Chronic lower Extremity Peripheral Arterial Disease: The Relentless Pursuit of Mediocrity

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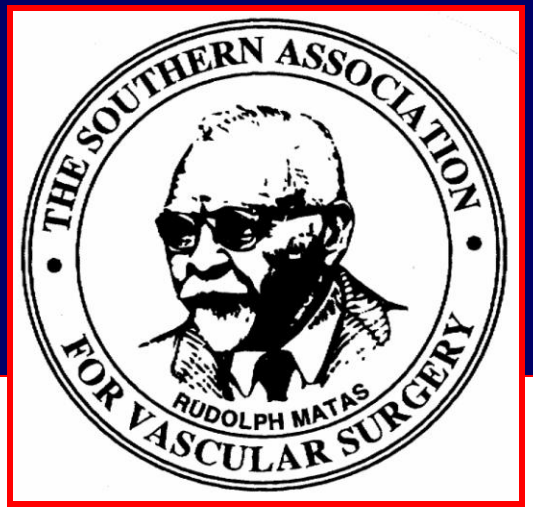
12th Annual W. Andrew Dale Memorial Lecture

Vanderbilt University

April 30, 2010



The History

"An informal meeting occurred
in December of 1975 during the annual meeting of the
Southern Surgical Association at the Homestead in Hot Springs, Virginia.
At that meeting Dr. John Foster of Nashville invited a few surgeons interested
in vascular surgery to his hotel room to discuss the feasibility
of organizing a regional vascular society.
That informal meeting lead to the planning of the
Southern Regional Vascular Group Organizational Meeting
which met on January 24, 1976 in Nashville, Tennessee"

Andrew Dale of Nashville, Tennessee

William Edwards of Nashville, Tennessee

"…junior faculty vascular surgery member from Vanderbilt, Dr. Richard Dean."

Observations from Blue Collar Academia

Vascular Surgery Service

2008

- AV dialysis access operations = 1128
- Infrainguinal procedures =494
- C
- C
- M
- E
- E
- E
- Mis
- Outpatient visits = 15,000
- Noninvasive vascular lab procedures = 16,699

Lower extremity ischemia
47.8% of total volume

Benevolent Stewards of our Data

Critical Analysis of Clinical Success after Surgical Bypass for Lower-Extremity Ischemic Tissue Loss Using a Standardized Definition Combining Multiple Parameters: A New Paradigm of Outcomes Assessment

Spence M Taylor, MD, FACS, David L Cull, MD, FACS, Corey A
Sarah Anne Harmon, Eugene M Langan III, MD, FACS, Jerry R

BACKGROUND: Success after surgical revascularization of the low
patency or limb salvage, fails to consider other int
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clinical predictors of failure.

STUDY DESIGN: For the purpose of this study, clinical success w
criteria: graft patency to the point of wound heal
ambulatory status for 1 year; and survival for 6 m
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clinical success. Bivariate and logistic regression a
graphic differences between success and failure.

RESULTS: Despite achieving acceptable graft patency (72.7%
months), clinical success combining all 4 define
predictors of failure included impaired ambulato
6.44), presence of infrainguinal disease (OR =
presence of gangrene (OR = 2.40), and hyperlipi
patients possessing every predictor except hyperl
150.6).

CONCLUSIONS: Despite achieving acceptable graft patency and l
achieved success when using a definition combini
current approach to critical limb ischemia in certai

Surg 2007;204:831–839. © 2007 by the America

From the Southern Association for Vascular Surgery

Determinants of functional outcome after revascularization for critical limb ischemia: An analysis of 1000 consecutive vascular interventions

Spence M. Taylor, MD, Corey A. Kalbaugh, MS, Dawn W. Blackhurst, DrPH, Anna L. Cass, MPH, E. Annie Trent, BS, Eugene M. Langan, III, MD, and Jerry R. Youkey, MD, *Greenville, SC*

Background: When reporting standards for successful lower extremity revascularization were established, it was assumed that arterial reconstruction, patency, and limb salvage would correlate with the ultimate goal of therapy: improved functional performance. In reality, factors determining improvement of ambulation and maintenance of independent living status after revascularization have been poorly studied. The purpose of this study was to assess the important determinants of functional outcome for patients after intervention for critical limb ischemia.

Methods: The results of 1000 revascularized limbs from 841 patients were studied. Indications were rest pain, 41.1%; ischemic ulceration, 35.6%; gangrene, 23.3%; infrainguinal, 70.9%; aortoiliac, 24.2%; and both, 4.9%. Treatment was by endovascular intervention, 35.5%; open surgery, 61.7%; and both, 2.8%. Patient were mean age of 68 ± 12 years, and 56.6% were men, 74.7% were white, 54.2% had diabetes mellitus, 67% were smokers, 13.4% had end-stage renal disease and were on dialysis, and 36% had prior vascular surgery. Patients were treated with conventional therapy by fellowship-trained vascular specialists at a single center and were analyzed according to the type of intervention, the arterial level treated, age, race, gender, presentation, the presence of diabetes, smoking history, end-stage renal disease, coronary disease, hypertension, hyperlipidemia, obesity, chronic obstructive pulmonary disease, previous stroke, dementia, prior vascular surgery, preoperative ambulatory status, limb loss ≤1 year of treatment, and independent living status. The technical outcomes of reconstruction patency and limb salvage as well as the functional outcomes of survival, maintenance of ambulation, and independent living status were measured for each variable using Kaplan-Meier life-table analysis, and differences were assessed using the log-rank test. A Cox proportional hazards model was used to assess independent predictors of outcome and obtain adjusted hazard ratios and 95% confidence intervals.

Results: At 5 years, 72.4% of the entire cohort had a patent reconstruction and 72.1% had an intact limb. Overall 5-year functional outcomes were 41.9% for survival, 70.6% for maintenance of ambulation, and 81.3% for independent living status. Outcome was not significantly affected by the type of treatment (endovascular or open surgery) or by the level of disease treated (aortoiliac, infrainguinal, or both). The most important independent, statistically significant predictors of particularly poor functional outcome were impaired ambulatory ability at the time of presentation (70% 5-year mortality, hazard ratio, 3.34; 39.5% failure to eventually ambulate, hazard ratio, 2.83; 30% loss of independent living status, hazard ratio, 7.97), and the presence of dementia (73% late mortality, hazard ratio, 1.57; 41.2% failure to eventually ambulate, hazard ratio, 2.20; 46.4% loss of independent living status, hazard ratio, 5.44). These factors were even more predictive than limb amputation alone.

Conclusion: Functional outcome for patients undergoing intervention for critical limb ischemia is not solely determined by the traditional measures of reconstruction patency and limb salvage, but also by certain intrinsic patient comorbidities at the time of presentation. These findings question the benefit of our current approach to critical limb ischemia in functionally impaired, chronically ill patients—patients who undoubtedly will be more prevalent as our population ages.

(J Vasc Surg 2006;44:747-56.)

From the American Venous Forum

One-year prospective quality-of-life outcomes in patients treated with angioplasty for symptomatic peripheral arterial disease

Corey A. Kalbaugh, MS, Spence M. Taylor, MD, Dawn W. Blackhurst, DrPH, Matthew B. Dellinger, BS, E. Annie Trent, BS, and Jerry R. Youkey, MD, *Greenville, SC*

Do Current Outcomes Justify More Liberal Use of Revascularization for Vasculogenic Claudication? A Single Center Experience of 1,000 Consecutively Treated Limbs

Spence M Taylor, MD, FACS, Corey A Kalbaugh, MS, Matthew G Healy, BS, Anna L Cass, MPH, Bruce H Gray, DO, Eugene M Langan III, MD, FACS, David L Cull, MD, FACS, Christopher G Carsten III, MD, FACS, John W York, MD, FACS, Bruce A Snyder, MD, FACS, Jerry R Youkey, MD, FACS

BACKGROUND: The purpose of this study was to reconsider current recommended treatment guidelines for vasculogenic claudication by examining the contemporary results of surgical intervention.

STUDY DESIGN: We performed a retrospective review of 1,000 consecutive limbs in 669 patients treated for medically refractory vasculogenic claudication and prospectively followed. Outcomes measured included procedural complication rates, reconstruction patency, limb salvage, maintenance of ambulatory status, maintenance of independent living status, survival, symptom resolution, and symptom recurrence.

RESULTS: Of the 1,000 limbs treated, endovascular therapy was used in 64.3% and open surgery in 35.7% of patients: aortoiliac occlusive disease was treated in 70.1% and infrainguinal disease in 29.9% of patients. The overall 30-day periprocedural complication rate was 7.5%, with no significant difference in complication rates when comparing types of treatment or levels
primary patency rates were 87.7% and 70.8%; secondary
limb salvage, 100% and 98.8%; and survivals, 95.4% and
y. More than 96% of patients maintained independence and
all symptom resolution occurred in 78.8%, and symptom
imbs treated, with slightly higher resolution and recurrence
ovascular therapy.
ilogenic claudication is safe, effective, and predominantly
a more liberal use of revascularization for patients with
nt nonoperative treatment guidelines may be based more on
e outcomes. (J Am Coll Surg 2008;xxx:xxx. © 2008 by the

...nical factors predict postoperative ...omes after major lower limb ... analysis of 553 consecutive

...Kalbaugh, MS, Dawn W. Blackhurst, DrPH, ...id L. Cull, MD, Hayley S. Messich, R. Todd Robertson, ...n W. York, MD, Christopher G. Carsten III, MD, ...ackson, MD, and Jerry R. Youkey, MD, *Greenville and Clemson, SC*

...erminant of functional independence, ambulation after major limb amputation has ...therefore, of this study was to investigate the relationship between a variety of ...d postoperative functional outcomes in order to formulate treatment recommen... ...ower limb amputation.

... December 2003, 627 major limb amputations (37.6% below knee amputations, ...% above knee amputations, and 23.6% bilateral amputations) were performed on ...7 years; 55% were men, 70.2% had diabetes mellitus, and 91.5% had peripheral ... was performed correlating various preoperative presenting factors such as age at ...ities, preoperative ambulatory status, and preoperative independent living status, ...nts of prosthetic usage, survival, maintenance of ambulation, and maintenance of ...ier survival curves were constructed and compared by using the log-rank test. Odds ...ith 95% confidence intervals were constructed by using multiple logistic regressions ...

...tive factors independently associated with not wearing a prosthesis in order of greatest ... amputation (OR, 9.5), above knee amputation (OR, 4.4), age >60 years (OR, 2.7), ...3.0), presence of dementia (OR, 2.4), end-stage renal disease (OR, 2.3), and coronary artery disease (OR, 2.0). Statistically significant preoperative factors independently associated with death in decreasing order of influence included age ≥70 years (HR, 3.1), age 60 to 69 (HR, 2.5), and the presence of coronary artery disease (HR, 1.5). Statistically significant preoperative factors independently associated with failure of ambulation in decreasing order of influence included age ≥70 years (HR, 2.3), age 60 to 69 (HR, 1.6), bilateral amputation (HR, 1.8), and end-stage renal disease (HR, 1.4). Statistically significant preoperative factors independently associated with failure to maintain independent living status in decreasing order of influence included age ≥70 years (HR, 4.0), age 60 to 69 (HR, 2.7), level of amputation (HR, 1.8), homebound ambulatory status (HR, 1.6), and the presence of dementia (HR, 1.6).

Conclusions: Patients with limited preoperative ambulatory ability, age ≥70, dementia, end-stage renal disease, and advanced coronary artery disease perform poorly and should probably be grouped with bedridden patients, who traditionally have been best served with a palliative above knee amputation. Conversely, younger healthy patients with below knee amputations achieved functional outcomes similar to what might be expected after successful lower extremity revascularization. Amputation in these instances should probably not be considered a failure of therapy but another treatment option capable of extending functionality and independent living. (J Vasc Surg 2005;42:227-35.)

...A comparison of percutaneous ... angioplasty versus amputation ... ischemia in patients unsuitable ...

Spence M. Taylor, MD, Corey A. Kalbaugh, MS, Dawn W. Blackh...
Eugene M. Langan III, MD, and Jerry R. Youkey, MD, *Greenville,*

Background: Percutaneous transluminal angioplasty (PTA), although not ... alternative for patients with critical limb ischemia who are believed to ... However, the efficacy of PTA in this setting has not been analyzed. The ... outcomes of PTA for limb salvage with outcomes of major limb amputation ... to be unsuitable for open surgery.

Methods: From a prospective vascular registry, 314 patients (183 underwen... PTA for limb salvage) were identified as physiologically impaired or unsui... having at least one of the following: functional impairment (homebou... impairment (dementia), or medical impairment (two of the following: end... and chronic obstructive pulmonary disease). Patients undergoing PTA ... amputation by examining the outcome parameters of survival, mainter... independent living status. Parameters were assessed by using Kaplan-Meier life-table curves (log-rank test and 95... confidence intervals [CIs]) and hazard ratios (HRs) from the Cox model.

Results: PTA resulted in a 12-month limb salvage rate of 63%. Thirty-day mortality was 4.4% for the amputation group and 3.8% for the PTA group. After adjustment for age, race, diabetes, prior vascular procedure, dementia, and baseline functional status, PTA patients had significantly lower rates of ambulation failure (HR, 0.44; $P = .0002$) and loss of independence (HR, 0.53; $P = .025$) but had significantly higher mortality (HR, 1.62; $P = .006$) than amputees. However, when life tables were examined, the maintenance of ambulation advantage lasted only 12 months (PTA, 68.6%; 95% CI, 59.6%-77.7%; amputation, 48%; 95% CI, 40.4%-55.5%) and was not statistically significant at 2 years (62.2% [95% CI, 48.8%-71.5%] and 44% [95% CI, 35.8%-52.2%], respectively). Maintenance of independent living status advantage lasted only 3 months, with no statistically significant difference at 2 years (PTA, 60.5%; 95% CI, 45.4%-75.6%; amputation, 52.6%; 95% CI, 40.4%-64.9%). Although mortality was high in both cohorts, patients who underwent amputation had a survival advantage for all time intervals examined (at 2 years: PTA, 29%; 95% CI,

Can We Do Better?

- We approach treatment haphazardly
- Preoccupation with the methods
- Physician oriented, not patient oriented outcomes
- We tend to follow the emperor

Objectives

Take Off the Emperor's Clothes

- Standardization
  - Endovascular versus Open surgery
- Claudication
- Critical Limb Ischemia

Treatment Standardization

What is the most treacherous public health threat of our time?

…for example….

