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Therapeutic Strategies for the "At-Risk" Vascular Limb

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Lower Limb Preservation in Diabetes - Postgraduate Masters Degree – Ulster University

Tuesday 4th July 2017

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Module Aims

- Provide students with advanced theoretical knowledge around strategic decision making pre-, immediately post-operatively and long term in Lower Limb Preservation in Diabetes.

- Emphasis on the understanding of surgical management options and limitations in critical limb vascular and/ or infectious disease, care of the residual limb, patient education, physical/ occupational therapy and behavioural health, leading to successful re-ablement and achievement of goals, with or without prosthesis.

- Continued assessment and interventions to prevent further amputation and secondary complications, as well as promoting care of the residual and contralateral limbs for life-long care are considered.

Learning Outcomes

Knowledge and Understanding

K1: Examine the guiding principles, medical and theoretical parameters underpinning identification of need to amputate, as a result of vascular, neuro-ischemic and/ or infectious disease in the diabetic patient.

K2: Apply a systematic understanding of a variety of surgical planning considerations (including not to operate) in limb preservation; preoperative patient evaluation and medical optimisation, consent, pain management, infection prevention/ management, pre-, Intra and post-operative considerations.

K3: Demonstrate a critical understanding of the surgical principles underpinning vascular and reconstructive approaches and procedures, that will optimise surgical outcome in limb preservation including residual limb shape and function.

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Intellectual Qualities

I1: Critically evaluate the current service from the perspective of the person with diabetes and their family.

I2: Analyse and synthesise information effectively and efficiently to determine individualised surgical action plans, based on medical and diagnostic information, and likely prognosis.

I3: Relate the effect of post-operative medical and wound care management strategies, including the use of further interventions such as education and behavioural health modification, in optimising patient perception of care, surgical outcome and preparing the residual limb for prosthetic rehabilitation.

I4: Critically analyse, synthesize and evaluate the research evidence for current best practice in limb preservation and rehabilitation and appropriately integrate new information into practice.

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Professional / Practical Skills

P1: Participate in a multidisciplinary approach to surgical planning, coordination and intervention, involving: prior communication with the patient, other professionals and personnel; negotiation of roles and responsibilities; recognition of unique / emergency situations that require the ability to carry out autonomous decision making.

P2: Synthesise information relating to health of the contralateral limb, functional goals, psychosocial influences, coping strategies, co- and pre-existing conditions or treatments and other influences on rehabilitation such as diet and nutrition.

P3: Utilise critical thinking skills to assimilate surgical principles and alternative interventions in the optimisation of wound healing and shaping of the residual limb in preparation for prosthetic rehabilitation.

P4: Effectively educate the patient and other individuals regarding critical principles of post-operative care, post-surgical rehabilitation strategy and prevention of deterioration.

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Transferable Skills

T1: Differentiate between national and international approaches to limb preservation and the roles and responsibilities of those involved in surgical management of the person with diabetes.

T2: Synthesize models of consultation and decision-making, related to practice and /or research.

T3: Critically reflect on the current service user's experience, to develop and improve the quality of practice and service delivery in a solution-focused, change-orientated, practical manner.

T4: Apply principles of change management to facilitate the development and implementation of best practice across all areas of limb preservation and patient rehabilitation.

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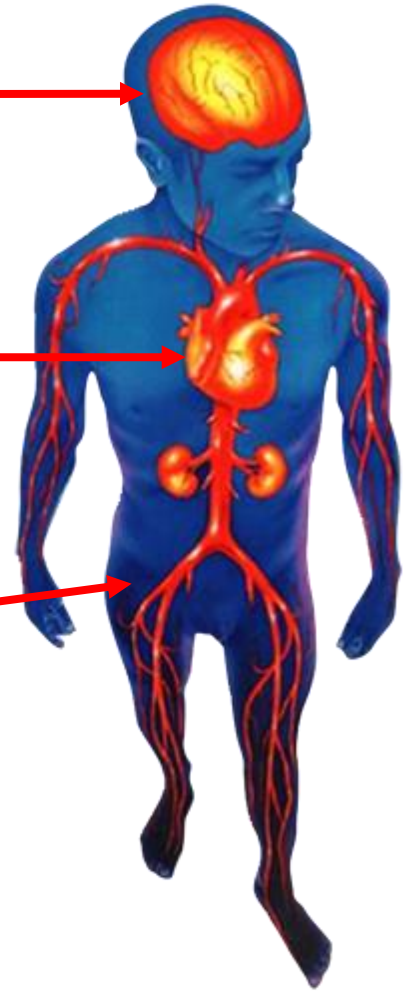
Atherosclerosis

- Derived from Greek.
- *Athere* meaning porridge or gruel.
- *Sclerosis* meaning induration or hardening.

History of Atherosclerosis

- Battle casualities from Korea.
- Average age 22.
- 45 - 77% already had atherosclerosis.
- 39% had coronary luminal narrowing from 10-90%.
- 3% had complete occlusion of 1 or more coronary vessels.
  - Enos WF, *JAMA* 1953

Atherosclerosis – A Systemic Process



Cerebrovascular disease

- Ischaemic stroke.
- Transient Ischaemic Attack (TIA).

Cardiovascular disease

- Myocardial Infarction (MI).
- Angina (stable/unstable).

Peripheral arterial disease (PAD)

→ Intermittent claudication

- Pain on walking.

→ Severe limb ischaemia

- Rest pain.
- Gangrene, necrosis.

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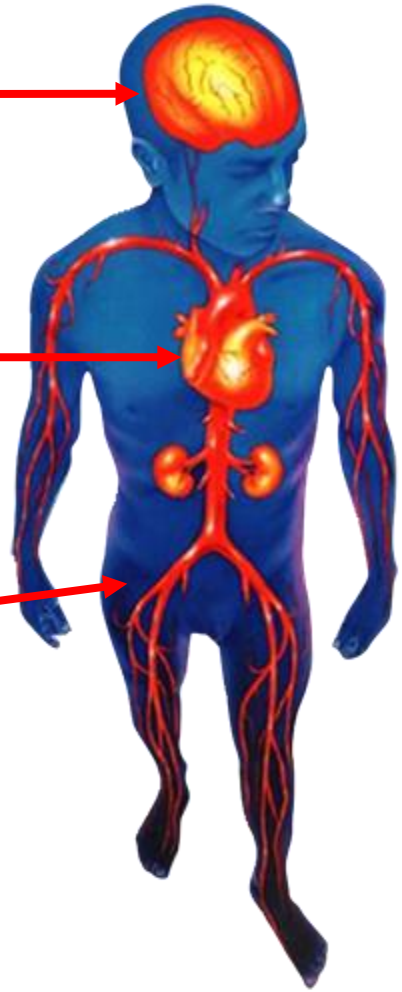

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Peripheral Arterial Disease

- Peripheral arterial disease (PAD)definitions have evolved over the last 20 years.

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- PAD previously defined as the presence of atherosclerosis distal to the aortic bifurcation. It remains one of the major manifestations of atherosclerosis in the lower extremities. *However, this neglected the upper extremities and PAD should be defined as the presence of atherosclerosis distal to the aortic arch.*

  - Sigvant B, *J Vasc Surg* 2007

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  - Sigvant B*, J Vasc Surg* 2007

- PAD is now the preferred term for partial or complete obstruction of ≥1 peripheral arteries.
  - Hiatt WR, *Circulation* 2008

Epidemiology

- 20% of people over 55 years of age.
  - Hankey GJ, *JAMA* 2006
- 27 million people affected in Europe and USA.
  - Hankey GJ, *JAMA* 2006
- Framingham study reported that the annual incidence increases from <0.4 per 1000 in men aged 35 to 45 years to 6 per 1000 in men aged 65+ years.
  - Kannel WB, *J Am Geriatr Soc* 1985
- Higher prevalence of PAD in black patients (white 3.5% vs. black 6.7% vs. Asian 3.7%).
  - Vitalis A, *Expert Rev Cardiovasc Ther* 2017

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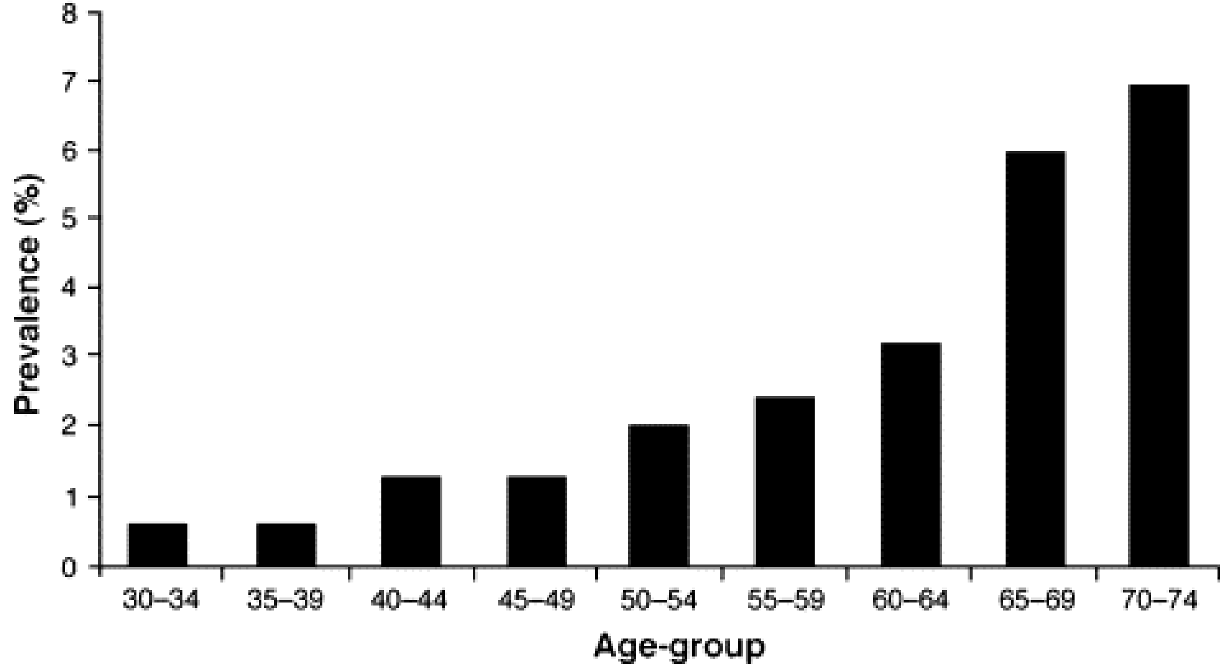
Prevalence



