adjusted life-years (QALYs) after various management strategies in a CLI patient cohort during a 10-year period. Direct and indirect cost estimates for these strategies were obtained using transition cost-accounting methodology. Incremental cost-effectiveness ratios (ICERs), in 2009 U.S. dollars per QALYs, were calculated compared with the most conservative management strategy of local wound care with amputation as needed.
• **RESULTS:**
  • With an ICER of $47,735/QALY, an initial surgical bypass with subsequent endovascular revision(s) as needed was the most cost-effective alternative to local wound care alone. Endovascular-first management strategies achieved comparable clinical outcomes but at higher cost (ICERs $\geq$101,702/QALY); however, endovascular management did become cost-effective when the initial foot wound closure rate was >37% or when procedural costs were decreased by >42%. Primary amputation was dominated (less effectiveness and more costly than wound care alone).

• **CONCLUSIONS:**
  • Contemporary clinical effectiveness and cost estimates show an initial surgical bypass is the most cost-effective alternative to local wound care alone for CLI with tissue loss and can be supported even in a cost-averse health care environment.
• Clinical outcomes and cost model that ran 1,000 simulated trials of 1,000 patients each.
• Parameters drawn from MOVIE trial.
• Older (>80) patients with contralateral amp undergoing treatment for CLI.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Median limb salvage</th>
<th>Median ambulatory time</th>
<th>Median total cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary amp</td>
<td>None</td>
<td>1.5 yrs</td>
<td>$185,955</td>
</tr>
<tr>
<td>Wound care</td>
<td>1.5 yrs</td>
<td>&lt;1 yr</td>
<td>$129,651</td>
</tr>
<tr>
<td>Surgical bypass</td>
<td>3 yrs</td>
<td>2.4 yrs</td>
<td>$113,944</td>
</tr>
<tr>
<td>Endo +/- surgery</td>
<td>3 yrs</td>
<td>2.4 yrs</td>
<td>$108,794</td>
</tr>
<tr>
<td>Endo +/- endo</td>
<td>3 yrs</td>
<td>2.5 yrs</td>
<td>$104,118</td>
</tr>
</tbody>
</table>
Endo revasc with endo revision 5 yr limb-salvage rate of 80.5%, median salvage period of 3 yrs, median ambulatory period of 2.5 yrs, and was the least expensive.

‘revascularisation still appears to be the most cost-effective alternative to wound care and primary amputation’
• “My co-investigators and I are concerned that this nation may no longer be able to sustain the high costs associated with treating a very common and preventable disease such as PAD, especially when the many invasive treatments are not always durable,” says Hirsch.
THANK YOU!!!!!!!!!