The greatest public health threat of the 1950's and thus, the greatest opportunity for pioneering research

Acquired Heart Disease

The Research Pioneers

So, today?....

The failing business model of medicine; the major symptoms being poor quality, inadequate access and unaffordable cost.

Learning to think of the failing American medical business model as a “disease”

Comparative Effectiveness Research:

Research Labs of the Future?

You will be the Investigator and the "Lab Rat"

Healthcare Delivery Research

Ex dy

Business Failure

Think:

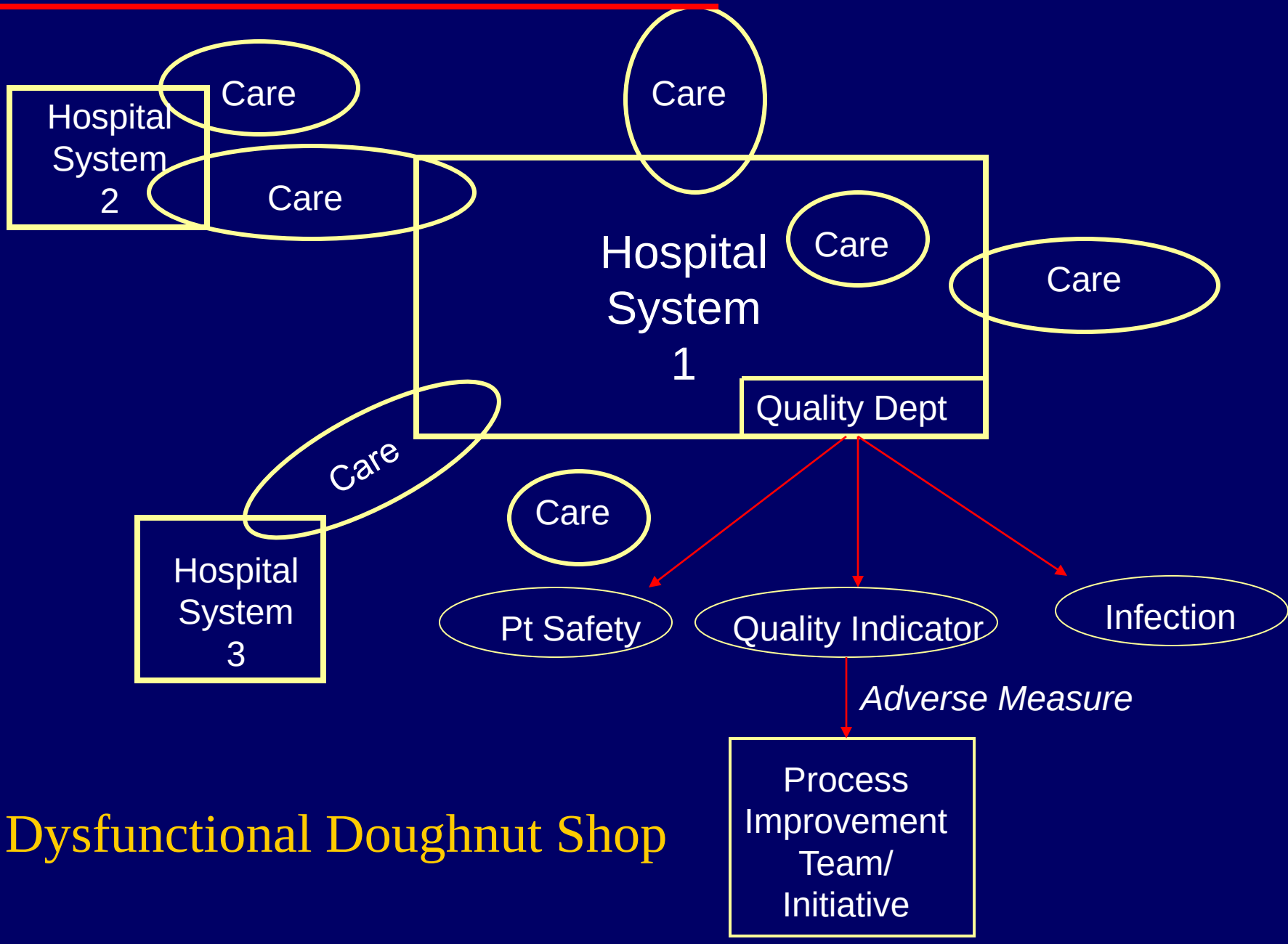
1) Like Business People
2) “Process Engineering”
3) **Standardization**

The Doughnut Shop

- One Factory
- Multiple Bakers
  - Cook at other bakeries
  - Cook other things….not just doughnuts
- Multiple Recipes
  - Cooks often change their own recipes
- A “Signature Doughnut”?
  - Ingredients?
  - Shipping/packaging

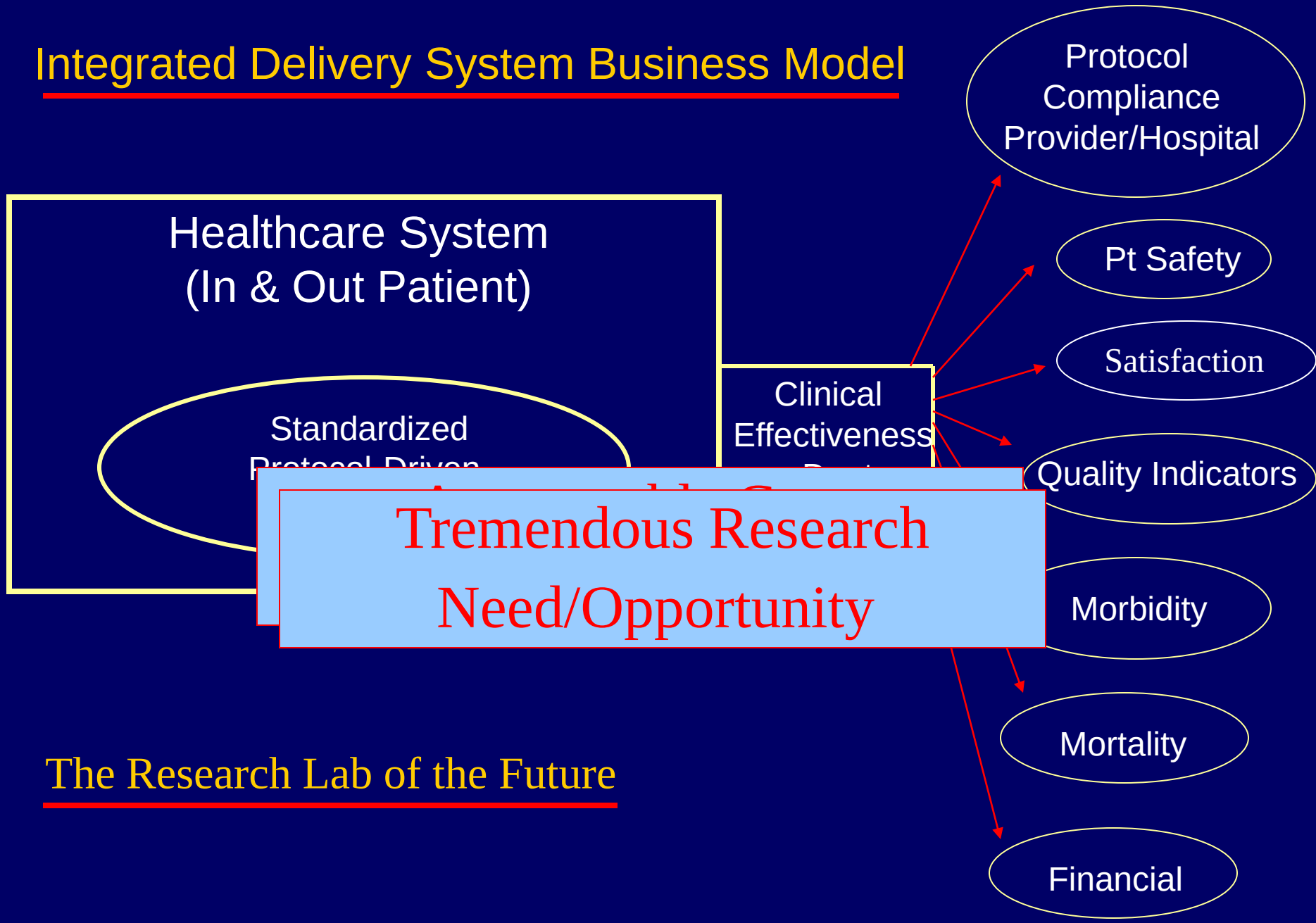
Can this be a successful business?

Independent Physician/Hospital Model



The Dysfunctional Doughnut Shop

Integrated Delivery System Business Model



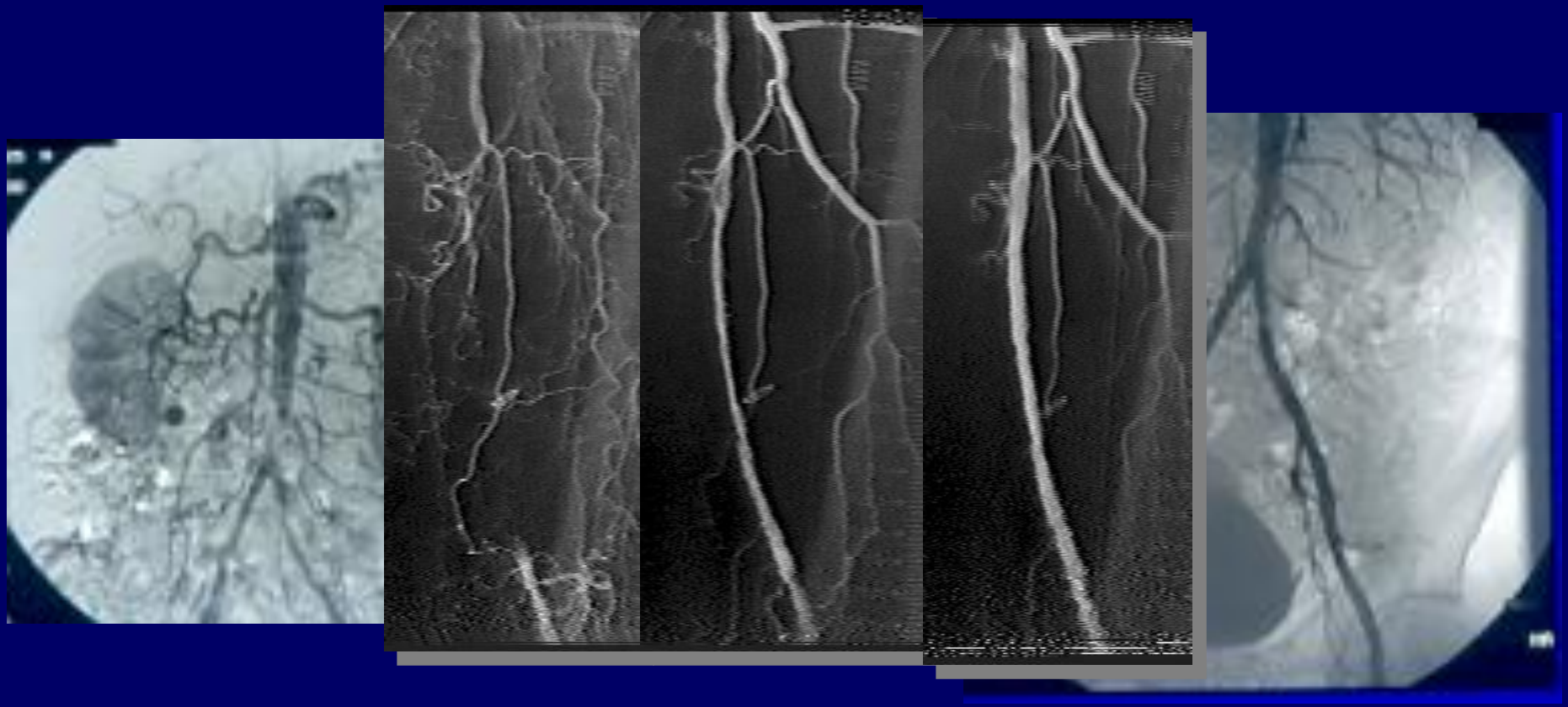
The Research Lab of the Future

So, how are we doing?

