SALVAGING THE DIABETIC FOOT
PRESERVATION PEARLS

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Disclosures

Speaker’s Bureau:
- Wright Medical Group
- Cardiovascular Systems Inc
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Consultant:
- Wright Medical Group

Stockholder:
- EZ Frame/Signal Medical
AMPUTATION

Picture of an amputation in the operating theatre of old Saint Thomas Hospital, London, around 1775
Foot Ulcer is Precursor to 85% of LE Amputations in DM

- 71,000 hospital discharges for DM related major amputations
- Av Hospital stay...10.5 days
- 4.3 amps per 1000 pts with DM

2005, Centers for Disease Control, Atlanta, Georgia
Infected and/or Ischemic Ulcers

*Major cause of DM related hospitalizations
*DM ulcer Hospitalizations: 59% longer
*Frequently associated with Neuropathy and PAD
25% of DM will develop a foot ulcer

-More than 50% of these wounds will become infected

20% of these infections result in Major or Minor Amputations

CDC, 2011, Nat’l Diabetes Fact Sheet
Amputation and P.A.D.

• About 5% of patients with **PAD** undergo **Major** Amputation…many without pre-amp angiography

• Higher incidence in persons with diabetes
• Significant risk of morbidity and mortality
• *Up to 85% of amputations are preventable utilizing CONTEMPORARY methods in a TEAM APPROACH* 

Personal Costs of Major Amputation

• Less than half of amputees regain the ability to walk

• 15% require amputation of the other limb within 2 years

• Amputees have a 20%-35% increased risk of MI, stroke, and infection

• Less than half of amputees survive more than 2 years
Improvement in Diabetic Care and Vascular Repair has made MINOR Amputations or distal foot amputations (toe, TMA) increasingly popular

• Over the past 15 years, the incidence of Major Amps (BKA, AKA) has steadily declined… Minor Amps (partial foot amps) have increased proportionately

BUT

1/3 of MINOR amps are revised to a higher level

Minor Amps are associated with a significant failure rate and numerous complications

- 30-50% of Minor Amps will experience complications including dehiscence, ulceration or failure of the wound to heal

*33% of patients with Minor Amp (toe, TMA) will require revision surgery*

VS

*80% of major amps (BKA, AKA) heal, only 10% requires subsequent amputation


15-45% of patients with MINOR or PARTIAL FOOT AMPUTATIONS experience some form of subsequent tissue breakdown and secondary AMPUTATION. TWO-THIRDS undergo a higher level of amputation on the same LIMB.

OVERALL PICTURE

- Patients with DYSVASCULAR Partial Foot Amputations have a short life expectancy...25-40% of these patients die within a year of their amp

Average Life Expectancy is less than 2 years

Contextualize Published High Rate of Complications and Reamputations with Shortened Life Expectancy

## EPIDEMIOLOGY

### POST AMPUTATION MORTALITY RATES

<table>
<thead>
<tr>
<th>Amputation Type</th>
<th>1 Month</th>
<th>3 Year</th>
<th>5 Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOE</td>
<td>1.7%</td>
<td>41.5%</td>
<td>46%</td>
</tr>
<tr>
<td>TMA</td>
<td>2.7%</td>
<td>41.5%</td>
<td>45%</td>
</tr>
<tr>
<td>BKA</td>
<td>7%</td>
<td>41.5%</td>
<td>56%</td>
</tr>
</tbody>
</table>

EPIDEMIOLOGY
12 MONTH MORTALITY RATE

TOE-FOOT-ANKLE AMP 27.1%

TRANS TIB AMP 34%

15-30% of patients who undergo Partial Foot Amputation will be DEAD within 12 months

OVERALL PICTURE

Some Surgical and Rehabilitation Programs report good results without Complications


Literature is unclear…

WHAT MAKES SOME REPORTS/PROGRAMS SO MUCH MORE EFFECTIVE AND SUCCESSFUL?

Pupp GR, Personal Communication 2015, Providence Hospital.
Success-Altering Guidelines to change OUTCOMES
MINOR or PARTIAL FOOT AMPUTATIONS

NEED TO LIMIT FURTHER TISSUE BREAKDOWN AND LIMB LOSS

NEED AGGRESSIVE MEDICAL MANAGEMENT including PATIENT EDUCATION

* UNDERSTAND PATHOPHYSIOLOGY
* AGGRESSIVE VASCULAR APPROACH
* AGGRESSIVE SURGICAL APPROACH
* MEDICAL STABILIZATION
* CUSTOM PROSTHETICS & ORTHOTICS
* LIFELONG SURVEILLANCE
9 RISK FACTORS for Atherosclerosis

- Smoking
- Age
- Diabetes
- Obesity
- Genetics
- Dyslipidemia
- Hypertension
- Hypercoagulability States
- Hyperhomocysteinemia