In older-age groups no gender difference

10 - 50% - never consulted doctor

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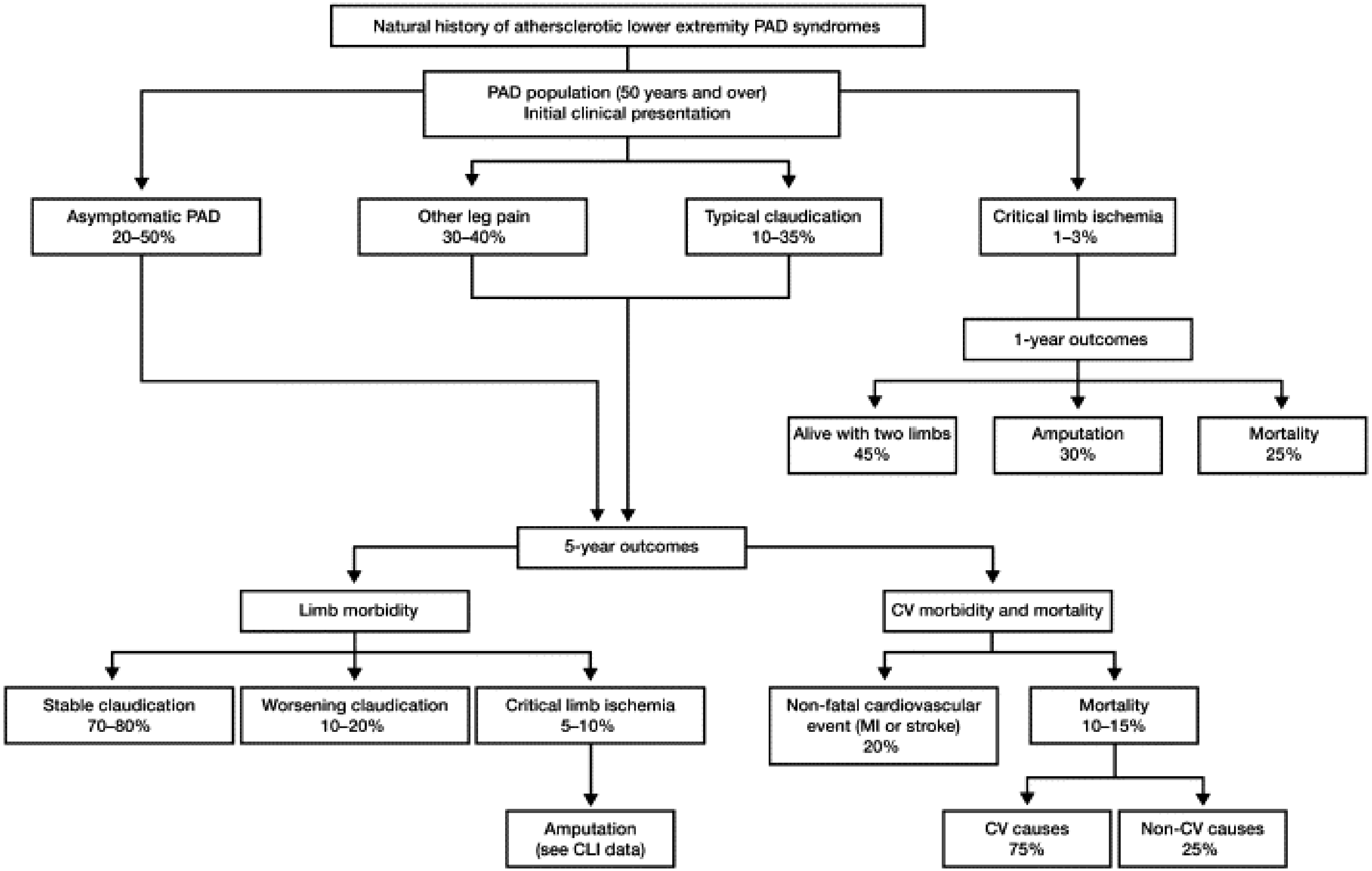
Clinical Presentation

- Only 10-30% of patients will have symptoms.
  - McDermott MM, *Cleve J Clin Med* 2006

- Symptoms deteriorate in 25% of patients.
  - Schmieder FA, *Am J Cardiol* 2001

- 2% to 4% will require amputation.
  - Dormandy J, *Semin Vasc Surg* 1999

Natural History of PAD



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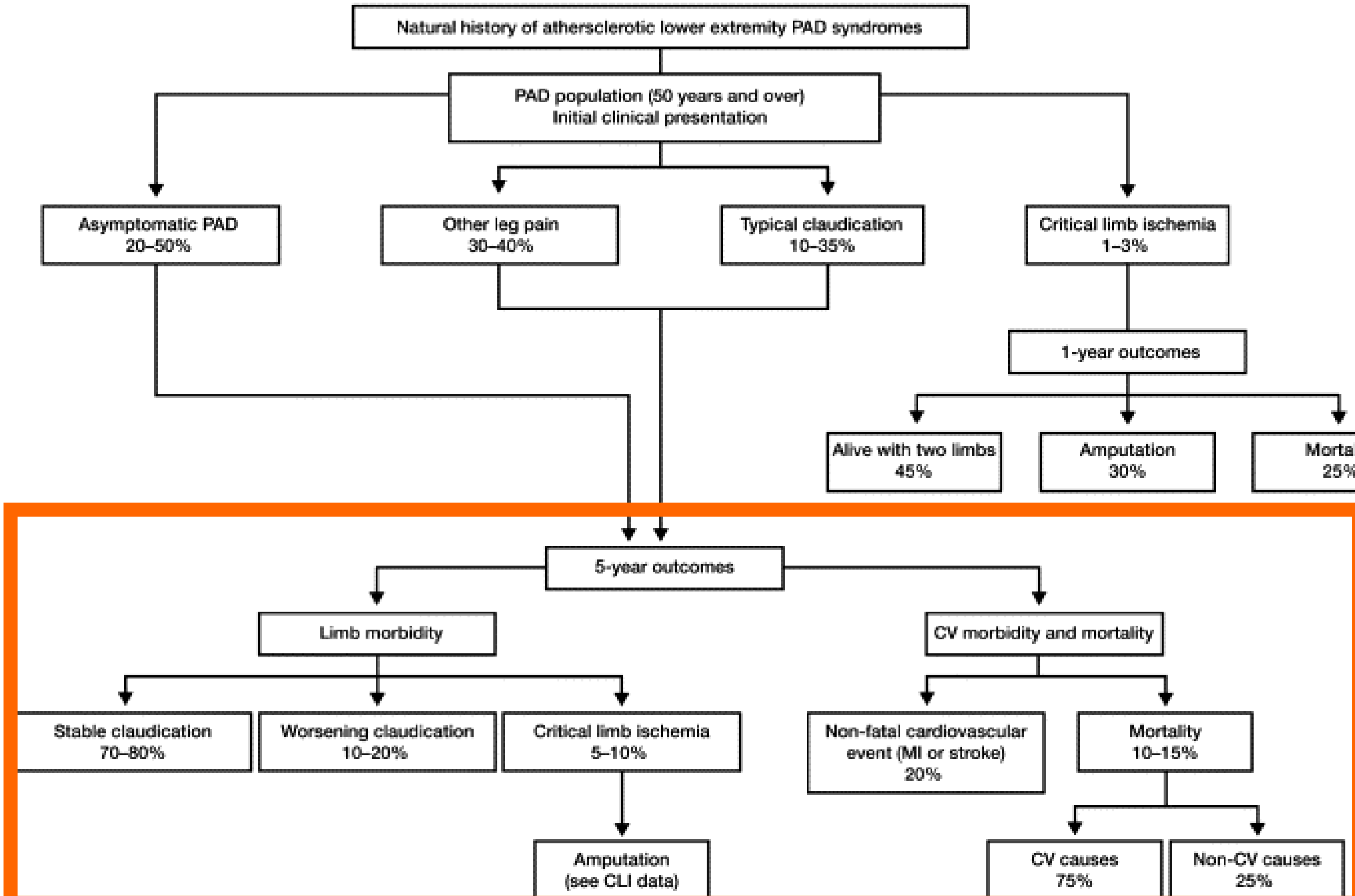

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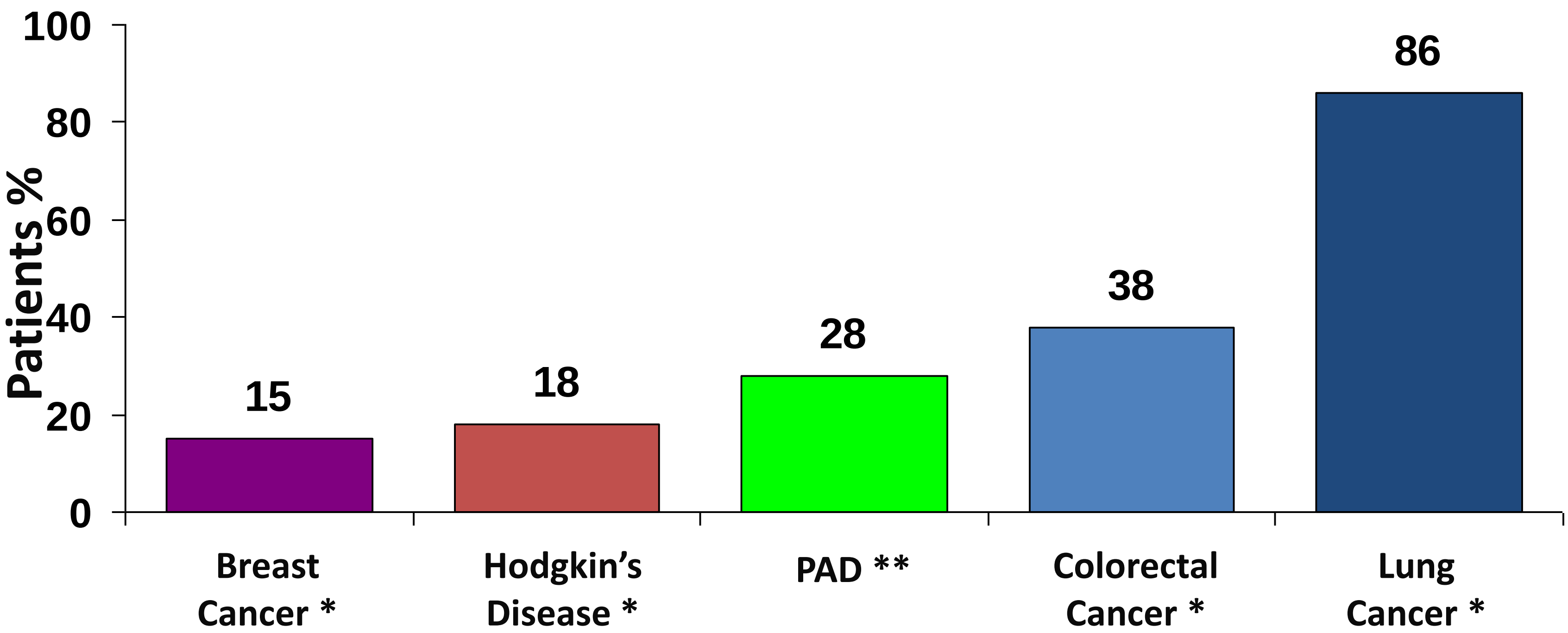
Relative 5-Year Mortality Rates



* American Cancer Society. *Cancer Facts and Figures*. 1997.
** Kempczinski, RF, Bernhard VM. IN: Rutherford RB, ed. Vascular Surgery. Philadelphia, PA: WB Saunders; 1989: chap 53.