Endovascular vs Open Surgery

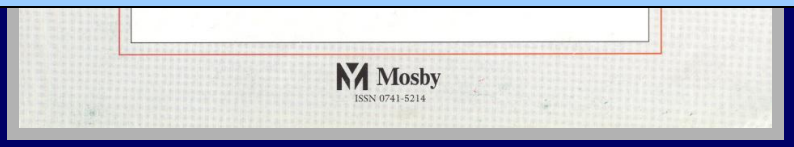
Angioplasty

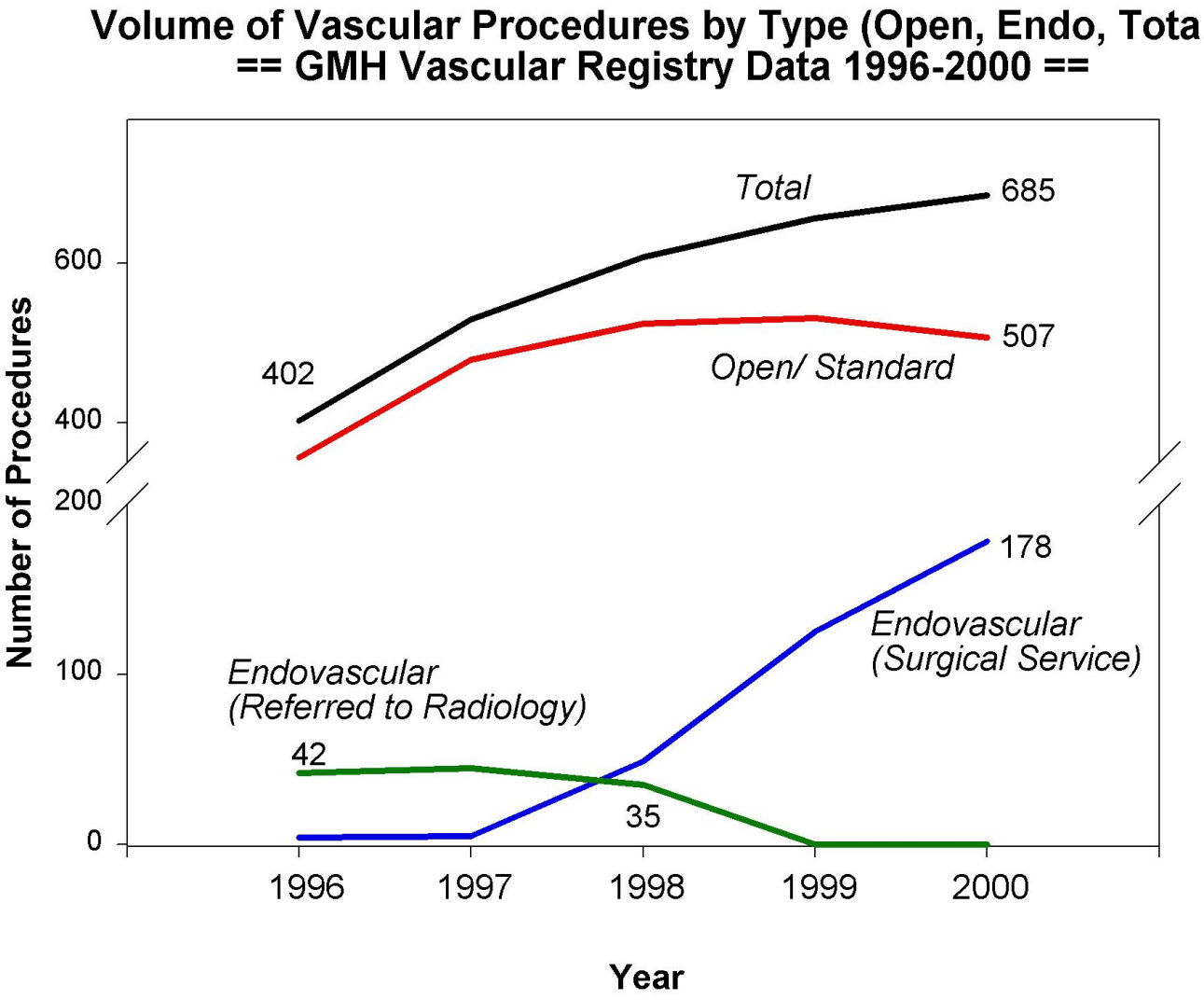
No artery is exempt



Facts

1. PTA best for short stenosis, large arteries, good runoff, less severe disease and non- diabetics
2. Surgery best for longer lesions, occlusions, smaller arteries and more severe disease
3. PTA is better tolerated than open surgery but less durable
4. Surgery is less well tolerated but is more durable
5. Class one data comparing the two modalities is sparse
6. What we know has not changed in 30 years




Volume of Vascular Procedures by Type (Open, Endo, Total)
== GMH Vascular Registry Data 1996-2000 ==
Number of Procedures
600
400
200
100
0
Total
685
507
Open/ Standard
402
178
Endovascular
(Surgical Service)
Endovascular
(Referred to Radiology)
42
35
1996
1997
1998
1999
2000
Year

The Facts Supporting the Change?

The popularity of percutaneous intervention is the product of changing attitudes (*i.e. philosophy*), not improved technology or new evidence

Treatment Chaos

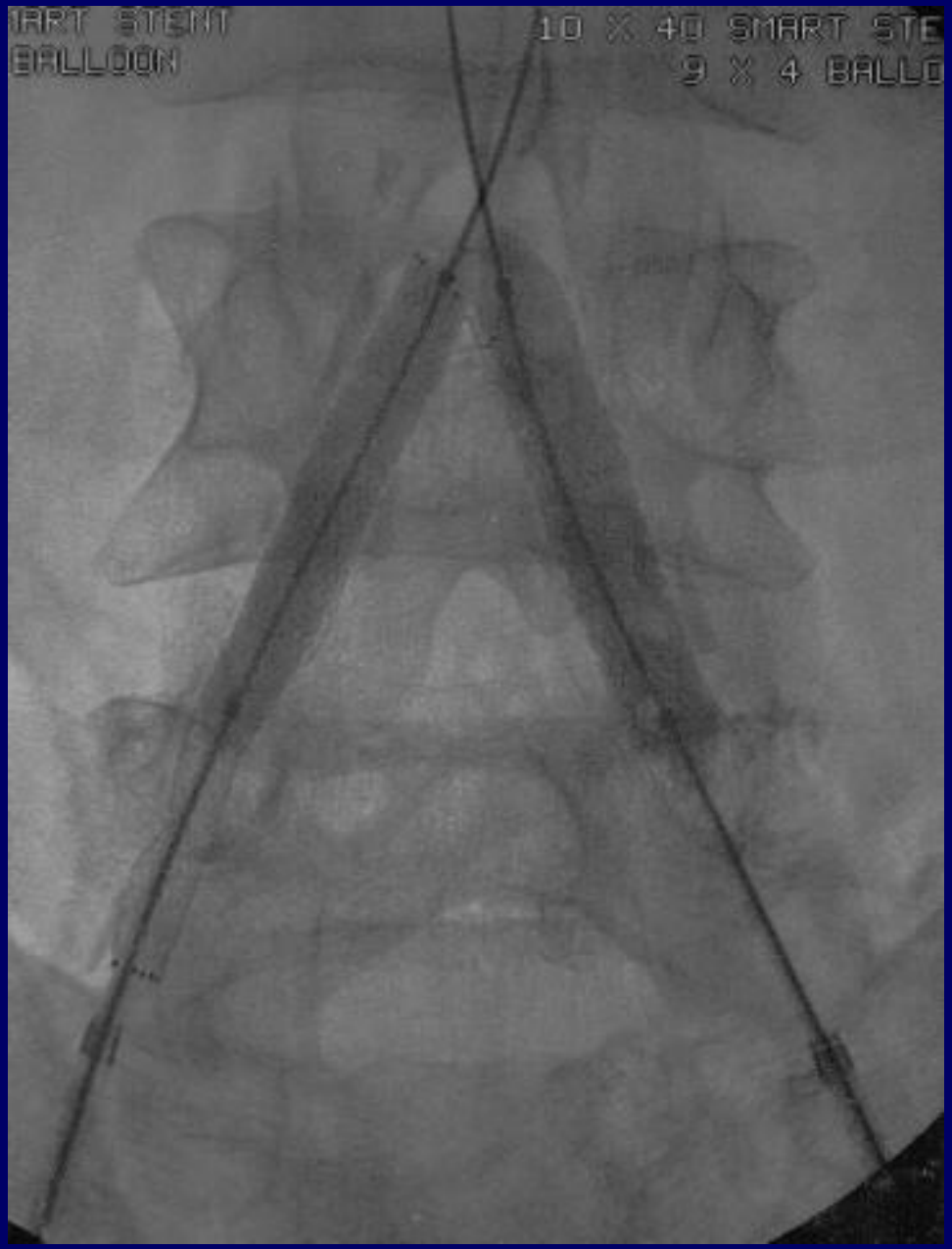

GREENVILLE MEMORIAL M
TIMOTHY SUL

Dr Taylor's Solution:

Fem-Fem or Aorto-bifem bypass

Dr Gray's Solution:

BJ (Balloon Job)!


ART STENT
BALLOON
10 X 40 SMART STE
9 X 4 BALLO


RT
POST STENT/PTA


Critical Analysis of Clinical Success
after Surgical Bypass for Lower-Extre
Tissue Loss Using a Standardized De
Combining Multiple Parameters:
A New Paradigm of Outcomes A
Spence M Taylor, MD, FACS, David L Cull, MD, FACS, Corey A
Sarah Anne Harmon, Eugene M Langan III, MD, FACS, Jerry R
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STUDY DESIGN: For the purpose of this study, clinical success w criteria: graft patency to the point of wound heal ambulatory status for 1 year; and survival for 6 m utive patients undergoing bypass for Rutherford clinical success. Bivariate and logistic regression a graphic differences between success and failure.
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Conclusions: Patients who present with critical limb ischemia and physiologic impairments that preclude open surgery seem to have comorbidities that blunt any functional advantage achieved after PTA for limb salvage. PTA in this setting affords very little benefit compared with amputation alone. (J Vasc Surg 2007;45:304-11.)
Outcomes Justify More Liberal Use of
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Conclusions: Patients with limited preoperative ambulatory ability, age ≥70, dementia, end-stage renal disease, and advanced coronary artery disease perform poorly and should probably be grouped with bedridden patients, who traditionally have been best served with a palliative above knee amputation. Conversely, younger healthy patients with below knee amputations achieved functional outcomes similar to what might be expected after successful lower extremity revascularization. Amputation in these instances should probably not be considered a failure of therapy but another treatment option capable of extending functionality and independent living. (J Vasc Surg 2005;42:227-35.)

“Toyota Corolla Care”

The LEGS Score: A Proposed Grading System to Direct Treatment of Chronic Lower Extremity Ischemia

Spence M. Taylor, MD,* Corey A. Kalbaugh, BS,† Bruce H. Gray, DO,* Peter J. Mackrell, MD,* Eugene M. Langan, III, MD,* David L. Cull, MD,* Bruce A. Snyder, MD,* Christopher G. Carsten, III, MD,* Marcus D. Stanbro, DO,* and Jerry R. Youkey, MD*

*From the *Section of Cardiac and Vascular Surgery, Greenville Hospital System, Greenville, South Carolina, and the †Department of Bioengineering, Clemson University, Clemson, South Carolina*

Objective

To prospectively compare the Lower Extremity Grading System (LEGS)-derived "recommended treatment" to the actual treatment performed and to analyze LEGS intergrader scoring consistency by comparing blinded scoring results between physician graders.

Summary Background Data

Due to technical advances and the increased medical complexity of the aging population, the most appropriate treatment for chronic lower extremity ischemia—open surgery versus endovascular—is again in flux. In an attempt to standardize management, the LEGS score, based on the best available outcomes data, was devised by the physicians of an established vascular service.

Methods

From March to June 2002, all chronically ischemic lower extremities that met standard indications for revascularization were prospectively enrolled and independently graded with the LEGS score by an "endovascular surgeon" and an "open surgeon" for comparative analysis. The results were then blindly evaluated to determine whether the LEGS-derived "recommended treatment" agreed with the actual treatment rendered and to assess for intergrader consistency. Agreement was assessed using kappa statistical analysis.

Results

Of the 137 presenting limbs (mean patient age 66.4 yo; 43% claudication, 57% limb-threatening ischemia), 107 were treated (65% endovascular, 30% open surgery, 5% amputation), 16 were pending treatment, and 14 were not treated because of patient refusal (n = 13) or death (n = 1). The LEGS score predicted the actual or offered clinical treatment in 90% of cases. The LEGS score comparison between physician graders resulted in identical "recommended treatment" in 116 of 128 cases for a 90.6% agreement.

Conclusions

A reproducible scoring system to guide the treatment of patients with chronic lower extremity ischemia is possible. While systems like the LEGS score may have potential clinical application, their use as a treatment standardization tool for future prospective outcomes comparisons between open and endovascular surgery will be essential.

The Lower Extremity Grading System (LEGS) Score

Arteriographic Findings	**Presentation**	**Functional Status**	**Co-morbidities**	**Technical Factors**
- Aortic < 3 cm aortic stenosis/ occlusion or 3-5 cm stenosis of aorto-iliac bifurcation 8 > 3 cm aortic stenosis/ occlusion or > 5 cm stenosis of aorto-iliac bifurcation 0 - Iliac TASC A or B 8 TASC C 2 TASC D 0 or - Fem-pop-tib < 5 cm occlusion/stenosis 5 > 5 cm occlusion w/ distal target 0 Isolated common/deep femoral stenosis 0 > 5 cm occlusion w/o distal target 6	- Claudication 5 - Limb threatening ischemia 2	- Ambulatory 0 - Ambulatory/ at home only 2 - Non-ambulatory/ transfer only 5 - Non-ambulatory 20	- Obesity 2 - High risk coronary artery disease 3 - Age > 70 1 > 80 2	All Cases - Redo surgery 2 - Redo angioplasty -2 Infrainguinal Cases - Blind segment target 2 - No venous conduit 6 - No vein w/ foot infection 8
Possible score: 0-8	Possible score: 2-5	Possible score: 0-20	Possible score: 0-7	Possible score: -2-12

Recommended Treatment: (sum of total score from each column)

-0 – 9 = open surgery

-10 – 19 = endovascular

-≥20 = primary amputation

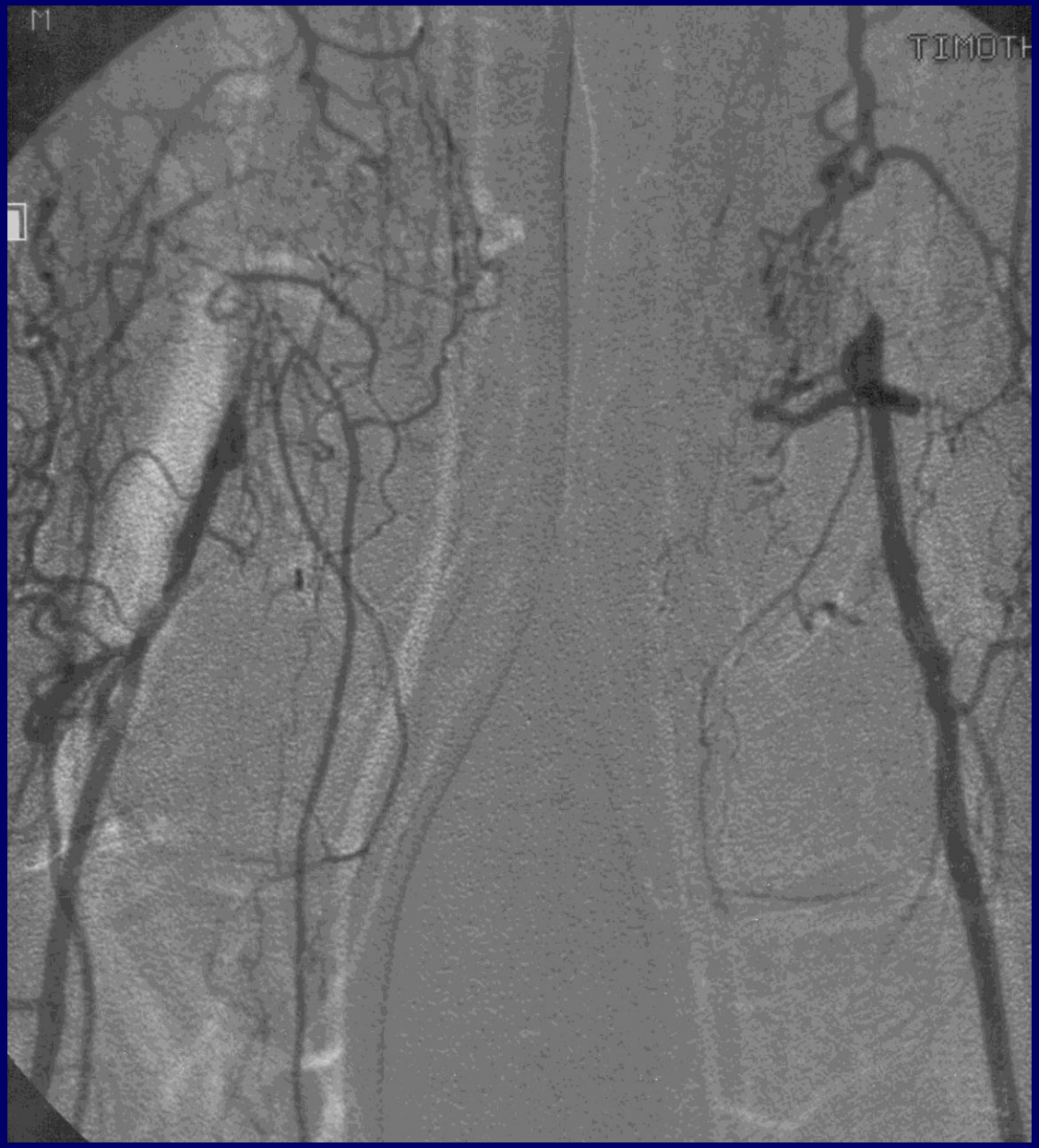
* If a heel ulcer and ESRD are present, double the score

Mr. S

- 60 yo man w/ bilateral calf claudication and a non-healing right toe ulcer

- ABI - 0.5 bilaterally


TIMO


M
TIMOTH

Mr. S

LEGS Score

Right Leg

Anatomic Level	Presentation	Functional Status	CoMorb	Tech Factors
Long Fem	CLI	Ambulatory O/H		
0	2	0	—	—

Score = 2

↓ Treatment = Fem-pop

Left Leg

Anatomic Level	Presentation	Functional Status	CoMorb	Tech Factors
Short Fem	Claudication	Ambulatory O/H		
5	5	0	—	—

Score = 10

↓ Treatment = Endovascular

Does a standardization tool to direct invasive therapy for symptomatic lower extremity peripheral arterial disease improve outcomes?