Atherosclerotic Diseases (CAD, CVD, PAD)
AHA/ACC Guidelines for PAD Management---Testing-Screening

Individuals at Risk for Lower Extremity Peripheral Arterial Disease:

- Age less than 50 years, with diabetes and one other atherosclerosis risk factor (smoking, dyslipidemia, hypertension, or hyperhomocysteinemia)
- Age 50 to 69 years and history of smoking or diabetes
- Age 70 years and older

- Leg symptoms with exertion (suggestive of claudication) or ischemic rest pain
- Abnormal lower extremity pulse examination
- Known atherosclerotic coronary, carotid, or renal artery disease
- Leg discomfort, cold feet, distal hair loss, ischemic ulceration or gangrene

Available at: http://www.acc.org/clinical/guidelines/pad/index.pdf Section 2.1.1, Table 2, page 8
AVOID MEDICAL-LEGAL ARENA

High Index Of Suspicion for PAD in Patients who have

“RISK FACTORS”

Communicate Pathology and Treatment Alternatives with Patient/Family

Establish Patient as an Educated TEAM MEMBER

“A LAWYER WITH A BRIEFCASE CAN STEAL MORE THAN A HUNDRED MEN WITH GUNS.”

Don Corleone
The Godfather
CRITICAL LIMB ISCHEMIA (CLI) PREVALENCE*

CLI is the most severe form of Peripheral Arterial Disease (PAD), with an estimated 2 million people suffering from CLI.

Over 150,000 lower extremity amputations are performed in the United States every year due to CLI.

In the United States, the leading cause of amputation for CLI patients is diabetes and vascular disease.

The prognosis for patients with critical limb ischemia is poor:

- 25% mortality rate in first year---less than the survival rate of breast & colon cancers
- 25% amputation rate in first year---Up to 40% of those patients with CLI who have an amputation, will die within 2 years

* From EN-1378.A  Why Outflow Matters
CLI

• CAD…main cause of death due to impaired ejection fraction
  * major independent prognostic factor

• Not a slow progressive process
CLI: “end stage” of PAD?

Rutherford grade 4-6          Fontaine stage III-IV

BUT

Recent Evidence: CLI does **not** always progress through various stages

Multicenter prospective study: **NO** symptoms of PAD before onset of CLI in 50% of patients 6 months later

-CLI progression from PAD is Variable and Unpredictable

Don’t Treat CLI Conservatively
CLI with extensive tissue necrosis
Skin Perfusion Pressure Technology

Specialized laser sensor delivers light to, and collects it from, the capillary bed.

A pressure cuff occludes distal arterial flow (capillaries)

As cuff pressure is released, the returned light signal detects Doppler shift of capillary blood flow

Skin Perfusion Pressure is detected by:
- Capturing the onset of capillary flow return
- Determining pressure (mmHg) at which onset of return flow
Skin Perfusion Pressure

- SPP indicates pressure at which blood flow resumes in the capillaries
  - Abnormal SPP < 30 mmHg; adequate perfusion for healing at SPP > 50 mmHg
- PVR documents arterial pressure pulses
  - A normal PVR coupled with an abnormal SPP can be indicative of small vessel disease
SPP Demonstrates Direct Flow to Angiosome

• Angiosomes:
  • Distal Arterial Anatomy
  • Regions of tissue primarily sourced by a single artery.

• Below the knee arteries:
  • Anterior tibial
  • Peroneal
  • Posterior tibial

• 6 distinct Angiosomes in the ankle/foot
Limb Preservation

- **Lower Extremity Benefits of Skin Perfusion Pressures:**
  - Map and monitor PAD/CLI...SURVEILLANCE post intervention
  - Evaluate tissue where symptoms are present.
  - Obtain guidance regarding foot/ankle surgical procedures
    - Revascularization, Charcot Reconstruction, bunion and arthritic repair, wound debridement, trauma
The Importance of Appropriate Vascular Referral

- Reduce the Effects of the Disease
- Improve Walking Ability and Quality of Life
- Lower Malpractice Risk
- Lower the Risk of Heart Attack and Stroke
  - PAD Patients at 6-7x greater risk for Polyvascular Disease

Allows for optimal successful treatment of lower extremity disease
  - Perform Surgical procedures Successfully
  - Treat Wounds Successfully

REDUCE OR ELIMINATE AMPUTATION RISK
REQUIRES “RED GOLD”
THE GOAL OF THE LIMB SALVAGE CLINIC

Obtain a foot and ankle that can be fitted with a shoe or brace allowing a stable platform to ambulate by healing and preventing ulcerations, decreasing pain and...