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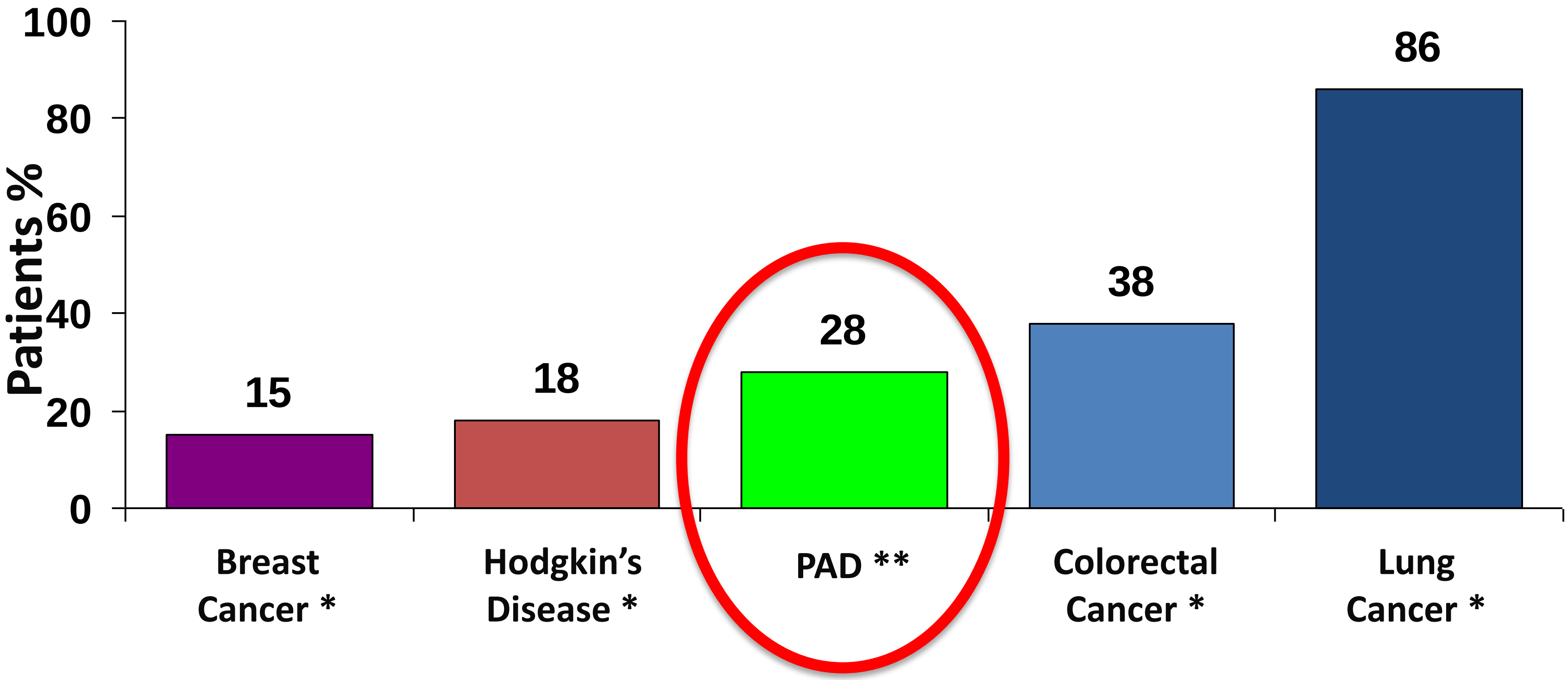

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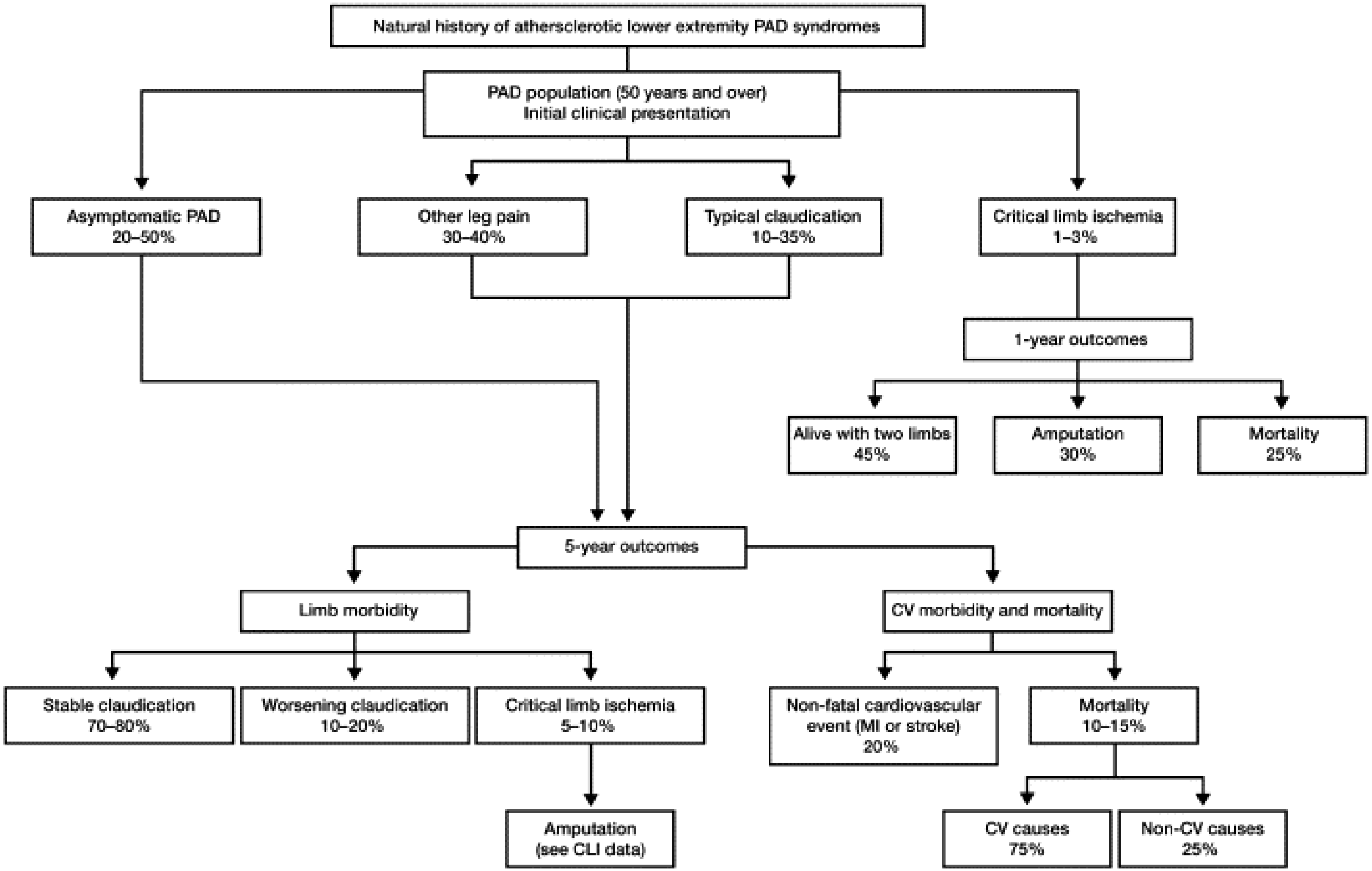

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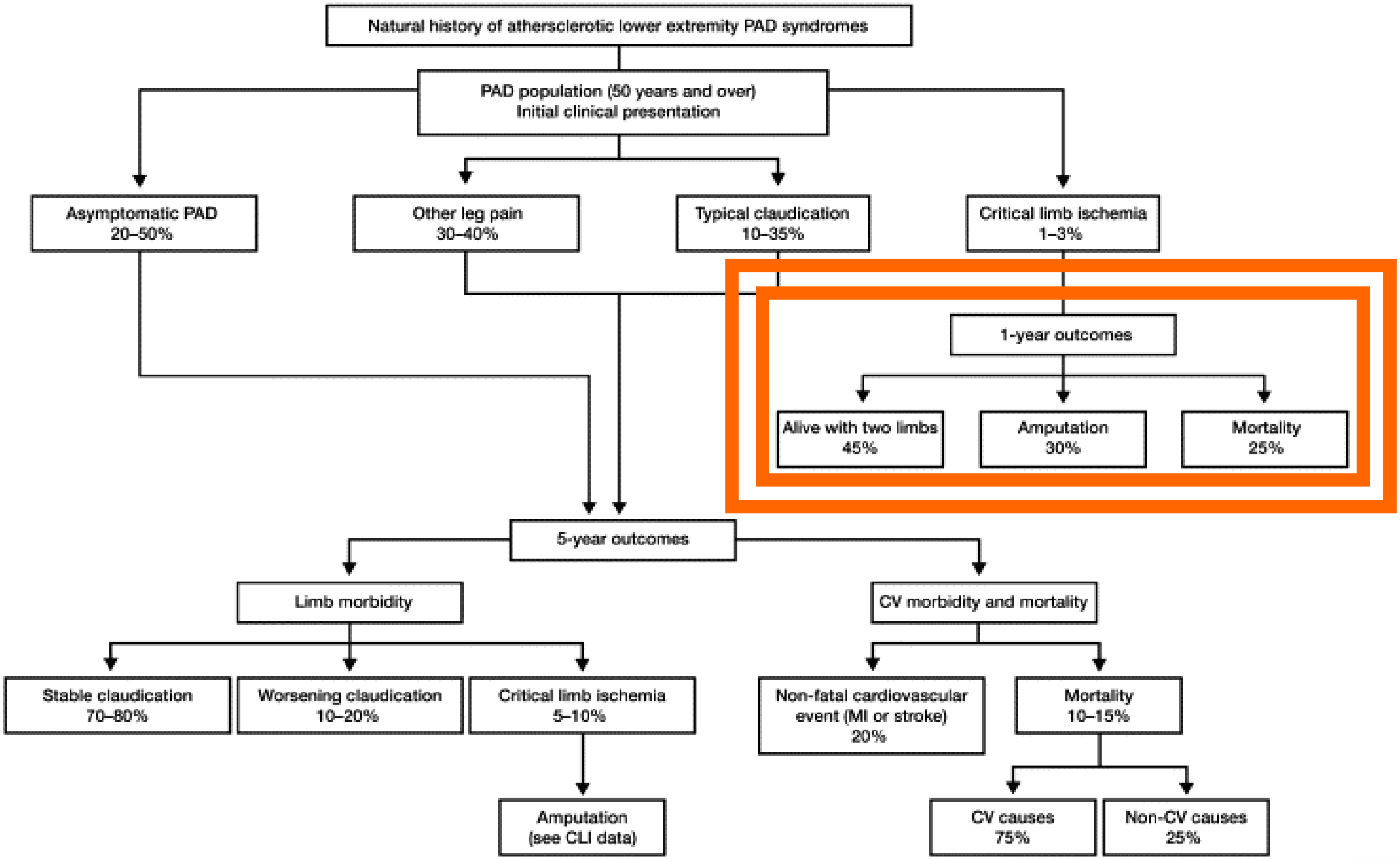

Types of Limb Ischaemia

- Acute:
  - Sudden reduction in limb perfusion.
- Chronic:
  - Intermittent Claudication.
  - Critical Ischaemia.

Acute Ischaemia – Definition

Acute Ischaemia – Definition

- A sudden decrease in limb perfusion causing a potential threat to limb viability.
  - Norgren L & Hiatt WR - TASC II, *J Vasc Surg* 2007

- Acute limb ischaemia is a result of an occlusion of a native artery or vascular bypass / endovascular prosthesis.
  - Less than two week duration – usually hours.
  - Severity of ischemia at presentation is the most important factor affecting outcome of the leg.

Acute Ischaemia – Aetiology

- Embolism:
  - Atrial fibrillation (80%).
  - Mural thrombosis post-MI.
  - Atherosclerotic plaques.
  - Vegetation's – septic / neoplastic.
  - Aneurysms.
  - In 20% of cases, no source of emboli is found.