Case Control Study

100pts LEGS v 100pts Contrary

*LEGS better outcomes@ 6mos

-Patency

-Limb salvage

-Ambulation

performed before implementation of the algorithm were treated contrary to LEGS, and thus contrary to objectively determined best therapy, compared with 8.3% (30 of 362) after LEGS implementation ($P < .001$).

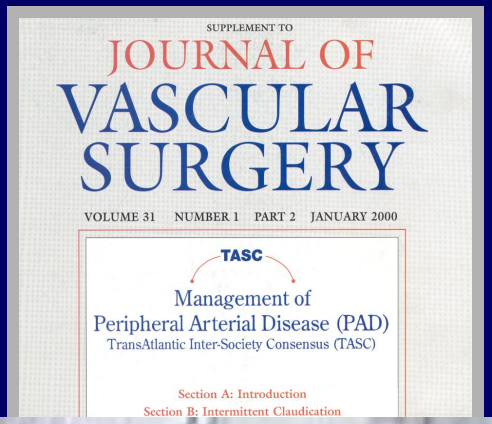
Conclusions: Limbs treated according to our standardization tool resulted in better outcomes compared with limbs treated contrary to the algorithm. These data suggest that routine use of an appropriately validated treatment standardization algorithm is capable of improving overall results for invasive treatment of lower extremity peripheral arterial disease. (J Vasc Surg 2004;40:907-15.)

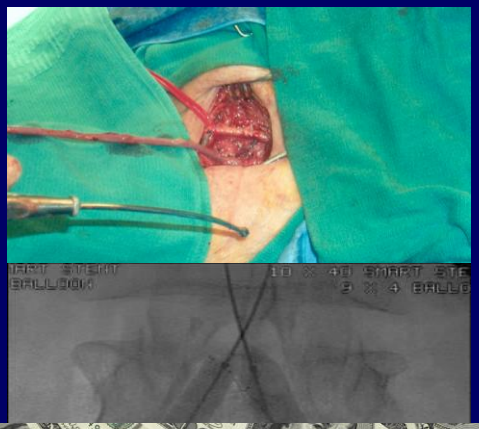
Practice and Disease Patterns in Greenville

(%)	Claudication (N=663 pts)	Rest Pain (N=392 pts)	Tissue Loss (N=677 pts)	p-value
Endo/Open	66.2 / 33.3	67.6 / 29.8	51 / 47.4	<0.001
AOID/ Infrainguinal	64.9 / 32.6	31.6 / 63.5	16.4 / 77.1	<0.001

-We are on the “Endo Bandwagon”
- “60/40” – “50/50” Endo/Open

Judgment

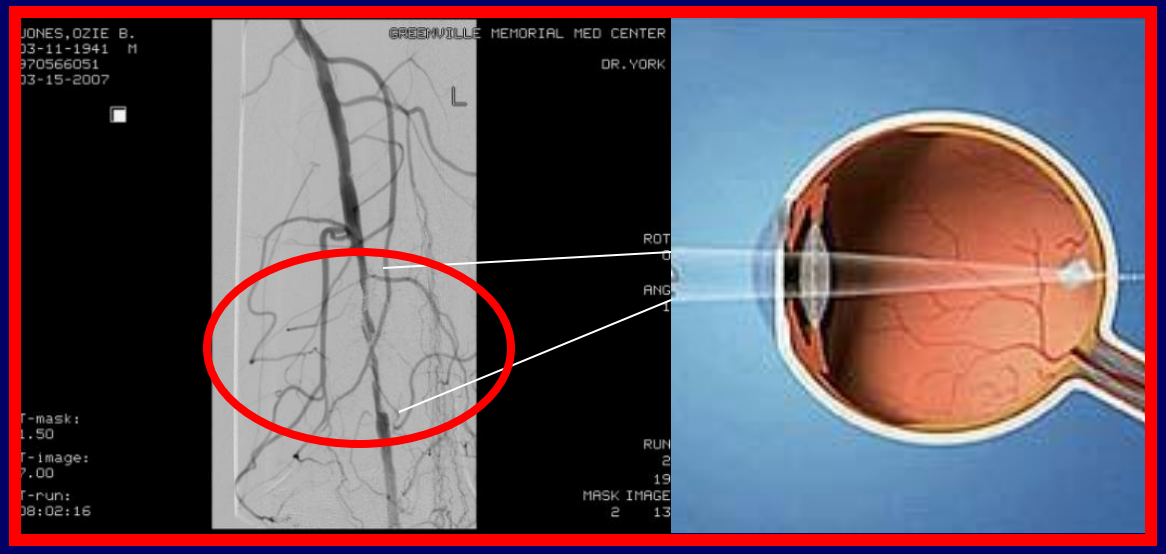

SUPPLEMENT TO
JOURNAL OF
VASCULAR
SURGERY
VOLUME 31 NUMBER 1 PART 2 JANUARY 2000
TASC
Management of
Peripheral Arterial Disease (PAD)
TransAtlantic Inter-Society Consensus (TASC)
Section A: Introduction
Section B: Intermittent Claudication




Time
And effort


CMS
reimbursement

“The Oculostenotic Reflex”



“Oculostenotic Syndrome”

A condition afflicting educated individuals who possess no resistance to the oculostenotic reflex citing a series of rationalizations for their behavior

- “Well tolerated/ rarely harmful/and may help”
- “The patient would want me to try everything minimally invasive prior to offering open surgery”

Angioplasty Anonymous?

Current Status:

It is what it is….

So, how is that working for us?

An Assessment: Rx for Tissue Loss

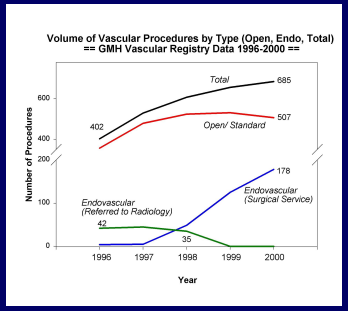
Cull DL, et al: SSA 2009

"Open Era"
1996
n=570

↑ 30%

"Endo Era"
2005
n=749

"75%/25%"



"50%/50%"

1) # of 2° revascularizations doubled (8%-19%)

2) Amputation rate not improved ~ 50% @ 3years

An Assessment

Cull DL, et al: SSA 2009

Our shift from open surgery to endovascular, while less invasive, has increased the “amount of care” without improving outcomes

Mediocrity…and I offer no solutions

- To solve the healthcare crisis we need to approach scientifically-STANDARDIZE
- PAD is a great example of how NOT to use value based outcomes to drive care
- A shift to endo has occurred with little convincing evidence that care has been improved

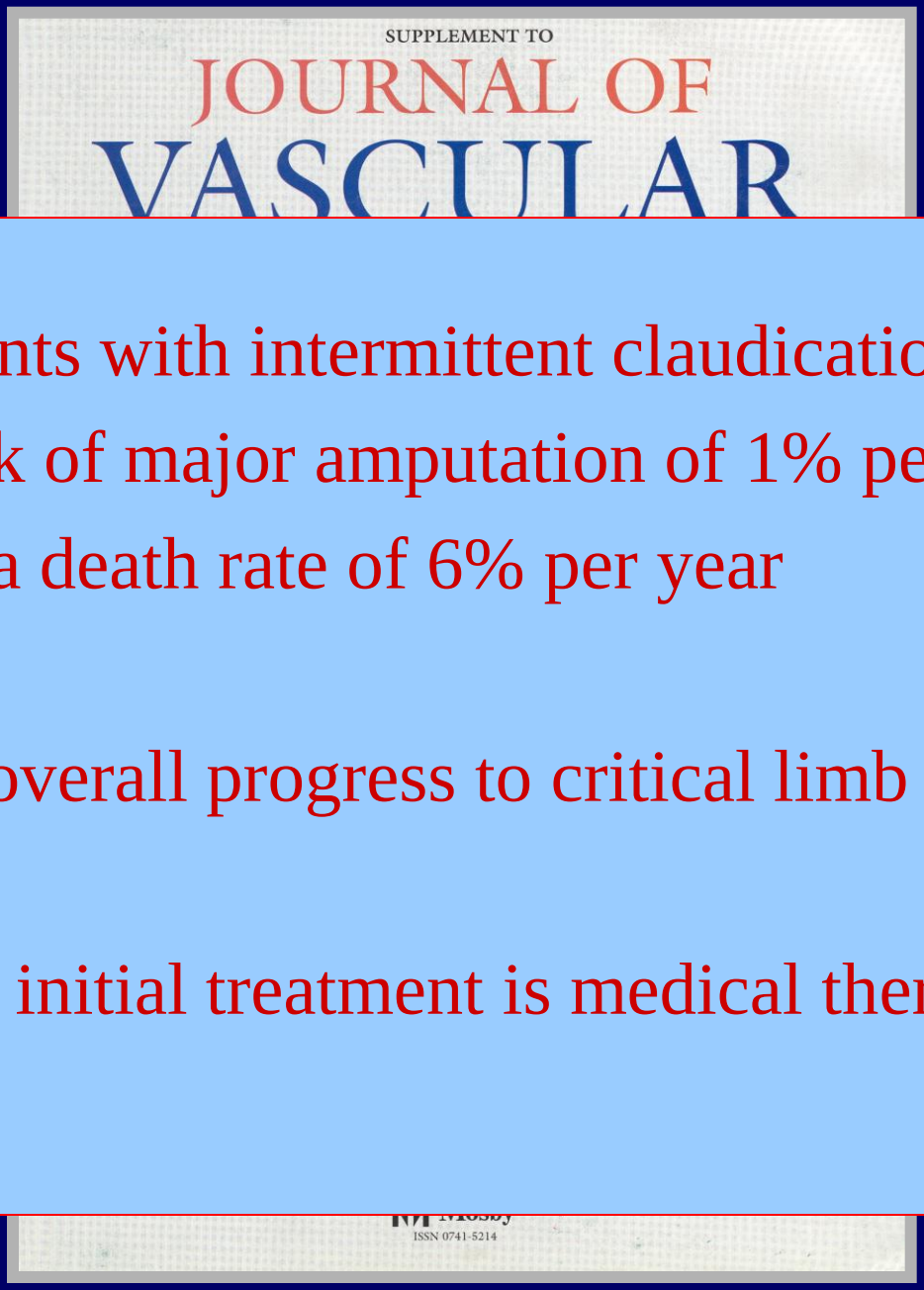
Claudication

The World Is Changing

- 61 year-old man with claudication left leg
-
-
-
-
-
- cessation

Seen recently walking around the hospital and informed me that his leg is doing well after the balloon angioplasty performed by his cardiologist

Where am I missing the boat?



1) Patients with intermittent claudication have a risk of major amputation of 1% per year and a death rate of 6% per year

2) 6% overall progress to critical limb ischemia

3) Best initial treatment is medical therapy

Claudication - Medical Treatment

- Stop smoking
- Exercise program
- Drug therapy

Claudication - Medical Treatment

Smoking

- Highly addictive - relapse common
- 63% of patients - despite a major smoking related illness, will continue to smoke
- Successful secession long-term in 6% of patients

N Engl J Med 1999;340:685-91

Atherosclerosis 1996;120:25-35.