AVOIDING MAJOR AMPUTATIONS
Tissue Preservation vs. Functional Preservation

- Maximum tissue preservation does not automatically equate to maximum function.
- At times preservation of 1 or 2 toes becomes a limitation to function when compared to a well balanced TMA.
- Focus has shifted from preserving tissue to restoring function and avoiding future tissue breakdown.
HUH?
FUNCTIONAL LIMB PRESERVATION

Balance Tissue Loss against Limb Function

- TAL with Forefoot Ulcers
- Tendon Transfer with Mid-Ft Amps
- TMA instead of 3-4 toe amps

GOALS: Wear shoe/brace, return to activities, avoid further wounds & surgery
Post TMA

“Motor Imbalance Lesions”

No TAL
No Orthotic
BK Amputation?
Stage 1 Midfoot Charcot
Frequently Misdiagnosed
HIGH INDEX OF SUSPICION FOR CHARCOT
Edema-Heat-Minimal Pain (Proportionately)

EARLY MISDIAGNOSIS:
Limb threatening deformity and infection
Charcot Arthropathy…Referral to Center of Excellence to Avoid MAJOR AMP?
CONSULTATION

Board Certified Orthotist
Orthotist Intervention

• Critical In Preventing Re-Ulceration
• Decreases Recurrence
• Redistribution of Weight and Deforming Forces
Orthotist Intervention
Custom Molded Shoes & Braces
King’s College Study – London, England

-Therapeutic Shoe/Brace Use – 17% Recurrence Of Ulcer(s)
-Regular Shoe Use – 83% Recurrence Of Ulcer(s)
Orthotist Intervention
Custom AFO’s
Modular Above-The-Ankle Brace
Limb Preservation

Team Approach

Podiatrist

Vascular/Endovascular Specialist

Endocrinologist

Infectious Disease

Internal Medicine/Primary Physician

Nephrologist

Plastic Surgeon

Cardiologist

Orthopedist/General Surgeon

Radiologist

Psychiatrist/Psychologist

Orthotist

Diabetic Nurse Specialist
DIABETIC LIMB SALVAGE

THE IMPACT OF PODIATRIC MEDICINE
DIABETIC LIMB SALVAGE

79% Decrease in Major Amputations after Implementation of Multidiciplinary Team

83% Reduction in Major Amputations over 55 months after collaboration of Vascular Surgery and Podiatry

DIABETIC LIMB SALVAGE

“A TEAM APPROACH AT A TEACHING INSTITUTION”

19 DM Pts scheduled or at risk for Major Amputation

4 mos to 9.2 yr followup…
18 pts Successful Salvage utilizing Vascular Services/Team Approach
1 pt AKA

Pupp GR, Denamur C. JAPMA, 2002
DIABETIC LIMB SALVAGE

82% Reduction in Major Amputations through a Multidisciplinary Team Approach over a 4 Year Study

Driver V, et al. Diabetes Care 28; 2005
DIABETIC LIMB SALVAGE

Thomson Reuters Study…32,000 Patients with Diabetes demonstrated:
29% Lower Risk of Amputation
24% Lower Risk for Hospitalization
with use of Podiatry services

Retrospective Study in United Kingdom showed 62% reduction in Major Amputations for 11 Years after implementing a Diabetic Foot Care Service

Podiatric Care as part of a Diabetic Team at Duke University reduced risk for Amputation by 64%

MINOR or PARTIAL FOOT AMPUTATIONS

NEED TO LIMIT FURTHER TISSUE BREAKDOWN AND LIMB LOSS

NEED AGGRESSIVE MEDICAL MANAGEMENT including PATIENT EDUCATION

*UNDERSTAND PATHOPHYSIOLOGY
*AGGRESSIVE VASCULAR APPROACH
*AGGRESSIVE SURGICAL APPROACH
  *MEDICAL STABILIZATION
*CUSTOM PROSTHETICS & ORTHOTICS
  *LIFELONG SURVEILLANCE
TEAM APPROACH

• MANDATORY in Limb Preservation

• Utilize Specialists who are familiar with Contemporary Methodology

• Understand Epidemiology of Limb Salvage

• SUCCESSFUL in Decreasing Major Amputations and Improving QOL
THANK YOU
EPIDEMIOLOGY
Median Survival Times

- BKA 2.3%
- Foot 4.2%

CLI

OPTIMAL OUTCOMES:
Collaborative skilled multidisciplinary team effort on a timely basis

COMMON GOAL:
- consistent high rates of wound healing & limb salvage
- improved patient function
- acceptable treatment morbidity
SUCCESSFUL LIMB SALVAGE REQUIREMENTS:

• COMPETENT SCHOLARLY TEAM APPROACH

  • Understand Pathophysiology
  • Aggressive Vascular Approach
  • Aggressive Surgical Approach
    • Medical Stabilization
  • Custom Orthotics & Prosthetics
    • Lifelong Surveillance
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