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- Thrombosis:
  - Most common cause of acute limb ischaemia.
  - Atherosclerosis / Popliteal aneurysm / Bypass occlusion / Iatrogenic (closure device failure/post intervention) / thrombotic conditions.

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- Thrombosis:
  - Most common cause of acute limb ischaemia.
  - Atherosclerosis / Popliteal aneurysm / Bypass occlusion / Iatrogenic (closure device failure/post intervention) / thrombotic conditions.

- Rare causes:
  - Dissection / Trauma / Drug use / External compression / Iliac endofibrosis / Popliteal entrapment / Cystic adventitial disease.

Acute Ischaemia – Clinical Presentation

- Embolism - Classical "P"s presentation as no collaterals have established:
  - Pain.
  - Pallor.
  - Paralysis.
  - Paraesthesia.
  - Pulselessness.
  - Perishingly cold.

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  - Perishingly cold.

- Thrombosis typically results in less severe ischaemia, stepwise fashion, previous claudication or absent pulses in contralateral limb makes in-situ thrombosis more likely.

Acute Ischaemia – Clinical Presentation

- A mottled appearance which blanches on digital pressure occurs when the capillaries are filled with deoxygenated stagnant blood and indicates severe ischaemia.

- Sensorimotor defects imply muscle and nerve ischaemia which may still be salvageable.

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Acute Ischaemia – Clinical Presentation

- Severe localised or generalised tenderness in muscle compartments indicates severe ischaemia or necrosis and suggests irreversible ischaemia.

- Fixed skin staining is non-blanching and occurs when capillaries rupture leading to the fixed rubruous colour indicating irreversible ischaemia.

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Acute Ischaemia - Severity

- Rutherford classification:
  - I – Viable.
  - IIa - Threatened (salvageable if promptly treated).
  - IIb- Threatened (salvable if immediately treated).
  - III – Irreversible.

0–6 hours	6–12 hours	over 12 hours
		
Painful, marble white foot Neurosensory deficit	Mottled appearance due to capillary pooling Blanches on digital pressure	Fixed staining: mottled areas coalesce and no longer blanch to pressure Anterior compartment red and tender
Reversible	Partly reversible	Irreversible

Acute-on-Chronic Ischaemia

- Sudden and rapid worsening of ischaemic symptoms and signs over a time period up to 14 days.
    - ABC of Arterial and Venous Disease, *BMJ* 2000
- Caused by thrombus superimposed on an atherosclerotic stenoses.
- Predisposing factors:
    - Dehydration.
    - Hypotension.
    - Unusual posture or activity.
    - Malignancy.
    - Hyperviscosity.
    - Thrombophilia.

Chronic Ischaemia

Intermittent Claudication

- Claudication means to limp.
  - (Latin: Claudicare)

- Defined as the presence of ;
  - Reproducible crampy lower limb pain.
  - Precipitated by walking.
  - Relieved by rest.
  - With an ankle brachial-pressure index less than 0.9.

- Norgren L & Hiatt WR - TASC II, *J Vasc Surg* 2007

Critical Ischaemia

- Defined as;
  - Rest pain with tissue loss +/- gangrene.
  - Requiring regular analgesia for a period greater than 2 weeks.
  - ABPI <0.3 or ankle pressure less <30mmHg (40mmHg in Diabetics).
    - Norgren L & Hiatt WR - TASC II, *J Vasc Surg* 2007

- Indicates significant threat of limb loss.

Pain

- Site.
- Radiation.
- Intensity.
- Duration.
- Onset.
- Character.

Pain

- Site - Calf, thigh or buttock.
- Radiation - Generally radiates proximally.
- Intensity - Increasing intensity as walking progresses. Causes walking to cease.
- Duration - Fairly constant duration.
- Onset - Fairly constant onset time.
- Character - Crampy.

Medical History

- Precipitating Factors.
- Alleviating Factors.
- Deterioration.
- Co-existing disease.
- Other causes.

Medical History

- Precipitating Factors:
  - Walking / exertion.
- Alleviating Factors:
  - Rest.
- Deterioration:
  - Can vary.
- Co-existing disease:
  - Cardiovascular disease.
- Other causes:
  - Back pain, arthritis or other orthopaedic pathology.

Additional Information

- How far ?
- What exactly stops walking ?
- Can you walk through the pain ?
- Flat or inclines better ?
- Timescale of progress ?
- Comparison of date-lines ?

Clinical Presentation

- No pain at rest or during the 1st few steps.
- A relatively consistent walking distance.
- Relief on standing for 1-3 minutes.
- No need to sit or lie.
- Recurrence on walking a similar distance.
- Worse on walking quickly or uphill.

Clinical Presentation

- Rest pain is defined as;
  - Characteristically boring, gnawing and severe pain.
  - Worse at night.
  - Present in the foot or toes and not the calf or thigh.

- True rest pain will wake the patient from sleep and requires strong opioid analgesia.

- Lying the limb in a dependant position may relieve the pain.

Differential Diagnosis

- Sciatica / Spinal Stenosis:
  - History of disc or back trouble.
  - Pain felt in back, down buttock and thigh.
  - No characteristic relationship to exercise.
  - Limited straight leg raising.
  - Neurological signs – muscle wasting, loss of power, reflexes and sensation.

Differential Diagnosis

- Osteoarthritis of the Hip:
  - Difficult to distinguish as pain is exacerbated by exercise.
  - Pain felt in hip joint and may be referred to the knee.
  - Varies from day to day.
  - Worse at the end of the day.

Differential Diagnosis

- Cauda Equina Claudication.
  - Two distinct pathologies.
  - Very difficult to distinguish.

    - Disc Pathology – partial compression cauda equina by a prolapsed disc.

    - Aorto-iliac disease – on exercise, a drop in blood pressure leads to ischaemia of the cauda equina.

Differential Diagnosis

- Anterior Tibial Compartment Syndrome:
  - Occurs in younger people.
  - More likely after unaccustomed exercise.
  - Pain felt in the anterior part of the lower leg.

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Differential diagnoses for lower limb exertional symptomatology.

Condition	Prevalence	Anatomical Distribution	Character of Pain	Effect of Exercise	Effect of Rest	Effect of Position	Additional Factors
Thigh and Buttock Claudication	Rare	Buttock, hip and thigh	Crampy, aching discomfort	Reproducible onset (same distance for each episode)	Quickly relieved	None	Proximal pulses may be reduced combined with normal distal pulses
Calf Claudication	3% - 5% of the adult population	Calf muscles	Crampy, aching discomfort	Reproducible onset	Quickly relieved	None	May have atypical symptoms on exercise
Foot Claudication	Rare	Foot arch	Severe pain on exercise	Reproducible onset	Quickly relieved	None	Numbness can also be associated with pain
Venous Claudication	Rare	Entire lower limb affected. Worse in calf.	Tight, bursting pain	Occurs after walking	Slow to settle	Elevation enhances recovery	Signs of deep venous congestion and oedema present. May have history of iliofemoral thrombosis
Chronic Compartment Syndrome	Rare	Calf muscles	Tight, bursting pain	Occurs after walking	Very slow to settle	Elevation enhances recovery	Tends to affect heavily muscled athletes
Spinal Stenosis	Common	Buttocks and posterior aspects of lower limb. Often bilateral	Pain and weakness	Occurs with exercise and can mimic claudication	Varies but can have a prolonged recovery time	Lumbar spine flexion eases discomfort	Exacerbated by standing and extending spine
Nerve Root Compression	Common	Radiation of pain down lower limb	Sharp	May be induced by sitting, standing or walking	Often present at rest	Positional change can improve symptoms	History of back pain
Bakers Cyst	Rare	Behind knee down calf	Tenderness and associated swelling	Occurs with exercise	Present at rest	None	Usually a constant discomfort
Hip Arthritis	Common	Lateral aspect hip and thigh	Dull to severe ache	Can occur following a period of exercise	Not relieved quickly	Rest and minimal weight bearing helps	Symptoms can vary. Increased in patients with high BMI
Foot or Ankle Arthritis	Common	Ankle and foot arch	Aching pain	Variable onset following exercise	Not quickly relieved	Rest and minimal weight bearing helps	Variable. Can relate to exercise but present at rest

- O'Donnell ME, *Ulster Med J* 2011

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Cardiovascular Risk Factors

Cardiovascular Risk Factors

- Constitutional:
    - Male Sex.
    - Age.
    - Family History.
    - ACE II Gene – Deletion Polymorphism.

Cardiovascular Risk Factors

- Hard Risk Factors:
  - Blood Pressure.
  - Cholesterol.
  - Cigarettes.
  - Diabetes.

Cardiovascular Risk Factors

- Soft Risk Factors:
  - Lack of Exercise.
  - Obesity.
  - Stress.

The "At-Risk" Population

- Age < 50 years with diabetes, and one additional risk factor (e.g., smoking, dyslipidemia, hypertension, or hyperhomocysteinemia).
- Age 50 to 69 years *and* history of smoking or diabetes.
- Age $\geq$70 years.
- Leg symptoms with exertion (suggestive of claudication) or ischaemic rest pain.
- Abnormal lower extremity pulse examination.
- Known atherosclerotic coronary, carotid or renal artery disease.

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Diabetes

- Diabetes is defined as a disease in which the body’s ability to produce or respond to the hormone insulin is impaired, resulting in abnormal metabolism of carbohydrates and elevated levels of glucose in the blood.

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Diabetes - Definition

- The term diabetes mellitus describes a metabolic disorder of multiple aetiologies characterised by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both. Diabetes mellitus can lead to the long-term damage, dysfunction and failure of various organs.
  - World Health Organisation 1999

- Type 1 and Type 2 have now been reintroduced for insulin-dependant and non-insulin-dependant diabetes respectively. blood.

Diabetes - Epidemiology

- The worldwide incidence of diabetes is increasing dramatically especially among children.
  - Fagot-Campagna A, *J Paediatr* 2000
- Currently, 2.1%, 3.9%, 8.0% of the world, UK and US populations respectively have diabetes with a projected 3.0% prevalence globally by 2010, corresponding to approximately 220 million patients.
  - World Health Organisation 1999
- This represents an increase of 61% in the United States since 1991
  - American Diabetes Association 1999
- A UK screening study in 1990 showed a prevalence of diabetes of 10.5% in 70-year olds and 13.8 % in 85-year olds.
  - Croxson SC, *Diab Med* 1991
- Combined prevalence of 2% in UK for all age groups ranging from 0.08% to 0.46% in patients under the age of 30 years and from 5.18% to 6.78% in patients over the age of 60 years
  - Primary Care Information Database - PRIMIS+ 2007

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World 2011 = 366 million
2030 = 552 million
Increase = 51%
37.7
51.2
36%
52.8
64.2
22%
71.4
120.9
69%
32.6
59.7
83%
14.7
28.0
90%
25.1
39.9
59%
131.9
187.9
42%

Diabetes and Peripheral Arterial Disease

- 15% of diabetics are affected by PAD at 10 years following diagnosis, rising to 45% at 20 years.
  - Kreines K, *Diabetes Care* 1985
- 20% of patients with PAD have diabetes.
  - Muribato JM, *Circulation* 1997
- PAD disease distribution different in diabetes.
  - Strandness DE, *Diabetes* 1961
- PAD more aggressive in diabetics with an 11-times higher rate of major lower limb amputation and a doubling of the five-year mortality.
  - Elhadd TA, *Pract Diabetes Int* 1999
- Diabetic ulcers heal more slowly and are the main cause of non-traumatic lower limb amputation in developed countries.
  - Caputo GM, *N Engl J Med* 1994

Why does diabetes lead to vascular pathology ??