Claudication

Exercise

- The benefits of supervised exercise are undisputed
- In a UK study where patients were followed for 6 years, there was no difference in walking distance between PTA and exercise despite initial improved ABIs in the PTA group
- Any benefit of PTA dissipated by 2 years in another randomized prospective study

Perkins JMT, Eur J Vasc Endovasc Surgery,1996

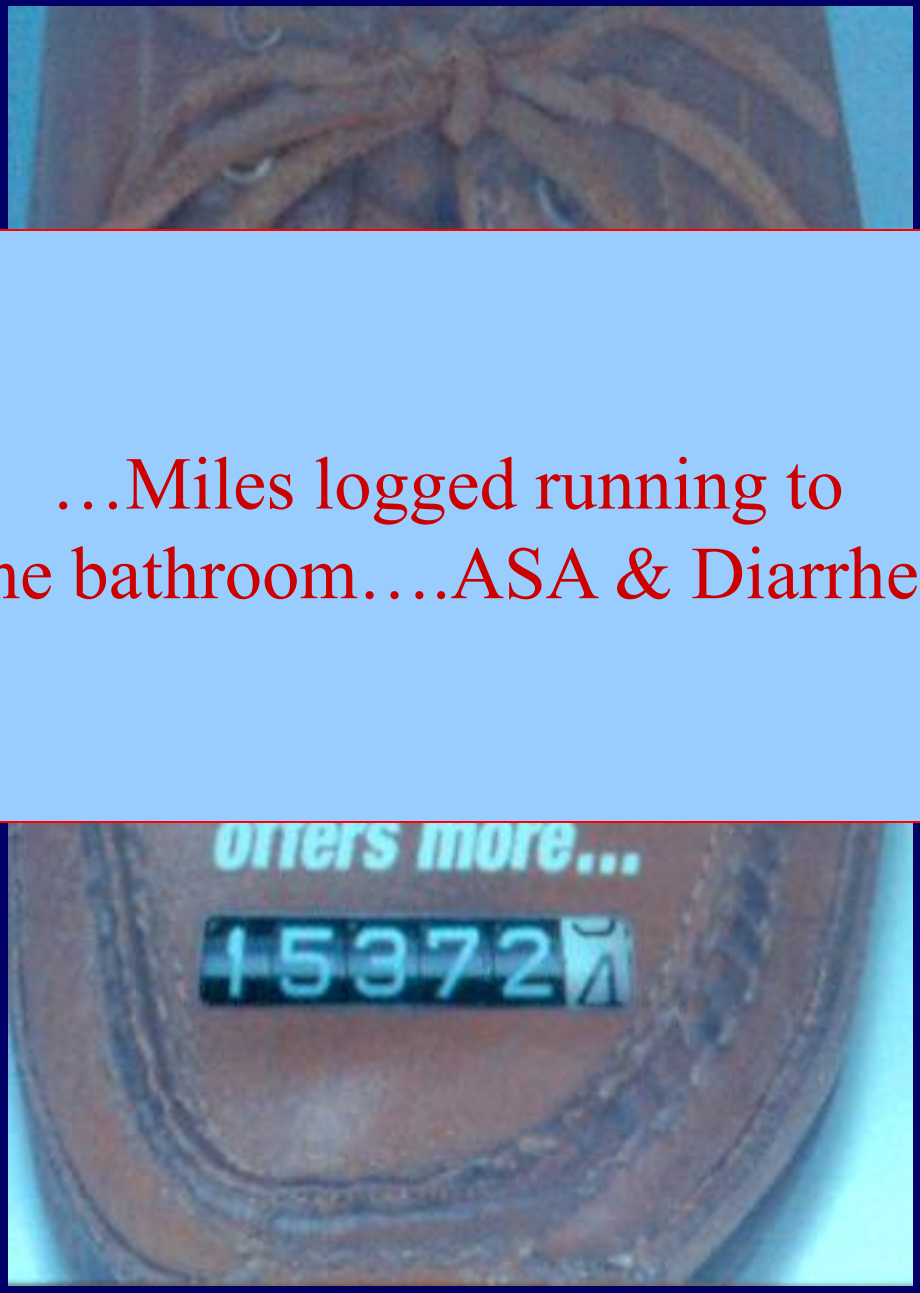
WhymanMR, J Vasc Surg,1996

Claudication - Medical Treatment

Exercise Program

- 34% - can not participate - other ailments
- 36% - unwilling to participate
- 30% - participate and do well

De La Haye, Vasa, 1992



…Miles logged running to
the bathroom….ASA & Diarrhea

Mediocrity?

- At best we help only one-third of our patients with claudication by non-interventional Rx

Claudication - Intervention/Outcomes

Feinglass PhD et al, J Vasc Surg, 2000, 31(1), 93-103

- 526 patients
- Objective patency data (ABI)
- SF36 physical function score
- SF36 bodily pain score
- WIQ walking distance score

Claudication - Intervention/Outcomes

- Functional improvement varied with ABI
- Functional gains - 1/2 that of hip replacement

  - similar to coronary angioplasty

From the American Venous Forum

One-year prospective quality-of-life outcomes in patients treated with angioplasty for symptomatic peripheral arterial disease

- Health assessment improved overall after PTA
- Strikingly better with claudication
- Health assessment did not improve with CLI and 1 year amputation-free survival was only 50%

hazard ratios (HRs) revealed that presentation was a significant predictor for outcomes of primary patency (HR, 4.2; P = .0002), secondary patency (HR, 6.0; P < .0001), limb salvage (HR, 20.2; P = .0047), survival (HR, 10.9; P = .0002), and amputation-free survival (HR, 11.2; P < .0001). Conversely, the level of disease was predictive of outcome only for primary patency (HR, 1.8; P = .00289).

Conclusions: Despite inferior reconstruction patency rates when compared with the historical results of open bypass, PTA provides excellent functional outcomes with good patient satisfaction, especially for treating claudication. These findings support a more liberal use of PTA intervention for patients with vasculogenic claudication. (J Vasc Surg 2006;44: 296-303.)

Claudicatio

Criti Limb Ischemia

Approach Differently

Vasculogenic Claudication

Critical Analysis

PubMed search
"Intervention for claudication"

- Claudication outcomes rarely studied in isolation

402 citations:
6 reports confined to cohorts of claudication only

taprald3/acs-acs/acs-acs/acs00508/acs5366d08z | Shindas | S=1 | 2/4/08 | Art: 4742

Do Current Outcomes Justify More Liberal Use of Revascularization for Vasculogenic Claudication? A Single Center Experience of 1,000 Consecutively Treated Limbs

Spence M Taylor, MD, FACS, Corey A Kalbaugh, MS, Matthew G Healy, BS, Anna L Cass, MPH, Bruce H Gray, DO, Eugene M Langan III, MD, FACS, David L Cull, MD, FACS, Christopher G Carsten III, MD, FACS, John W York, MD, FACS, Bruce A Snyder, MD, FACS, Jerry R Youkey, MD, FACS

AQ 1

BACKGROUND: The purpose of this study was to reconsider current recommended treatment guidelines for vasculogenic claudication by examining the contemporary results of surgical intervention.

STUDY DESIGN: We performed a retrospective review of 1,000 consecutive limbs in 669 patients treated for medically refractory vasculogenic claudication and prospectively followed. Outcomes measured included procedural complication rates, reconstruction patency, limb salvage, maintenance of ambulatory status, maintenance of independent living status, survival, symptom resolution, and symptom recurrence.

RESULTS: Of the 1,000 limbs treated, endovascular therapy was used in 64.3% and open surgery in 35.7% of patients: aortoiliac occlusive disease was treated in 70.1% and infrainguinal disease in 29.9% of patients. The overall 30-day periprocedural complication rate was 7.5%, with no significant difference in complication rates when comparing types of treatment or levels of disease. Overall reconstruction primary patency rates were 87.7% and 70.8%: secondary patencies were 97.8% and 93.9%: limb salvage, 100% and 98.8%: and survivals, 95.4% and 76.9%, at 1 and 5 years, respectively. More than 96% of patients maintained independence and ambulatory ability at 5 years. Overall symptom resolution occurred in 78.8%, and symptom recurrence occurred in 18.1% of limbs treated, with slightly higher resolution and recurrence noted in patients treated with endovascular therapy.

CONCLUSIONS: Contemporary treatment of vasculogenic claudication is safe, effective, and predominantly endovascular. These data support a more liberal use of revascularization for patients with claudication and suggest that current nonoperative treatment guidelines may be based more on surgical dogma than on achievable outcomes. (J Am Coll Surg 2008;xx:xxx. © 2008 by the American College of Surgeons)

Classic teaching has stressed nonoperative therapy for initial management of vasculogenic claudication, a condition that affects nearly 20% of Americans older than 70 years.[1] This recommendation is based on the frequently cited benign natural history of lower extremity peripheral arterial disease (PAD) and the marginal longterm benefits of surgery as it pertains to the risk of limb loss.[2-4] Nonoperative therapy consisting of smoking cessation, supervised walking or exercise, and pharmacologic intervention is safe and highly effective if successfully used for patients with claudication.[5-7] So, constraint when considering surgical intervention has been recommended except in severe cases of medically refractory, occupational threatening claudication.

During the past decade, however, percutaneous transluminal angioplasty (PTA), a procedure with lower morbidity than in open surgery, has emerged as a common treatment for many patients with lower extremity PAD. Subsequently, reports using PTA as the primary method of

Competing Interests Declared: None.
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ISSN 1072-7515/08/$34.00
doi:10.1016/j.jamcollsurg.2007.12.043

1000 Limb Claudication Study

- Treatment today = predominantly endovascular Rx (> 60%) and safe (< 1% mortality)
- Symptom resolution = nearly 80%; symptom recurrence = 18%
- Re-intervention for recurrent symptoms = 6.5%; amputation in this cohort was rare (< 2%)

1000 Limb Claudication Study

- Five year patency, maintenance of ambulation and maintenance of independence > 90%

- Five-year limb salvage = 99% ; survival = 77%
  - Survival - typical, limb salvage - superior to natural history reports

Are our attitudes about claudication wrong?

What about critical limb ischemia?

The Sentinel Case

Mrs C.

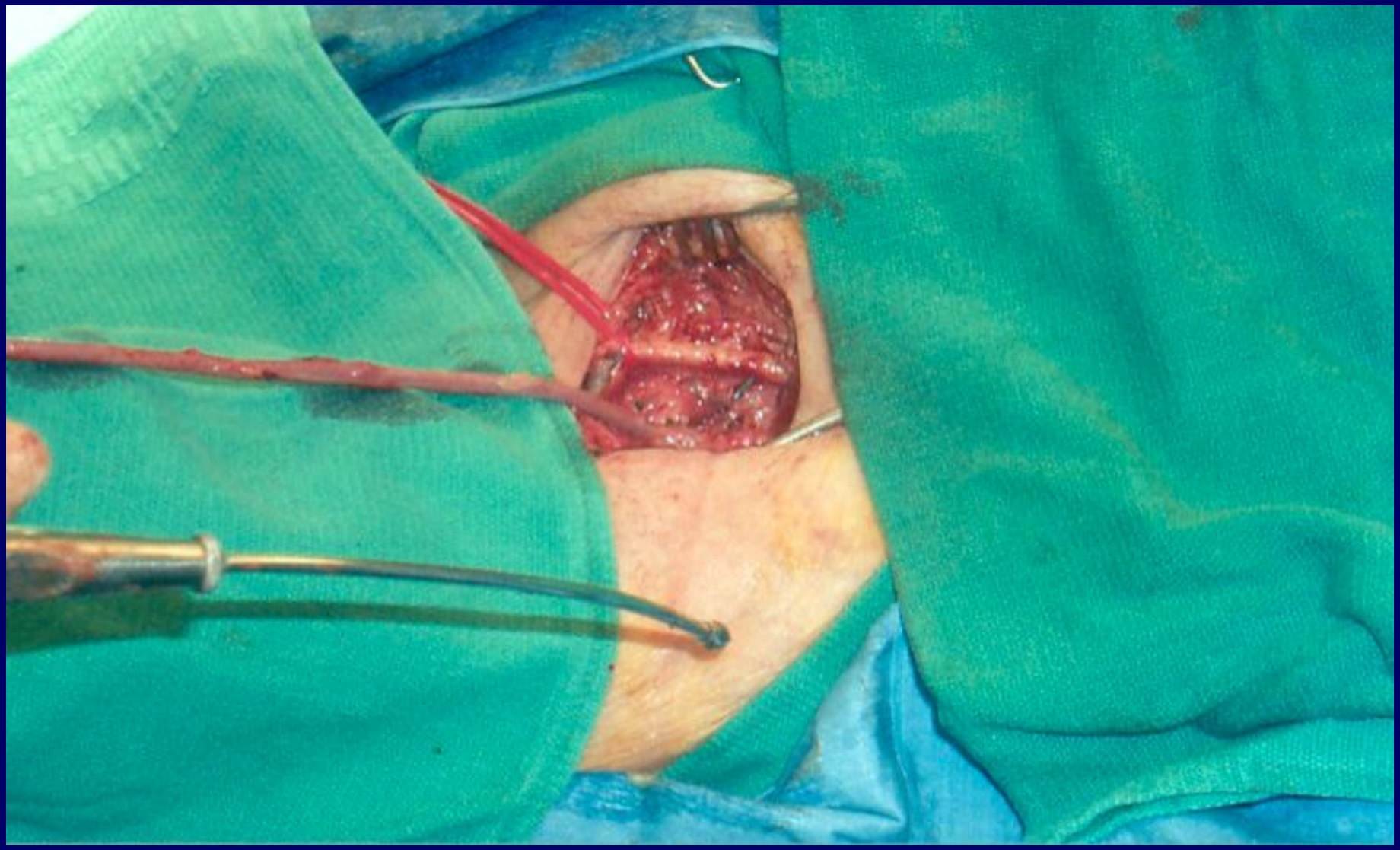
- 70 yr old WF-Transferred from out-lying hospital with Lt leg ischemic ulcers – blisters from CHF
- “Fully functional” prior to hospitalization.
- Smoker/ NIDDM
- Transferred “to the Mecca” for limb salvage

Mrs C.

- A-Gram shows normal aorta and iliacs,Lt SFA,popleteal occlusion,1vessel (Post tib) R/O below a diseased popliteal artery
- OK vein

Mrs C.

What to do?



Mrs C.

- Fem-Posterior tibial bypass
- Long drawn out course- 6 week
- Missed her first F/U

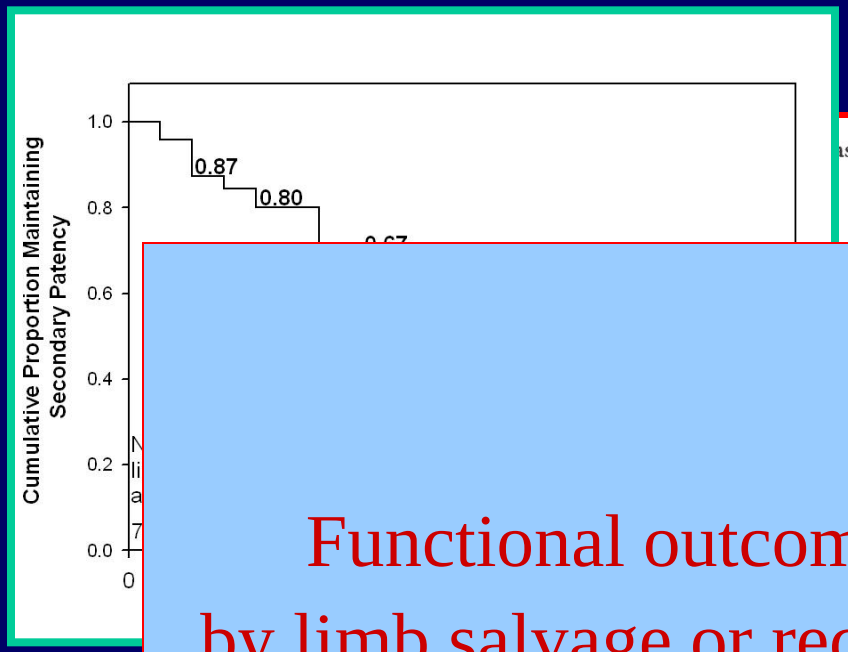
Do we need to change our attitudes about the management of critical limb ischemia?

Critical Limb Ischemia

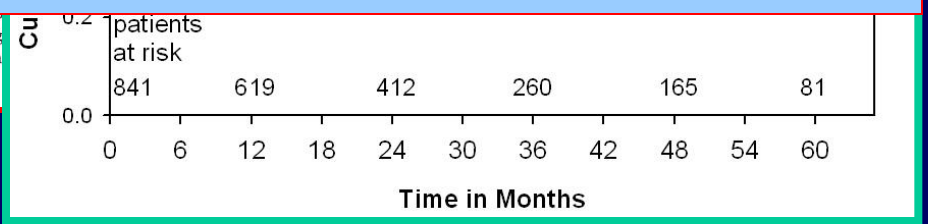
- Incredibly heterogeneous

Rest Pain- Tissue Loss
-Ulcer
-Gangrene

- Perhaps outcomes depend on presentation?
  - Pre-existing condition?
  - Rest pain?
  - Tissue loss?



Functional outcome not solely determined by limb salvage or reconstruction patency, but by functional, mental, and medical condition at presentation



Comparison of Interventional Outcomes According to Preoperative Indication: A Single Center Analysis of 2,240 Limb Revascularizations

Spence M Taylor, MD, FACS, David L Cull, MD, FACS, Corey A Kalbaugh, MS, Herman F Senter, PhD, Eugene M Langan III, MD, FACS, Christopher G Carsten III, MD, FACS, John W York, MD, FACS, Bruce A Snyder, MD, FACS, Bruce H Gray, DO, Mark P Androes, MD, FACS, Dawn W Blackhurst, DrPH

BACKGROUND: Outcomes after lower extremity revascularization are usually reported according to the level of peripheral arterial disease (PAD, aortoiliac or infrainguinal) or the method of treatment (open or endovascular surgery). Outcomes stratified by indication, ie, claudication or critical limb ischemia (rest pain and tissue loss), have not been well studied. The purpose of this study was to compare postoperative outcomes according to the preoperative indications.

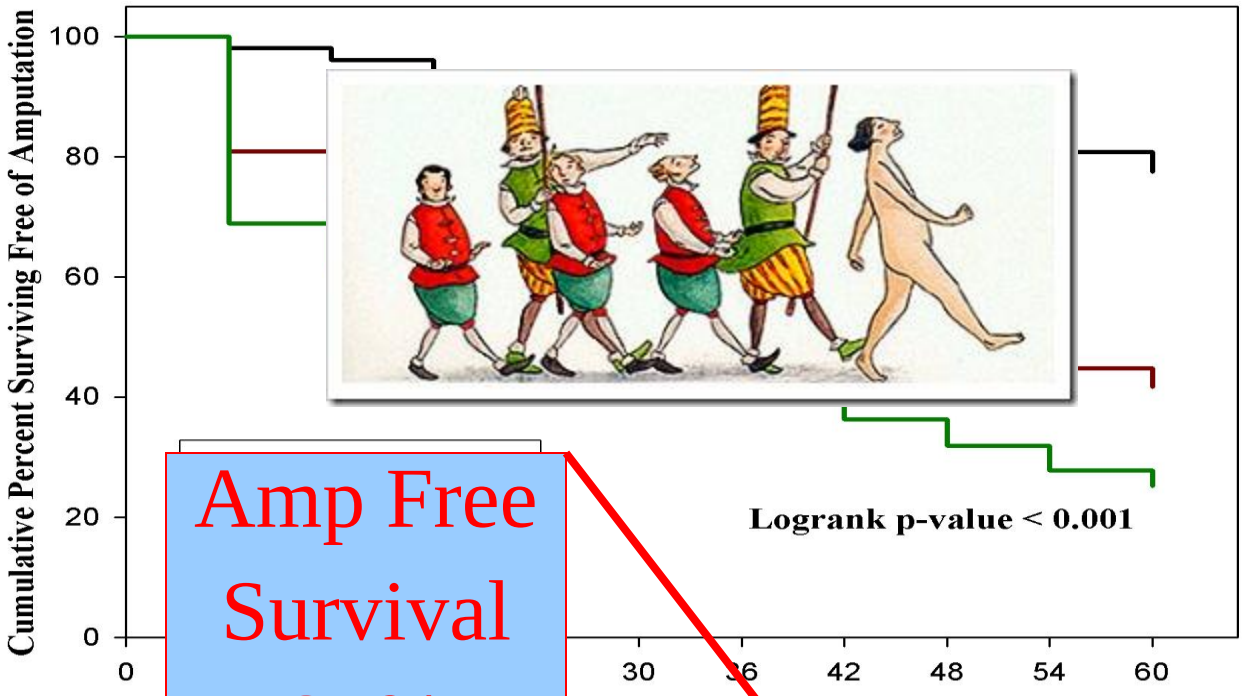
STUDY DESIGN: Outcomes of 2,240 consecutive limb revascularizations in 1,732 patients from January 1998 through December 2005 were stratified and examined according to preoperative indication: claudication (n = 999 limbs), ischemic rest pain (n = 464 limbs), or tissue loss (n = 777 limbs). End points measured included primary and secondary interventional or operative patency, limb salvage, survival, amputation-free survival, maintenance of ambulation, maintenance of independence, and resolution of presenting symptoms.

RESULTS: The proportion of medical comorbidities and the severity of disease increased significantly by cohort from claudication to rest pain to tissue loss. With a mean followup of 1,089 days (range 0 to 3,689 days), overall outcomes performance declined consistently according to indication for all end points measured at 5 years (claudication, rest pain, tissue loss, p value): secondary reconstruction patency (93%, 80%, 66%, respectively; $p < 0.001$), limb salvage (99%, 81%, 68%, respectively; $p < 0.001$), survival (78%, 46%, 30%, respectively; $p < 0.001$), amputation-free survival (78%, 42%, 25%, respectively; $p < 0.001$), maintenance of ambulation (96%, 78%, 68%, respectively; $p < 0.001$), maintenance of independence (98%, 85%, 75%, respectively; $p < 0.001$), and resolution of presenting symptoms (79%, 61%, 42%, respectively; $p < 0.001$).

CONCLUSIONS: There is a declining spectrum of outcomes performance from claudication to rest pain to tissue loss. These findings question the accuracy of all previously published data for critical limb ischemia, for which rest pain and tissue loss are usually blended and reported as a single outcomes value. (J Am Coll Surg 2009;208:770–780. © 2009 by the American College of Surgeons)

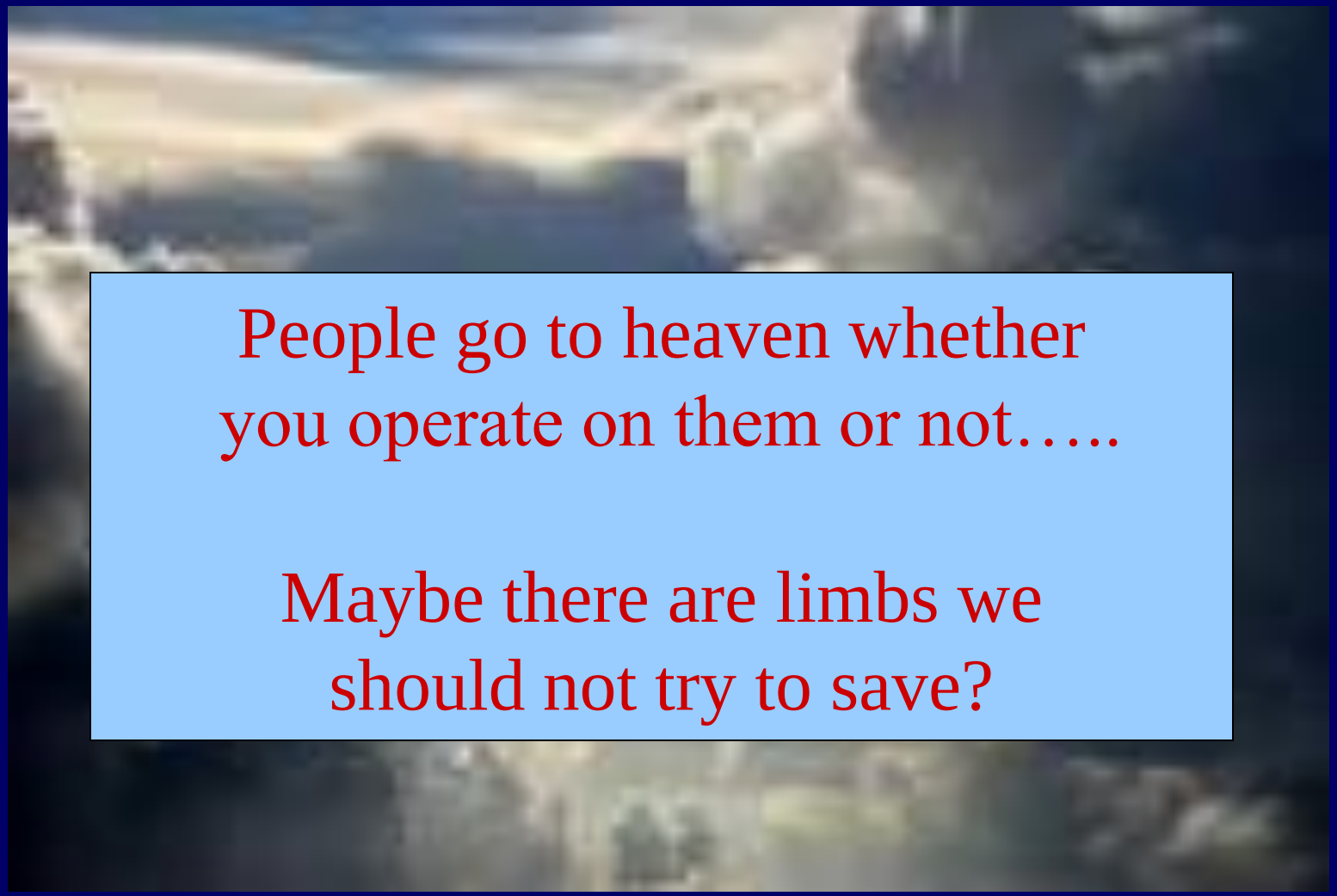
Southern Surgical Association 2008

- 2240 … 1998-Dec.
- 999 … cation
- 464
- 777



Amp Free Survival 25%

Operative Indication	Amputation-Free Survival			
	6 month	1 year	3 year	5 year
Claudication	98.1	96.1	87.2	77.5
Rest Pain	80.9	74.9	55.3	41.7
Tissue Loss	68.9	60.9	40.5	25.2


People go to heaven whether
you operate on them or not…..
Maybe there are limbs we
should not try to save?

Case Presentation

Mrs. H

- 93 year old female mentally sharp
- Assisted living facility; functionally independent
- Uses legs to transfer; wheelchair bound during the day but very active
- Baseline congestive heart failure
- Presents with gangrenous changes, second toe

Case Presentation

Osteomyelitis 2nd Toe

- Slight left knee contracture
- ABIof 0.39 and a great toe pressure of 13
- Triphasic common femoral waveform, superficial femoral artery occlusion with reconstitution of the tibial vessels at mid-shank

What should you do?

The solution is simple:

Angioplasty (BJ)

A comparison of percutaneous transluminal angioplasty versus amputation for critical limb ischemia in patients unsuitable for open surgery

Spence M. Taylor, MD, Corey A. Kalbaugh, MS, Dawn W. Blackhurst, DrPH, Dwight C. Kellicut, MD, Eugene M. Langan III, MD, and Jerry R. Youkey, MD, *Greenville, SC*

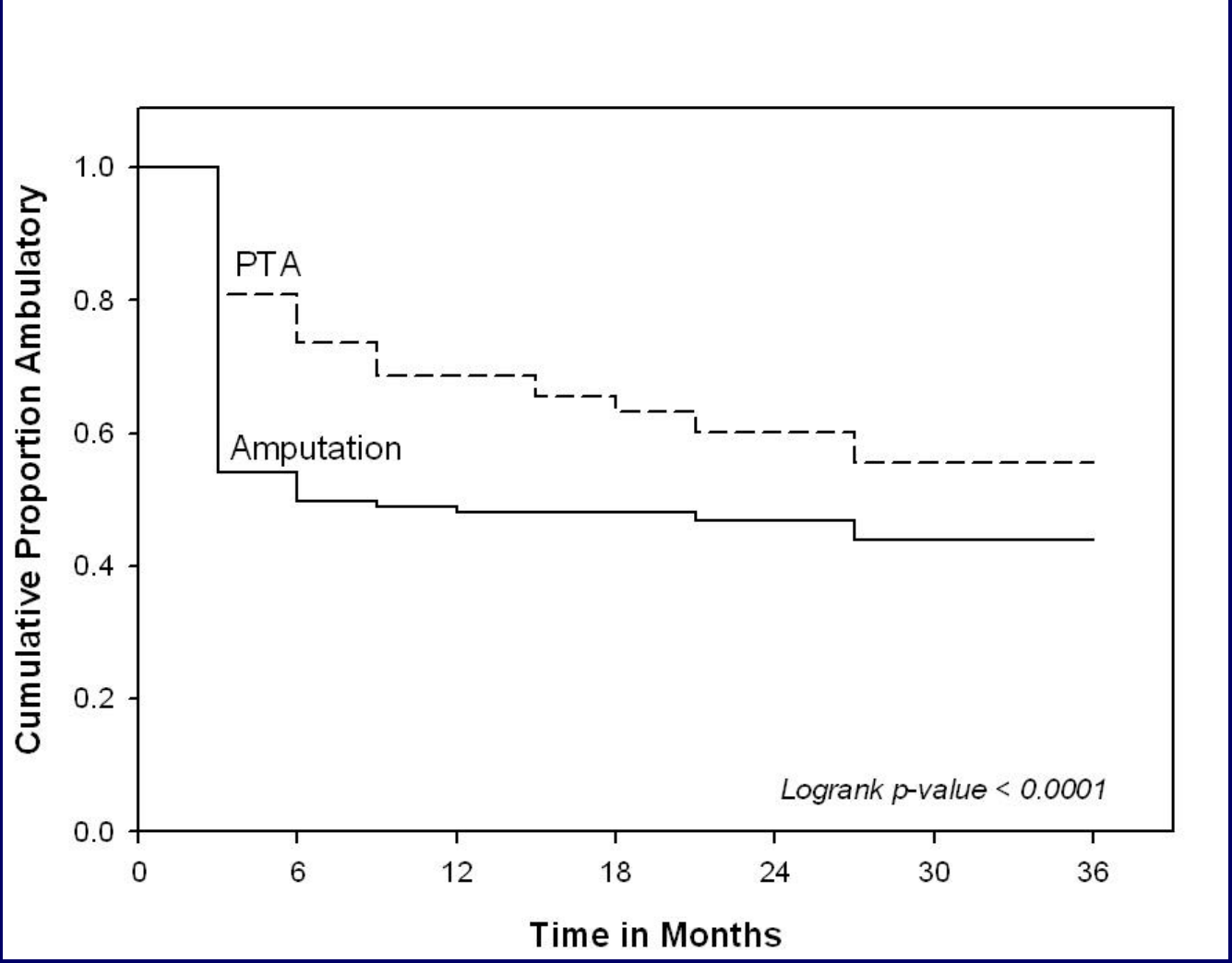
Background: Percutaneous transluminal angioplasty (PTA), although not the traditional therapy, seems to be a safe alternative for patients with critical limb ischemia who are believed to be unsuitable candidates for open surgery. However, the efficacy of PTA in this setting has not been analyzed. The purpose of this study was to compare the outcomes of PTA for limb salvage with outcomes of major limb amputation in physiologically impaired patients believed to be unsuitable for open surgery.