Why does diabetes lead to vascular pathology ??

- Pathophysiology of diabetic vasculopathy appears related to alterations in vascular homeostasis due to endothelial and smooth muscle cell dysfunction favouring a pro-inflammatory and thrombotic state which ultimately leads to atherothrombosis.

- Macro- and microvascular diabetic complications are mainly due to prolonged exposure to hyperglycemia clustering with other risk factors such as arterial hypertension, dyslipidemia as well as genetic susceptibility.

Paneni F, *Eur Heart J* 2013

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- Macro- and microvascular diabetic complications are mainly due to prolonged exposure to hyperglycemia clustering with other risk factors such as arterial hypertension, dyslipidemia as well as genetic susceptibility.
- The detrimental effects of glucose already occur with glycemic levels below the threshold for the diagnosis of diabetes. This is explained by the concept of "glycemic continuum" across the spectrum of prediabetes, diabetes and cardiovascular risk.
- Early dysglycemia caused by obesity-related insulin resistance or impaired insulin secretion is responsible for functional and structural alterations of the vessel wall culminating with diabetic vascular complications.

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Occurs early

Hyperglycaemia

Endothelial and Smooth Muscle Cell Dysfunction

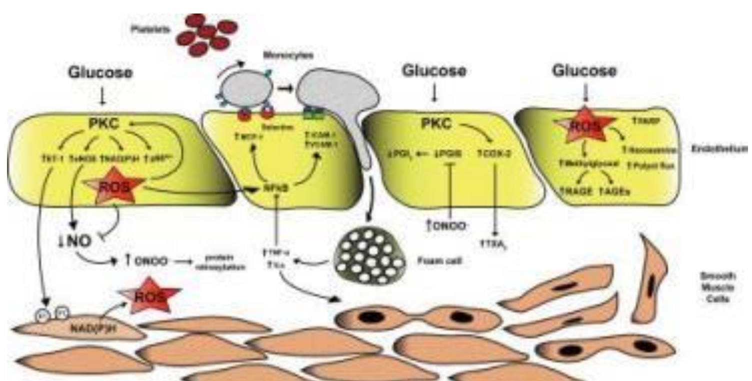
Paneni F, *Eur Heart J* 2013

Why does diabetes lead to vascular pathology ??

- The initial trigger whereby high glucose concentrations alter vascular function is the imbalance between nitric oxide (NO) bioavailability and accumulation of reactive oxygen species (ROS) leading to endothelial dysfunction.

- Hyperglycemia-induced generation of superoxide anion (O2−) inactivates NO to form peroxynitrite (ONOO−), a powerful oxidant which easily penetrates across phospholipid membranes and induces substrate nitration.

- Protein nitrosylation blunts activity of antioxidant enzymes and endothelial NO synthase (eNOS). Importantly, reduced NO bioavailability is a strong predictor of cardiovascular outcomes.



Current advances in pathophysiological mechanisms

- Hyperglycemia and insulin resistance are key players in the development of atherosclerosis and its complications where subsequent metabolic abnormalities cause overproduction of ROS which can cause endothelial dysfunction and inflammation playing a major role in precipitating diabetic vascular disease.

Paneni F, *Eur Heart J* 2013

Current advances in pathophysiological mechanisms

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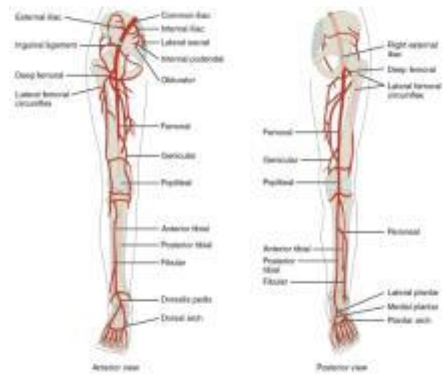
  - a) emerging role of endothelium in obesity-induced insulin resistance.
  - b) hyperglycemia-dependent microRNAs deregulation and impairment of vascular repair capacities.
  - c) alterations of coagulation, platelet reactivity, and microparticle release.
  - d) epigenetic-driven transcription of ROS-generating and pro-inflammatory genes.

Paneni F, *Eur Heart J* 2013

Global Clinical Evaluation

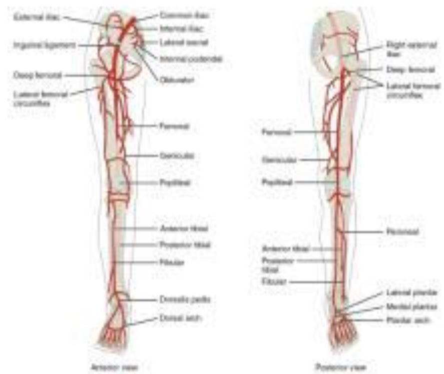
Global Clinical Evaluation

Blood Supply



Global Clinical Evaluation

Blood Supply



Septic Load

Vascular Examination

Vascular Examination

- Inspection.
- Palpation.
- Auscultation.
- Traditional Tests.
- Complete Cardiovascular Assessment.

Inspection

- Colour:
  - Pink.
  - Red.
  - White.
  - Blue.
  - Black.

Inspection

- Colour:
  - Pink, Red, White, Blue, Black.

- Trophic Changes:
  - Shiny skin.
  - Hair loss.
  - Loss of subcutaneous tissue.

Inspection

- Colour:
  - Pink, Red, White, Blue, Black.
- Trophic Changes:
  - Shiny skin, hair loss, loss of subcutaneous tissue.
- Ulceration at Pressure Points:
  - Lateral side of foot, head of 1st metatarsal, heel, malleoli.
  - Tips and between the toes.

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Palpation

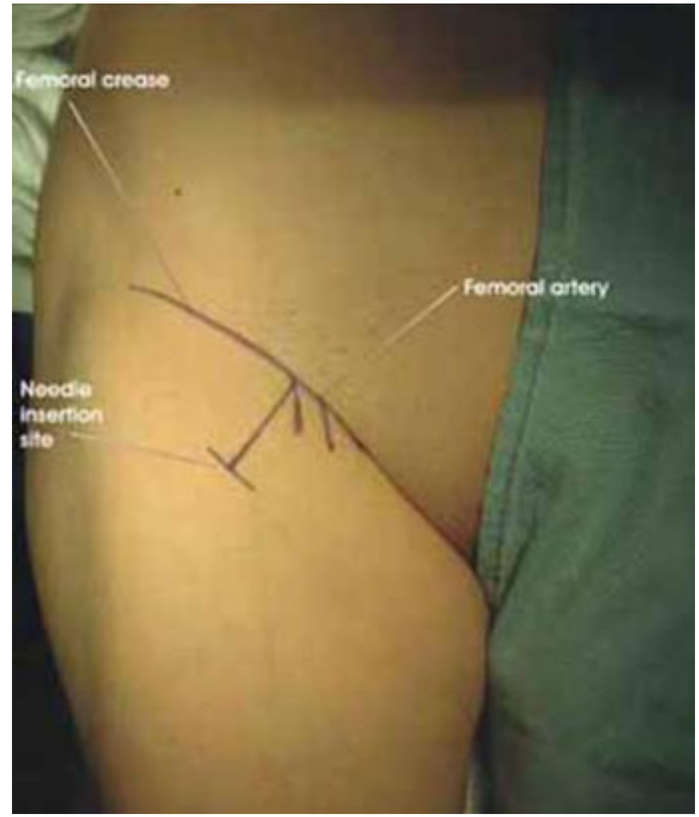
- Temperature of skin.
- Capillary Refill.

Pulses

- Femoral.
- Popliteal.
- Posterior Tibial.
- Dorsalis Pedis.

Femoral Artery

- Feel for the mid-inguinal point which is mid-way between the symphysis pubis and anterior superior iliac spine.



Popliteal Artery

- Ask the patient to bend their knee. Place the thumbs on the tibial tuberosity and feel the pulse behind the knee with 8 finger tips.

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Posterior Tibial Artery

- Palpate the artery mid-way between the medial malleolus and the prominence of the heel.

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Dorsalis Pedis Artery

- Look for the mid-line between the medial and lateral malleoli.

- Palpate down a line extending from this point to the web space between the 1st two toes just lateral to extensor hallucis longus.

Traditional Bedside Evaluation

- Arterial Insufficiency

  - Elevate leg to about 15^{o}
  - Look for venous guttering.

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Traditional Bedside Evaluation

- Buerger's Angle:
    - Elevate leg.
    - Continue with leg elevation until the limb becomes pale.
    - Note the angle from the horizontal baseline at which this occurs.
    - This is **Buerger's Angle.**

Traditional Bedside Evaluation

- Buerger’s Test:

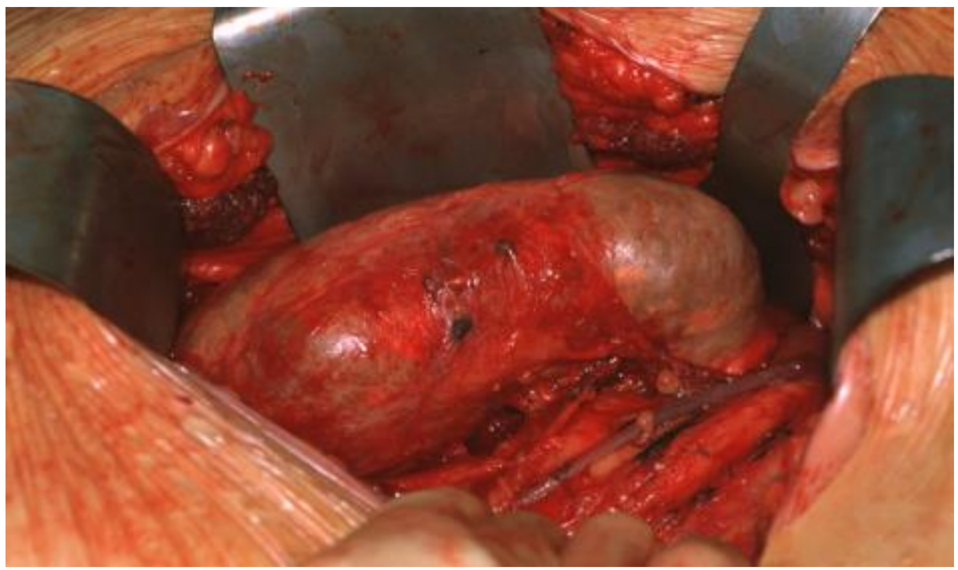
- Next, ask the patient to hang the leg over the side of the bed.
- Note the time of venous filling.
- Assess for the presence of reactive hyperaemia on dependency.
- If the foot goes crimson – **Buerger’s +ve Test.**

Systemic Examination

- Blood Pressure.
- Auscultation of the Heart.

Systemic Examination

- Palpation of the Abdomen.