Methods: From a prospective vascular registry, 314 patients (183 underwent amputation, and 131 underwent complex PTA for limb salvage) were identified as physiologically impaired or unsuitable for open surgery. This was defined as having at least one of the following: functional impairment (homebound ambulatory or transfer only), mental impairment (dementia), or medical impairment (two of the following: end-stage renal disease, coronary artery disease, and chronic obstructive pulmonary disease). Patients undergoing PTA were compared with patients undergoing amputation by examining the outcome parameters of survival, maintenance of ambulation, and maintenance of independent living status. Parameters were assessed by using Kaplan-Meier life-table curves (log-rank test and 95% confidence intervals [CIs]) and hazard ratios (HRs) from the Cox model.

Results: PTA resulted in a 12-month limb salvage rate of 63%. Thirty-day mortality was 4.4% for the amputation group and 3.8% for the PTA group. After adjustment for age, race, diabetes, prior vascular procedure, dementia, and baseline functional status, PTA patients had significantly lower rates of ambulation failure (HR, 0.44; $P = .0002$) and loss of independence (HR, 0.53; $P = .025$) but had significantly higher mortality (HR, 1.62; $P = .006$) than amputees. However, when life tables were examined, the maintenance of ambulation advantage lasted only 12 months (PTA, 68.6%; 95% CI, 59.6%-77.7%; amputation, 48%; 95% CI, 40.4%-55.5%) and was not statistically significant at 2 years (62.2% [95% CI, 48.8%-71.5%] and 44% [95% CI, 35.8%-52.2%], respectively). Maintenance of independent living status advantage lasted only 3 months, with no statistically significant difference at 2 years (PTA, 60.5%; 95% CI, 45.4%-75.6%; amputation, 52.6%; 95% CI, 40.4%-64.9%). Although mortality was high in both cohorts, patients who underwent amputation had a survival advantage for all time intervals examined (at 2 years: PTA, 29%; 95% CI, 19.9%-38.1%; amputation, 48.1%; 95% CI, 39.2%-56.9%).

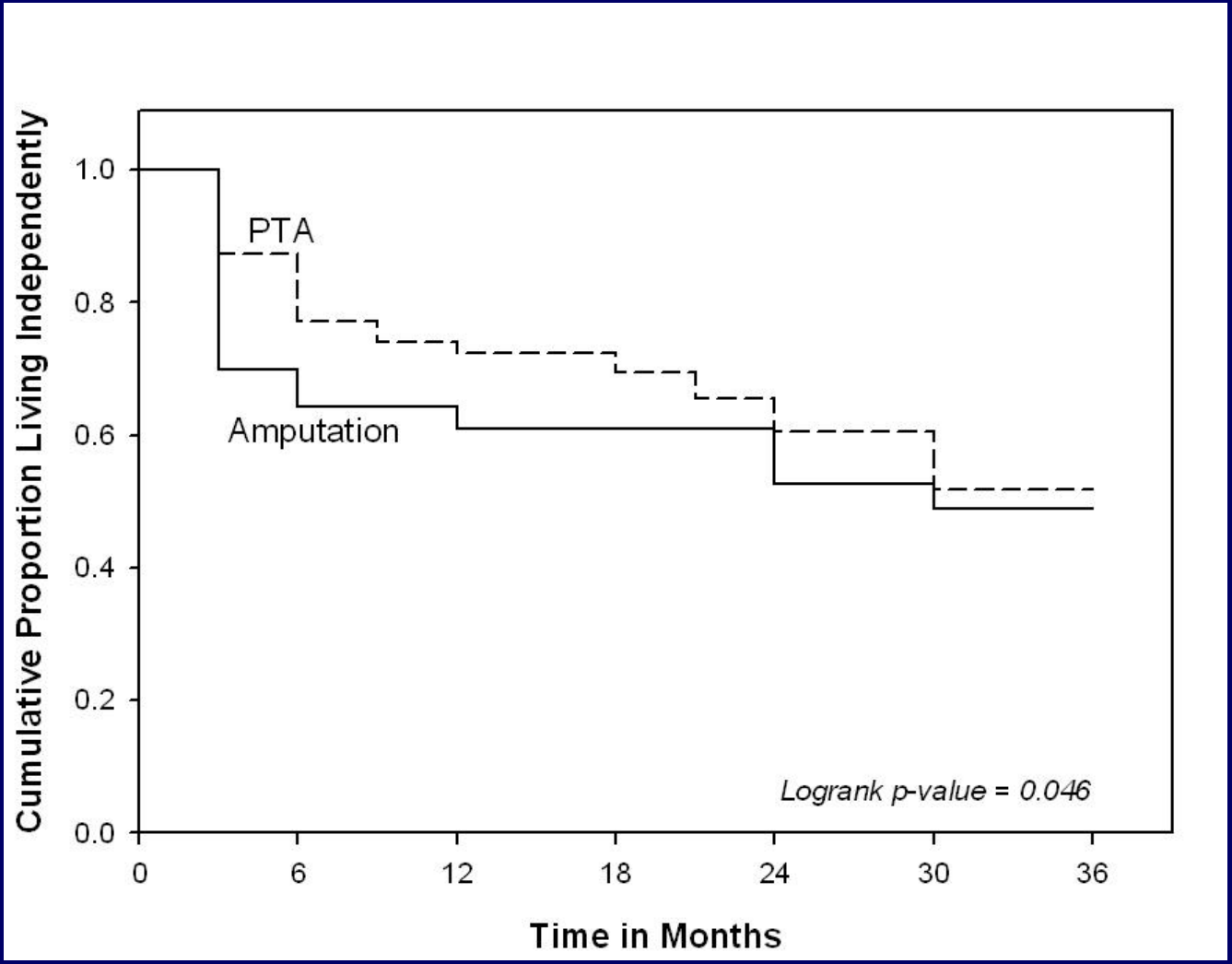
Conclusions: Patients who present with critical limb ischemia and physiologic impairments that preclude open surgery seem to have comorbidities that blunt any functional advantage achieved after PTA for limb salvage. PTA in this setting affords very little benefit compared with amputation alone. (J Vasc Surg 2007;45:304-11.)

Ambulation



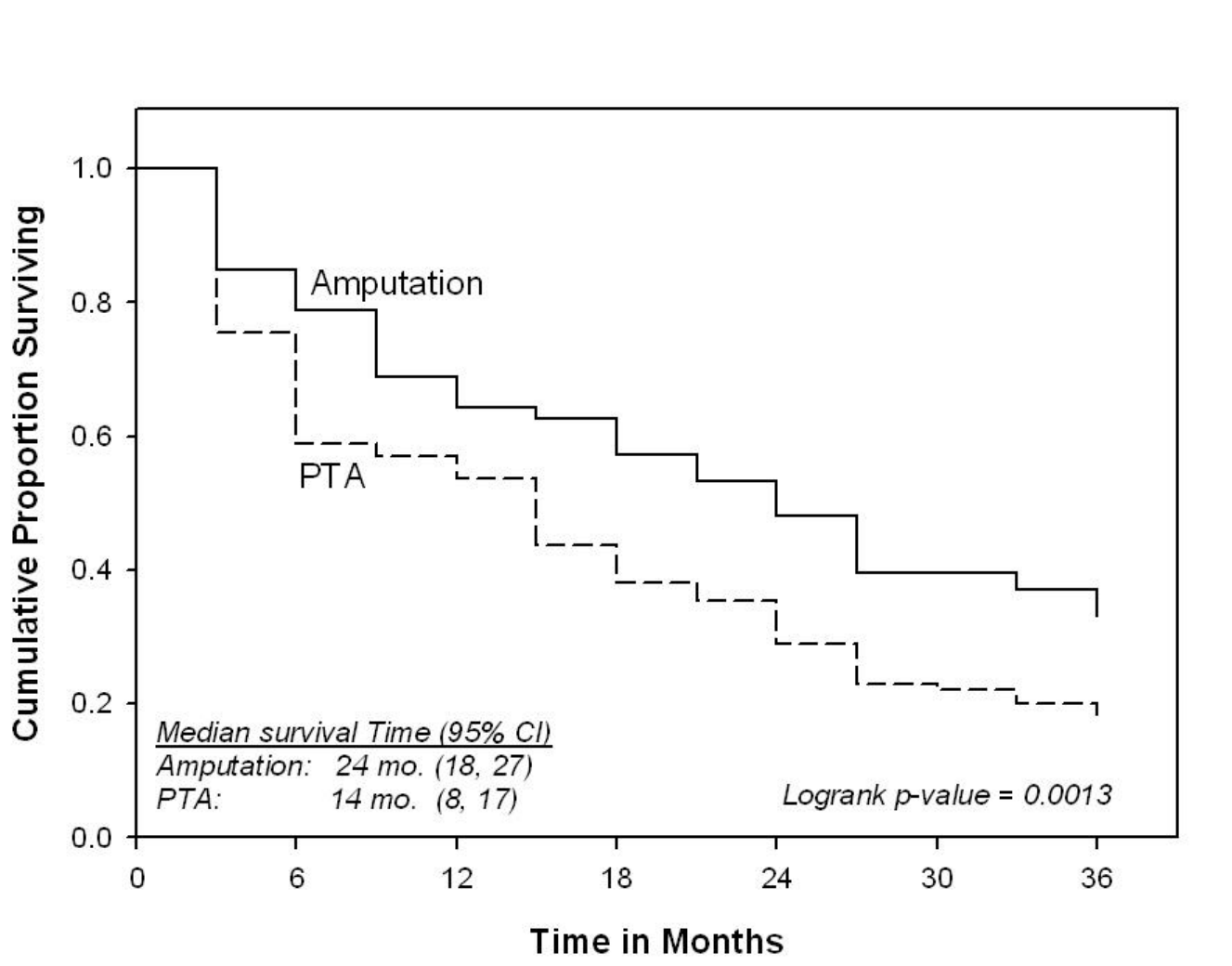
Advantage only 12 mos

Independent Living Status



Advantage only 3 mos.

Survival



Survival advantage for amputation vs PTA

Endo-basher!

Endo-basher!

Endo-basher!

What's the harm in trying endovascular intervention?

…It is well tolerated and safe, etc, etc, etc….

2008 Medicare Allowable

Superficial femoral artery PTA and stent

CPT Code	Professional Fee	Facility Fee
36247	$295.51	
75710-26	$53.24	$1,799.35
75625		
35474	$356.14	$1,413.88
75962-26	$25.26	
37205	$406.64	$5,516.44
75960-26	$38.49	
Total	$1,175.28	$8,729.67

$9,904.95

Critical Analysis of Clinical Success after Surgical Bypass for Lower-Extremity Ischemic Tissue Loss Using a Standardized Definition Combining Multiple Parameters: A New Paradigm of Outcomes Assessment

Spence M Taylor, MD, FACS, David L Cull, MD, FACS, Corey A Kalbaugh, MS, Anna L Cass, MPH, Sarah Anne Harmon, Eugene M Langan III, MD, FACS, Jerry R Youkey, MD, FACS

BACKGROUND: Success after surgical revascularization of the lower extremities, traditionally defined by graft patency or limb salvage, fails to consider other intuitive measures of importance. The purpose of the study was to construct a more comprehensive definition of clinical success and to identify clinical predictors of failure.

STUDY DESIGN: For the purpose of this study, clinical success was defined as achieving all of the following criteria: graft patency to the point of wound healing; limb salvage for 1 year; maintenance of ambulatory status for 1 year; and survival for 6 months. Between 1998 and 2004, 331 consecutive patients undergoing bypass for Rutherford III critical limb ischemia were measured for clinical success. Bivariate and logistic regression analyses were performed to determine demographic differences between success and failure.

RESULTS: Despite achieving acceptable graft patency (72.7% at 36 months) and limb salvage (73.3% at 36 months), clinical success combining all 4 defined parameters was only 44.4%. Independent predictors of failure included impaired ambulatory status at presentation (odds ratio [OR] = 6.44), presence of infrainguinal disease (OR = 3.93), end-stage renal disease (OR = 2.48), presence of gangrene (OR = 2.40), and hyperlipidemia (OR = 0.56). Probability of failure in patients possessing every predictor except hyperlipidemia at presentation was 97% (OR = 150.6).