Vascular Investigation

Vascular Investigation

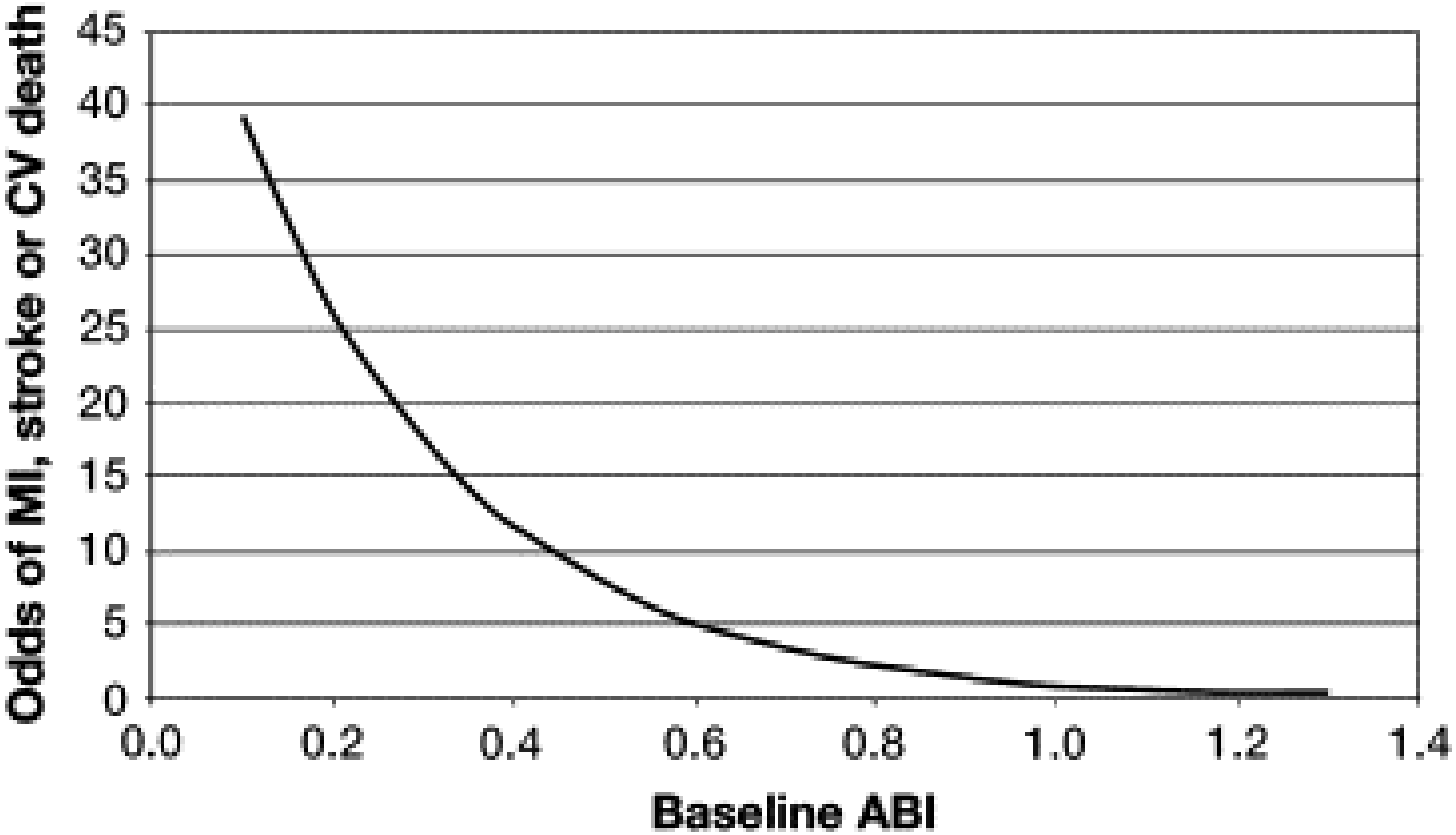
- **Ankle-Brachial Pressure Index (ABPI or ABI).**

- Cuff was inflated to 10mmHg above systolic pressure and deflated at 2 mmHg/s.
- The first reappearance of the pulse was taken as the systolic pressure.

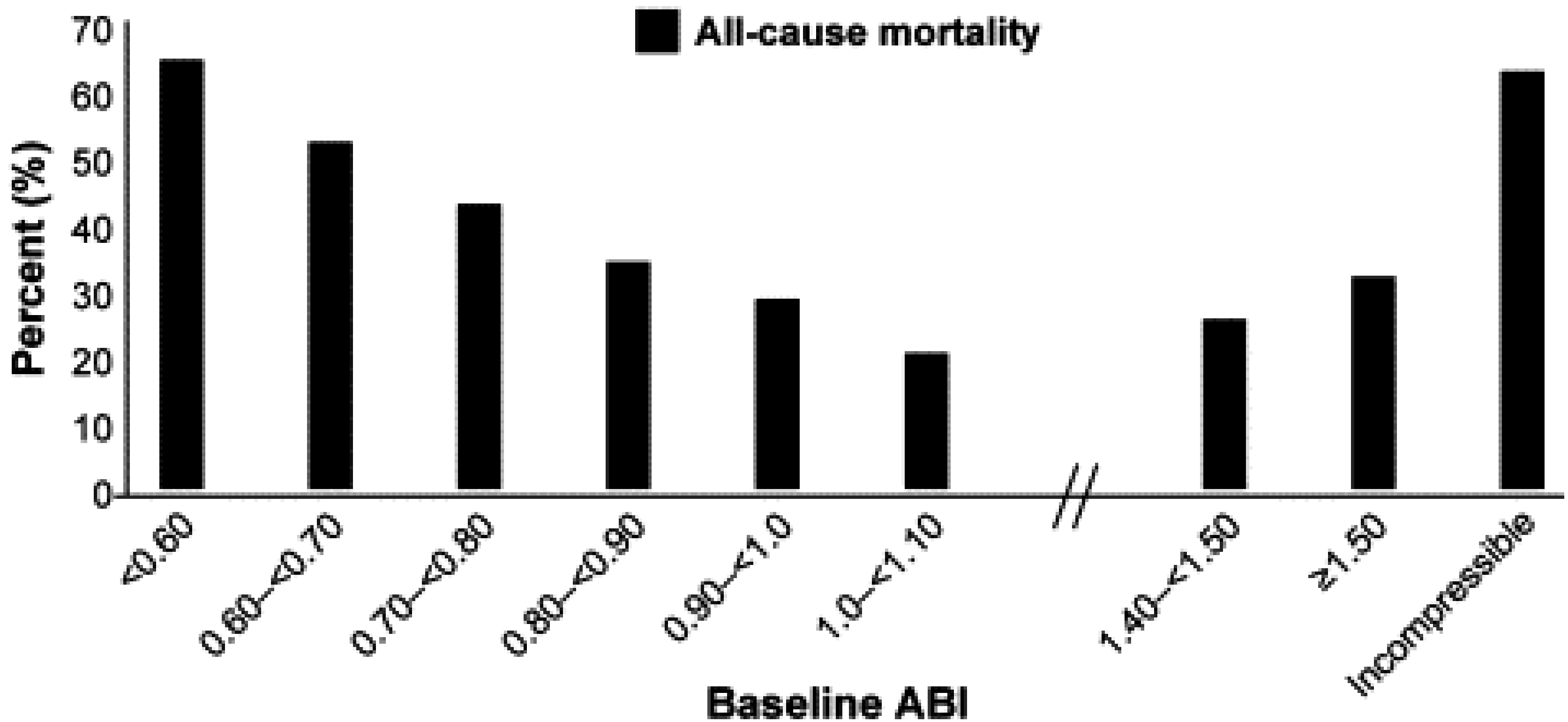
$$\frac{\text{Systolic ankle pressure (mm Hg)}}{\text{Systolic brachial pressure (mm Hg)}}$$

- Resting ABI of ≤ 0.90 indicates a haemodynamically significant arterial stenosis.
- An ABI ≤ 0.90 is also 95% sensitive in detecting arteriogram-positive lesions in symptomatic individuals.
- Calcification and inability to compress the arteries can occur in patients with diabetes or renal insufficiency resulting in a false elevation of ankle pressures, leading to an ABI ≥ 1.3.

ABPI as a Predictor of Risk



ABPI – Prediction of Mortality



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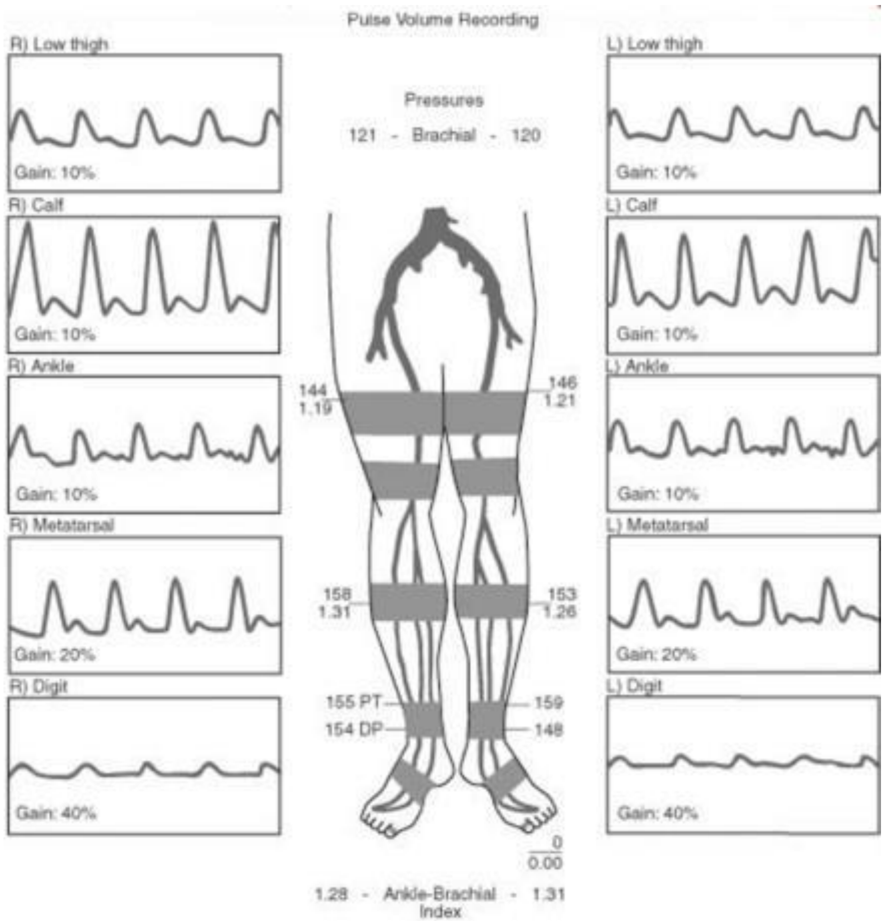
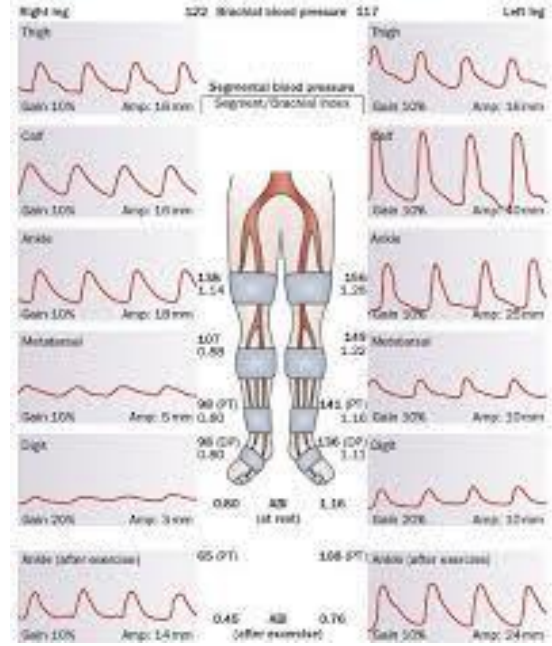
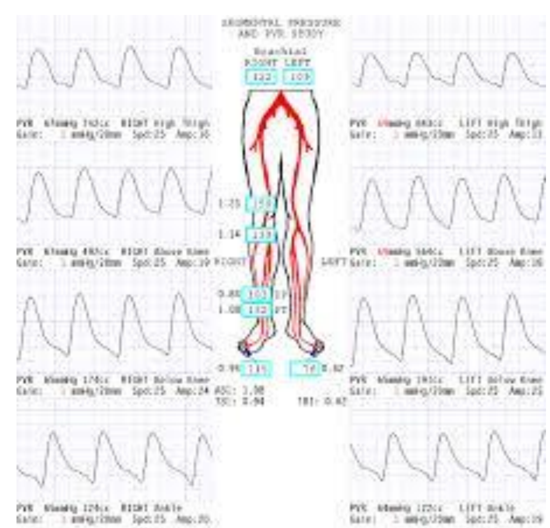
Segmental Waveforms







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Exercise ABPI

- Confirms the PAD diagnosis.
- Assesses the functional severity of claudication.
- May “unmask” PAD when resting the ABI is normal.