CONCLUSIONS: Despite achieving acceptable graft patency and limb salvage, fewer than half of the patients achieved success when using a definition combining multiple parameters. A reappraisal of our current approach to critical limb ischemia in certain high-risk patients is warranted. (J Am Coll Surg 2007;204:831–839. © 2007 by the American College of Surgeons)

A Definition of Success

Success after Revascularization for Tissue Loss

All of the following:

1. Graft patency to the point of wound healing
2. Limb salvage for one year
3. Maintenance of ambulatory status for one year
4. Survival for 6 months

Tested on 677 patients (316 endo & 361 open)

Clinical Success

- Overall = 40.9%
- Open Bypass = 43.3%
- Endovascular = 37.0%

P =0.06

677 Interventions for Tissue loss

Predictors in Combination	Probability of Failure (OR)
	(1.0)
Imp &	(10.5)
Imp Prior Vasc Intervention & Gan	3.7)

Success

Independent Predictors

- Impaired ambulation
- ESRD
- Diabetes
- Presence of gangrene
- Prior vascular intervention

Preoperative clinical factors predict postoperative functional outcomes after major lower limb amputation: An analysis of 553 consecutive patients

Spence M. Taylor, MD, Corey A. Kalbaugh, MS, Dawn W. Blackhurst, DrPH, Steven E. Hamontree, CPO, David L. Cull, MD, Hayley S. Messich, R. Todd Robertson, Eugene M. Langan III, MD, John W. York, MD, Christopher G. Carsten III, MD, Bruce A. Snyder, MD, Mark R. Jackson, MD, and Jerry R. Youkey, MD, *Greenville and Clemson, SC*

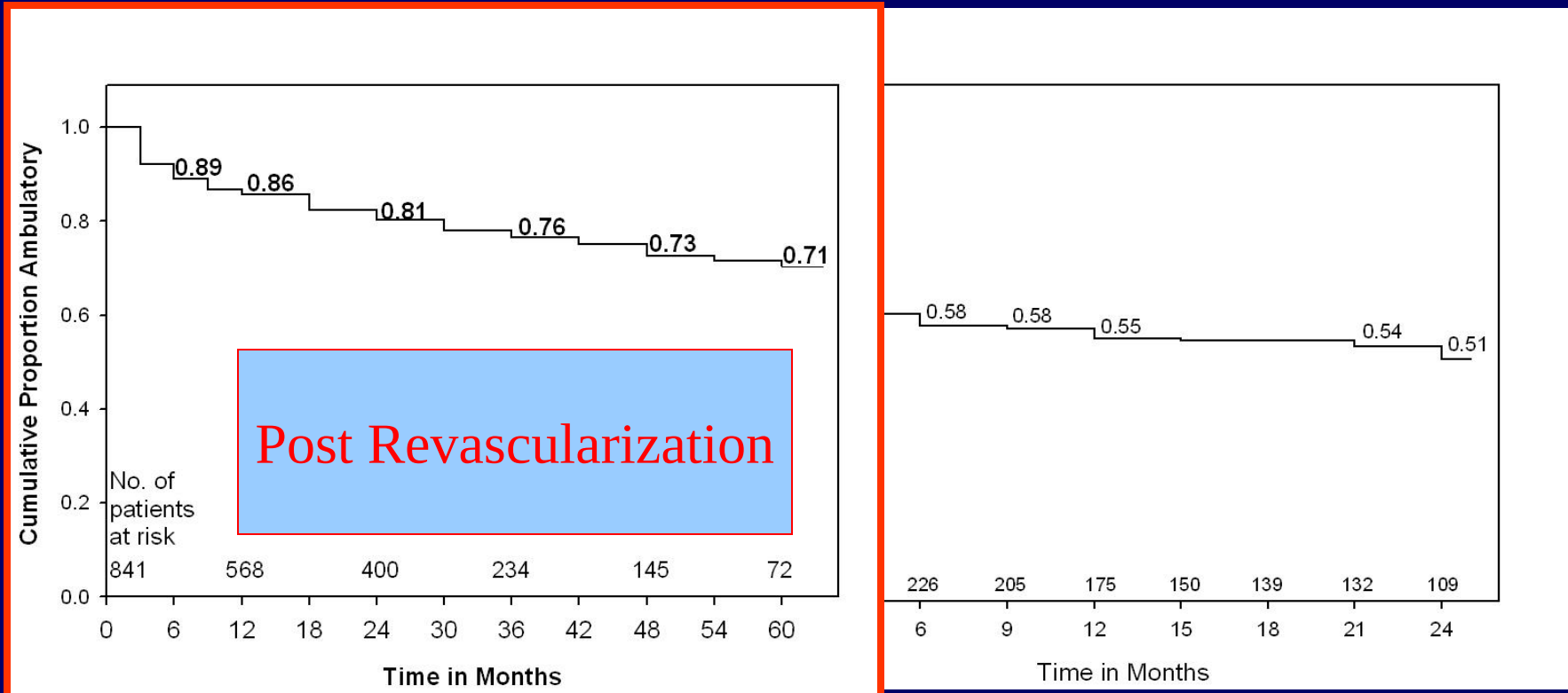
Background: Despite being a major determinant of functional independence, ambulation after major limb amputation has not been well studied. The purpose, therefore, of this study was to investigate the relationship between a variety of preoperative clinical characteristics and postoperative functional outcomes in order to formulate treatment recommendations for patients requiring major lower limb amputation.

Methods: From January 1998 through December 2003, 627 major limb amputations (37.6% below knee amputations, 4.3% through knee amputations, 34.5% above knee amputations, and 23.6% bilateral amputations) were performed on 553 patients. Their mean age was 63.7 years; 55% were men, 70.2% had diabetes mellitus, and 91.5% had peripheral vascular disease. A retrospective review was performed correlating various preoperative presenting factors such as age at presentation, race, medical comorbidities, preoperative ambulatory status, and preoperative independent living status, with postoperative functional endpoints of prosthetic usage, survival, maintenance of ambulation, and maintenance of independent living status. Kaplan-Meier survival curves were constructed and compared by using the log-rank test. Odds ratios (OR) and hazard ratios (HR) with 95% confidence intervals were constructed by using multiple logistic regressions and Cox proportional hazards models.

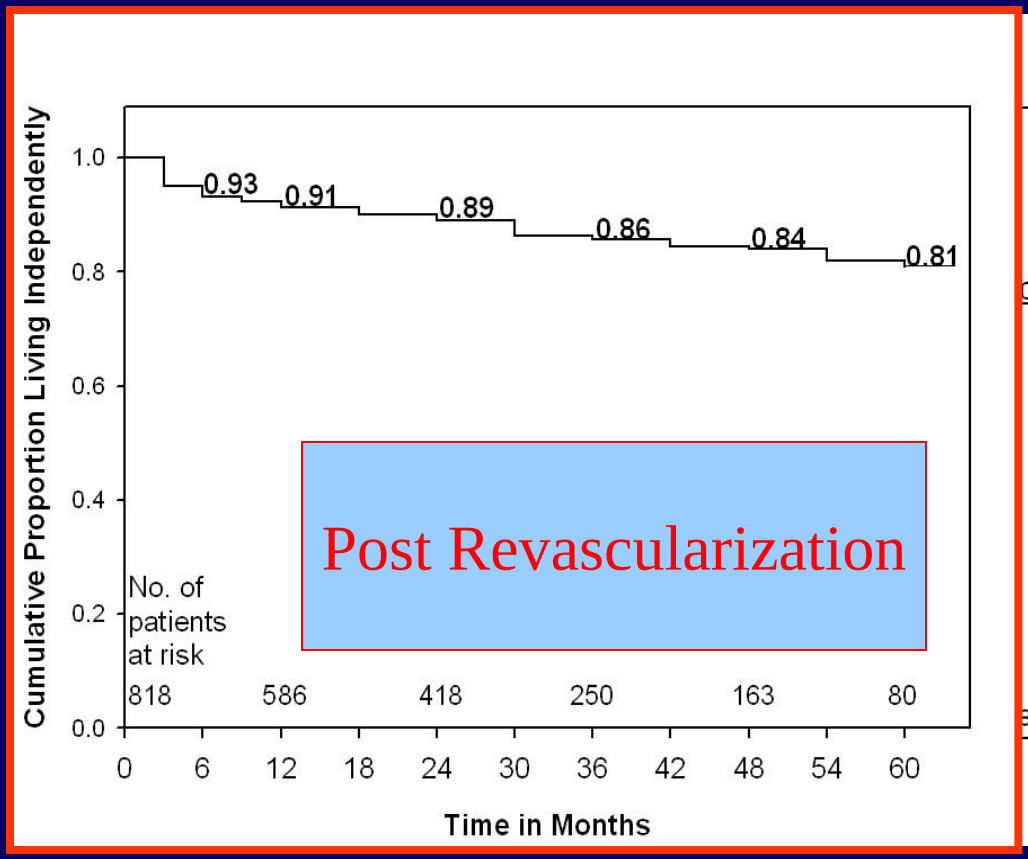
Results: Statistically significant preoperative factors independently associated with not wearing a prosthesis in order of greatest to least risk were nonambulatory before amputation (OR, 9.5), above knee amputation (OR, 4.4), age >60 years (OR, 2.7), homebound but ambulatory status (OR, 3.0), presence of dementia (OR, 2.4), end-stage renal disease (OR, 2.3), and coronary artery disease (OR, 2.0). Statistically significant preoperative factors independently associated with death in decreasing order of influence included age ≥70 years (HR, 3.1), age 60 to 69 (HR, 2.5), and the presence of coronary artery disease (HR, 1.5). Statistically significant preoperative factors independently associated with failure of ambulation in decreasing order of influence included age ≥70 years (HR, 2.3), age 60 to 69 (HR, 1.6), bilateral amputation (HR, 1.8), and end-stage renal disease (HR, 1.4). Statistically significant preoperative factors independently associated with failure to maintain independent living status in decreasing order of influence included age ≥70 years (HR, 4.0), age 60 to 69 (HR, 2.7), level of amputation (HR, 1.8), homebound ambulatory status (HR, 1.6), and the presence of dementia (HR, 1.6).

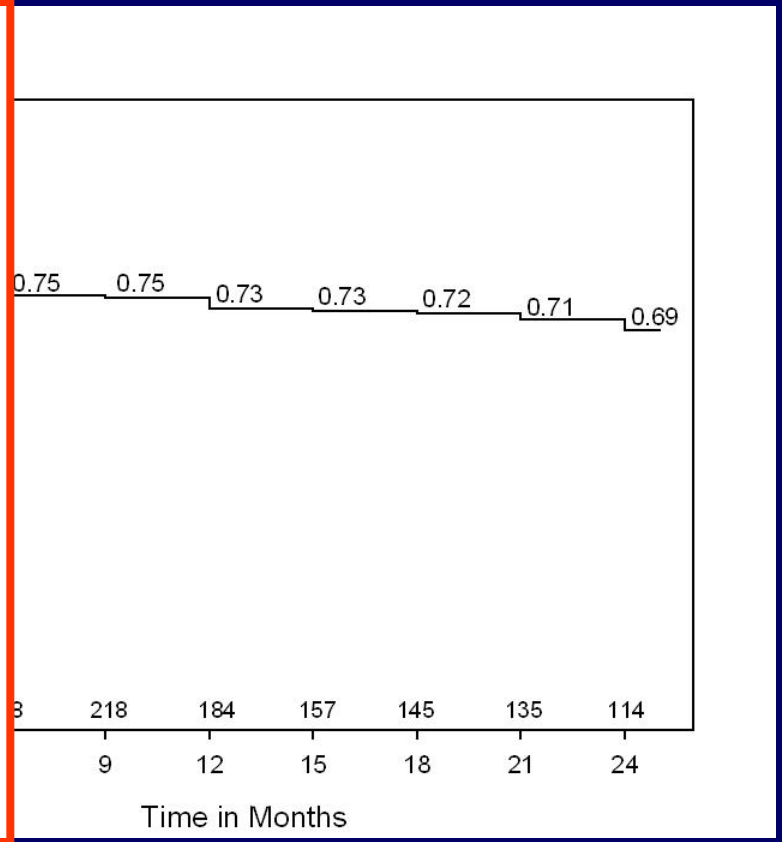
Conclusions: Patients with limited preoperative ambulatory ability, age ≥70, dementia, end-stage renal disease, and advanced coronary artery disease perform poorly and should probably be grouped with bedridden patients, who traditionally have been best served with a palliative above knee amputation. Conversely, younger healthy patients with below knee amputations achieved functional outcomes similar to what might be expected after successful lower extremity revascularization. Amputation in these instances should probably not be considered a failure of therapy but another treatment option capable of extending functionality and independent living. (J Vasc Surg 2005;42:227-35.)

Ambulatory Ability after Amputation



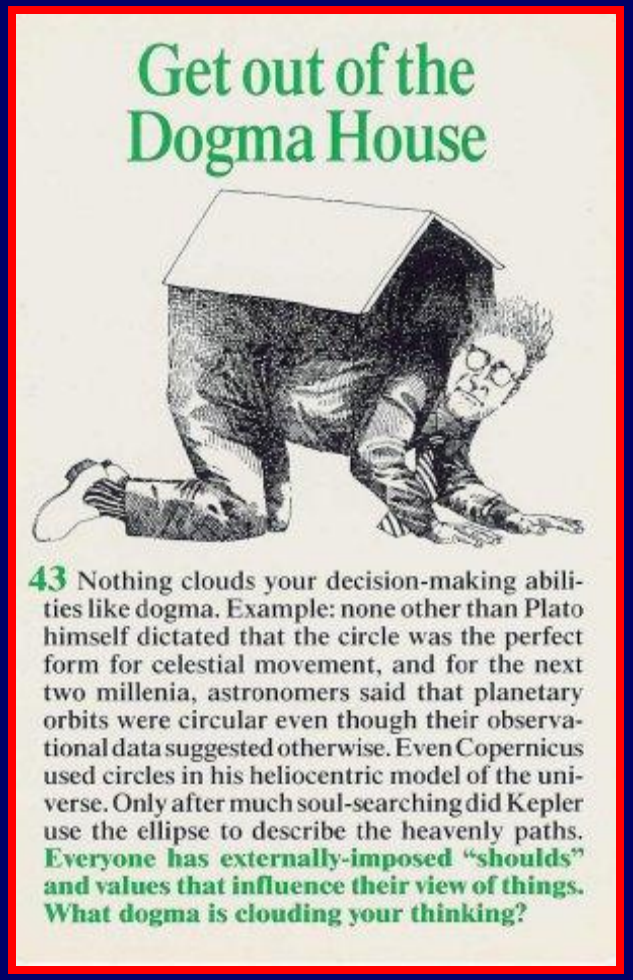
Maintenance of Independence after Amputation





The Search for Mediocrity

- Some patients have physiologic impairments that blunt any functional advantage of attempted limb salvage
- The Frontier: foot wound management
- Amputation not always a failure



Challenge the Dogma

Claudication:

Patients with systemic disease which precludes routine revascularization.

Claudication:

Patients with leg symptoms best ameliorated by revascularization despite systemic disease

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