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Under-utilised

Vascular Investigation

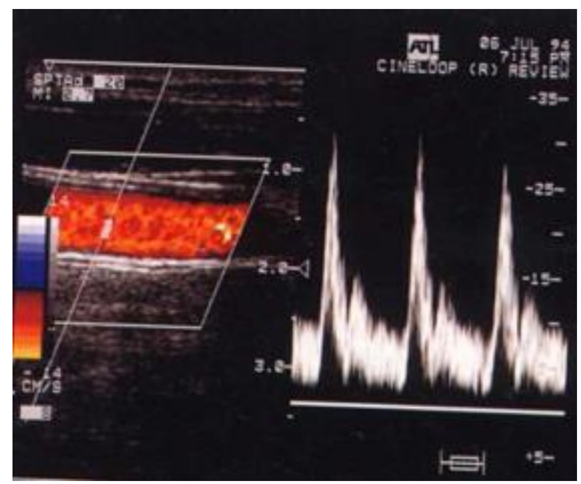
- Ankle-Brachial Pressure Index.
- **Arterial Duplex.**

Arterial Duplex

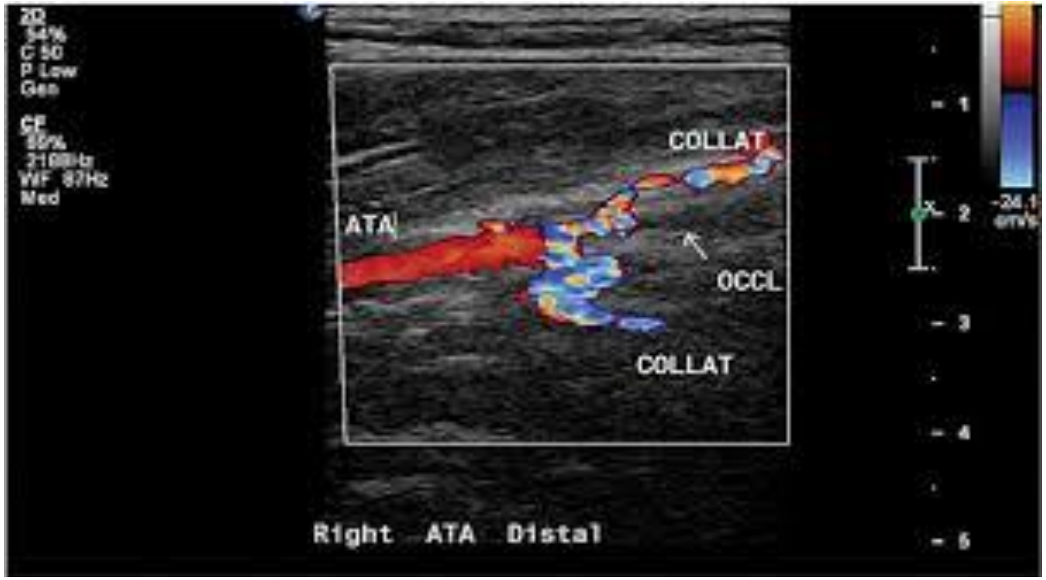
- Duplex ultrasound of the extremities is useful to diagnose anatomic location and degree of stenosis of peripheral arterial disease.

- Duplex ultrasound is useful to provide surveillance following femoral-popliteal bypass using venous conduit (but not prosthetic grafts).

- Duplex ultrasound of the extremities can be used to select candidates for:
  - endovascular intervention.
  - surgical bypass.
  - select the sites of surgical anastomosis.



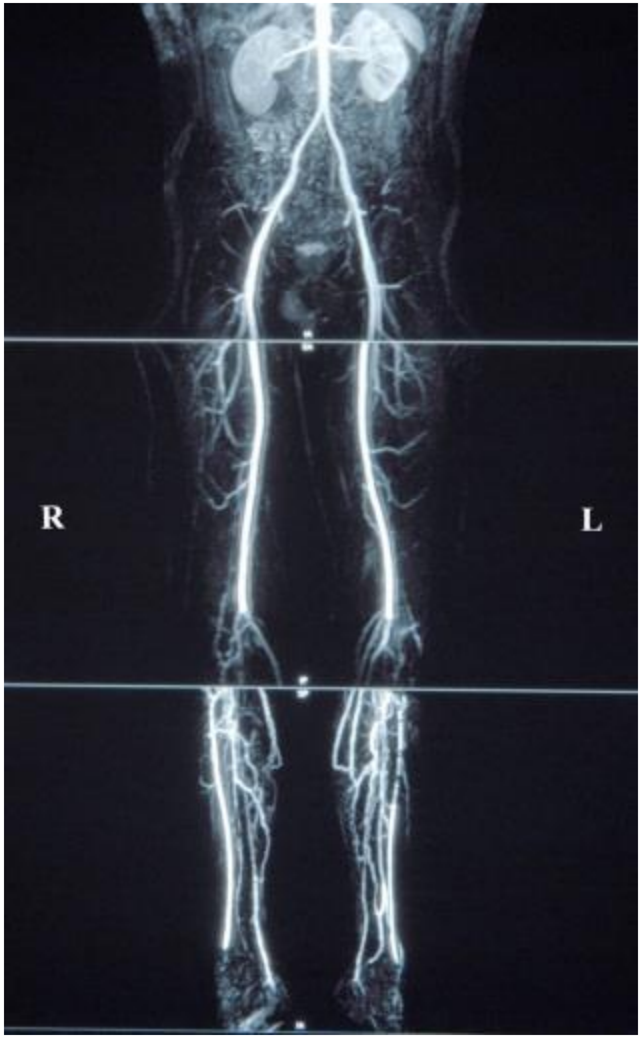
Arterial Duplex



Vascular Investigation

- Ankle-Brachial Pressure Index.
- Arterial Duplex.
- **Magnetic Resonance Angiography.**

Magnetic Resonance Angiogram



Vascular Investigation

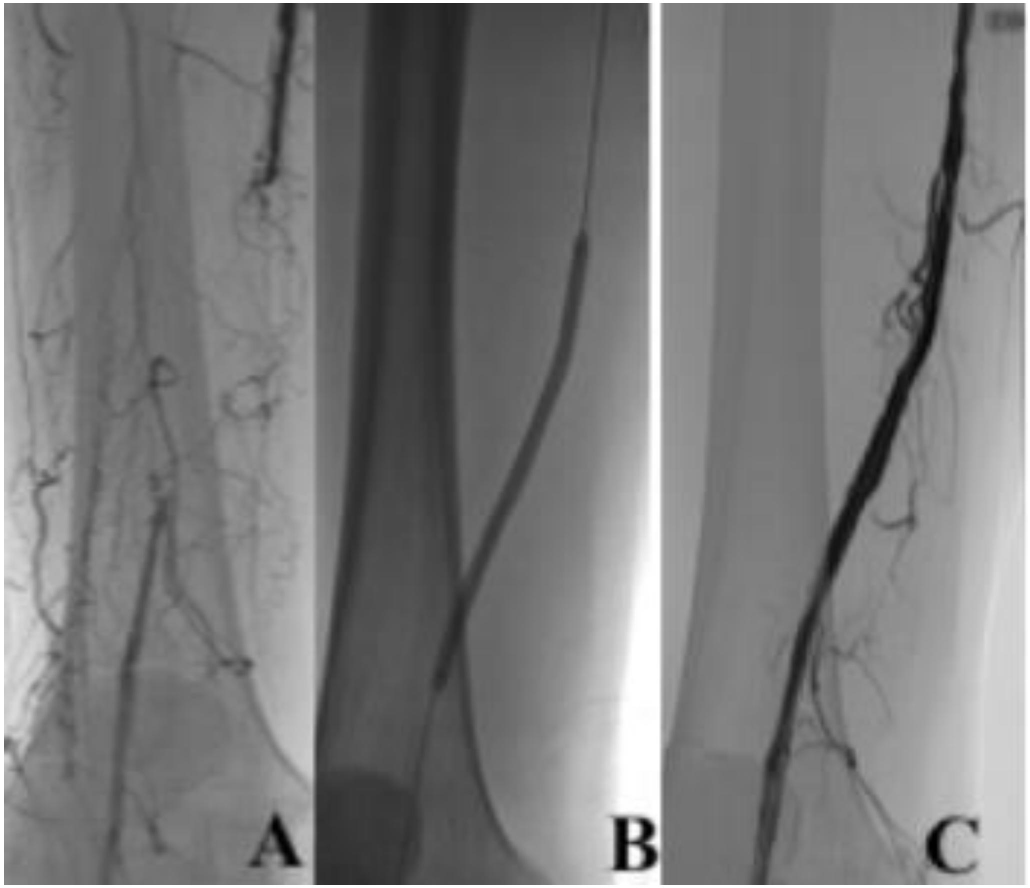
- Ankle-Brachial Pressure Index.
- Arterial Duplex.
- Magnetic Resonance Angiography.
- **Computerised Tomography Angiology.**

Computerised Tomography Angiogram

Vascular Investigation

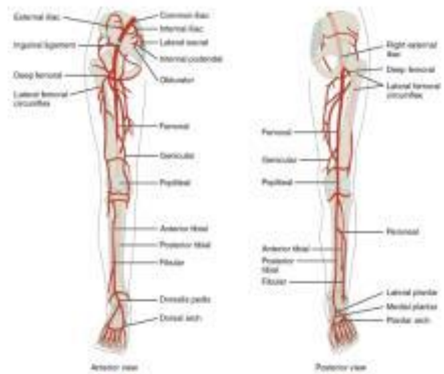
- Ankle-Brachial Pressure Index.
- Arterial Duplex.
- Magnetic Resonance Angiography.
- Computerised Tomography Angiology.
- **Transfemoral Angiography.**

Transfemoral Angiogram



Global Clinical Evaluation

Blood Supply



Septic Load

Septic Load Evaluation

Clinical Examination

Clinical Examination

- Clinical severity of infection may be quantified according to the infection category of the PEDIS (perfusion, extent/size, depth/tissue loss, infection and sensation) system proposed by the International Working Group on Diabetic Foot (IWGDF).

Schaper NC, *Diabetes Metab Res Rev* 2004
Lipsky BA, *Diabetes/Metabolism Research and Reviews* 2016

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  - Grade 4 wounds are severely infected, including any foot infection with systemic inflammatory response syndrome.

Schaper NC, *Diabetes Metab Res Rev* 2004
Lipsky BA, *Diabetes/Metabolism Research and Reviews* 2016

PEDIS Grades and Treatment Paradigms

Grade	Infection Severity	Clinical Manifestations	Treatment Parameters	Medications
1	Uninfected	Wound without purulence or inflammation	Outpatient	Topical antibiotics
2[b]	Mild	≥2: purulence or erythema, pain, tenderness, warmth, or induration; cellulitis ≤2 cm around ulcer; infection limited to skin/subcutaneous tissue; no other complications	Most not limb-threatening; most outpatient treatment	Cephalexin, trimethoprim-sulfamethoxazole (TMP-SMX), levofloxacin, amoxicillin-clavulanate, clindamycin
3[c]	Moderate	Infection as above plus >1: cellulitis >2 cm, streaking, deep tissue abscess, gangrene and with some life-threatening; involvement of muscle, tendon, joint, or bone	Most limb-threatening with some life-threatening; requires hospital treatment	TMP-SMX, amoxicillin-clavulanate, levofloxacin, ceftriaxone, linezolid, ertapenem, ticarcillin-clavulanate
4[d]	Severe	Infection plus systemic toxicity or metabolic instability; fever, chills, tachycardia, hypotension, confusion, vomiting, severe hyperglycemia, acidosis, or azotemia	Life-threatening; requires hospital treatment	Imipenem-cilastatin, vancomycin-ceftazidime, levofloxacin-clindamycin, piperacillin-tazobactam, ticarcillin-clavulanate

[a] *PEDIS stands for perfusion, extent/size, depth/tissue loss, infection, and sensation.*
[b] *Medications for treatment can be oral.*
[c] *Medications for treatment are oral or parenteral, based on clinical situation.*
[d] *Medications for treatment are IV, at least initially.*

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Research Article

A Comparison of Tissue versus Swab Culturing of Infected Diabetic Foot Wounds

Ying Huang, Ying Cao, Mengchen Zou, Xiangrong Luo, Ya Jiang, Yaoming Xue, and Fang Gao

Department of Endocrinology and Metabolism, Nanfang Hospital, Southern Medical University, Guangzhou 510515, China

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Microbiological Sampling

- Wound Swabs:
  - Swab culturing *may* be reliable for identification of pathogens in diabetic foot wounds classified as grade 2.
  - However, it is advisable to culture deep tissue specimens for wounds of grade ≥3 because swab culturing is associated with a high risk of missing pathogens especially Gram-negative bacteria.

Huang Y, *Int J Endocrinology* 2016

Microbiological Sampling

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  - Howev s for wounds of grad high risk of missin

ALWAYS TRY AND SEND TISSUE WHENEVER POSSIBLE

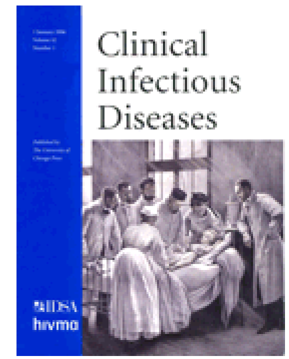
Huang Y, *Int J Endocrinology* 2016

MAJOR ARTICLE

Culture of Percutaneous Bone Biopsy Specimens for Diagnosis of Diabetic Foot Osteomyelitis: Concordance with Ulcer Swab Cultures

Eric Senneville,[1] Hugues Melliez,[1] Eric Beltrand,[2] Laurence Legout,[1] Michel Valette,[1] Marie Cazaubiel,[1] Muriel Cordonnier,[1] Michèle Caillaux,[1] Yazdan Yazdanpanah,[1] and Yves Mouton[1]

[1]Diabetic Foot Clinic and [2]Department of Orthopedic Surgery, Dron Hospital, Tourcoing, France



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Bone Sampling Evidence

- Retrospective review of 76 patients with 81 episodes of foot osteomyelitis who underwent a surgical percutaneous bone biopsy between January 1996 and June 2004 in a single diabetic foot clinic.
  - Patients were included with positive bone biopsy culture results who were antibiotic naïve for at least 4 weeks before biopsy.
  - Pathogens isolated from bone samples were predominantly staphylococci (52%) and gram-negative bacilli (18.4%).
  - The distributions of microorganisms in bone and swab cultures were similar, except for coagulase-negative staphylococci, which were more prevalent in bone samples ($P < .001$).
  - Bone and swab cultures identical in 12 (17.4%) of 69 patients with an overall concordance between the results of wound swab and bone biopsy cultures of 42.8% for Staphylococcus aureus, 28.5% for gram-negative bacilli, and 25.8% for streptococci.

- Senneville E, *Clin Infect Dis* 2006

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- No adverse events--such as worsening peripheral vascular disease, fracture, or biopsy-induced bone infection--were observed, but 1 patient experienced an episode of acute Charcot osteoarthropathy 4 weeks after bone biopsy was performed.

- The authors concluded that superficial swab cultures do not reliably identify bone bacteria while percutaneous bone biopsy appears to be safe for patients with diabetic foot osteomyelitis.
  - Senneville E, *Clin Infect Dis* 2006

International Journal of Surgery 9 (2011) 214–216

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Original Research

Role of bone biopsy specimen culture in the management of diabetic foot osteomyelitis

T.P. Elamurugan [a,*], S. Jagdish [a], Vikram Kate [a], Subhash Chandra Parija [b]

[a] Department of Surgery, Jawaharlal Institute of Postgraduate Medical Education and Research, Pondicherry 605006, India
[b] Department of Microbiology, Jawaharlal Institute of Postgraduate Medical Education and Research, Pondicherry, India

Bone Sampling Evidence

- Prospective study of all consecutive patients with suspected diabetic foot osteomyelitis between 2008 and 2010.
  - Superficial swab and percutaneous bone biopsy specimens were obtained for culture were obtained from 144 patients.
  - Positive culture results were obtained in 134 bone biopsy and 140 cases of superficial swab cultures.
  - Mean number of isolate per sample was similar with staphylococcus aureus the commonest organism grown in both cultures.
  - The bone pathogen was identified in the corresponding swab culture in only 55 cases (38.2%).
  - Staphylococcus aureus had the highest concordance percentage of 46.5% which was not statistically significant.

- Elamurugan TP, *Int J Surg 2011*

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  - Staphylococcus aureus had the highest concordance percentage of 46.5% which was not statistically significant.

- Authors concluded that superficial swab culture may not be accurate in identifying all the organisms causing diabetic foot osteomyelitis with simultaneous bone biopsy increasing the accuracy of detecting the bacterial isolate.

- Elamurugan TP, *Int J Surg 2011*

Organisms isolated in ulcer swab and bone biopsy specimen culture in diabetic foot ulcer patients with suspected osteomyelitis.

Organism	Swab (%) ($n = 288$)	Bone biopsy (%) ($n = 264$)
Staphylococcus aureus	66(22.9)	82(31.1)
Pseudomonas species	50(17.4)	50(18.8)
Acinetobacter baumannii	41(14.2)	35(13.3)
Escherichia coli	37(12.8)	37(14.0)
Proteus species	34(11.8)	25(9.5)
Klebsiella species	26(9.1)	19(7.2)
Streptococcus pyogenes	18(6.2)	8(3.0)
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Others	10(3.5)	6(2.3)

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Concordance between ulcer swab and bone biopsy specimen cultures diabetic foot ulcer patients with suspected osteomyelitis(n - 144).

Degree of concordance	No. of cultures	Percentage
Identical	17	11.8
At least 1 organism similar	38	26.4
Different	89	61.8

Concordance between ulcer swab and bone biopsy specimen cultures diabetic foot ulcer patients with radiologically proven osteomyelitis (n - 86).

Degree of concordance	No. of cultures (n - 86)	Percentage
Identical	12	13.9
Atleast 1 organism similar	24	27.9
Different	50	58.2

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Bone Sampling Evidence - Concerns

- Successful antibiotic treatment is more likely to occur when the choice of antibiotics is guided by cultures from bone biopsy.
- If surgery is not performed, bone cultures may be obtained via percutaneous biopsy through an area of uninvolved skin.
- However, the precision of this approach can be questioned and Senneville reported that after transcutaneous biopsies for culture, 1 in 4 “normal” results were false negatives.
- Needle aspiration when compared to transcutaneous bone biopsy was shown to be unreliable with only 33% concordance with transcutaneous biopsy culture results.

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- It is recommended that bone is best sampled under direct vision, or a reasonably size percutaneous biopsy should be undertaken to guide the choice of antibiotics.
  - Risk of tissue breech.
  - Introduction of organisms if performed through wound.
  - Patient compliance with procedure.
  - Healing.

Antibiotics

- Adhere to Hospital Trust Protocols.
- Beware of single agent therapy in chronic diabetic foot wounds.
- Review patient and their wounds on a regular basis.
- Optimise antibiotic therapy based on microbiological sampling.

Antibiotics

- Adhere to Hospital Trust Protocols.
- Beware of single agent therapy in chronic diabetic foot wounds.
- Review patient and their wounds on a regular basis.
- Optimise antibiotic therapy based on microbiological sampling.

Diagnostic Imaging

Plain Radiography

- The sensitivity of plain films in the diagnosis of osteomyelitis has shown variable results.
- It is related to the chronicity of the infection and at least 30–50% bone loss is required to show visible changes on plain radiographs and such changes take at least 2–3 weeks to manifest.
- The specificity of radiographs is also lowered due to difficulty in distinguishing osteomyelitis from Charcot neuroathropathy joint disease.
- The most common OM changes that may be seen on radiographs include osteopenia, periosteal thickening, cortical erosions, and new bone formation.
- Overall, the sensitivity and specificity are 54% and 68% respectively according to one meta-analysis.
- Nevertheless, plain radiographs should be performed initially as a baseline to assess the development and presentation of OM in a bone.
  - Malhotra R, *Diabetic Foot Ankle 2014*


Lossy compressed

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Plain X-ray – Clinical Correlation

Magnetic Resonance Imaging

- Magnetic resonance imaging (MRI) is presently considered the investigation of choice for diagnosing diabetic foot osteomyelitis.
  - Loss of signal in T1-weighted images and higher intensity on T2-weighted images can reveal the pathology as early as 3 days after infection.
  - However, this bone oedema can sometimes be difficult to differentiate from non-infectious causes of oedema.
- The accuracy of MRI is challenged when Charcot neuroarthropathy joint disease or recent surgical change is present.
- Meta-analyses and reviews show that MRI is probably the most useful imaging modality for assessing osteomyelitis with a sensitivity of about 90% and a specificity of about 80%.
- Although MRI provides a good anatomical correlation, it is limited in terms of functional correlation.

- Malhotra R, *Diabetic Foot Ankle 2014*

Magnetic Resonance Imaging

Magnetic Resonance Imaging

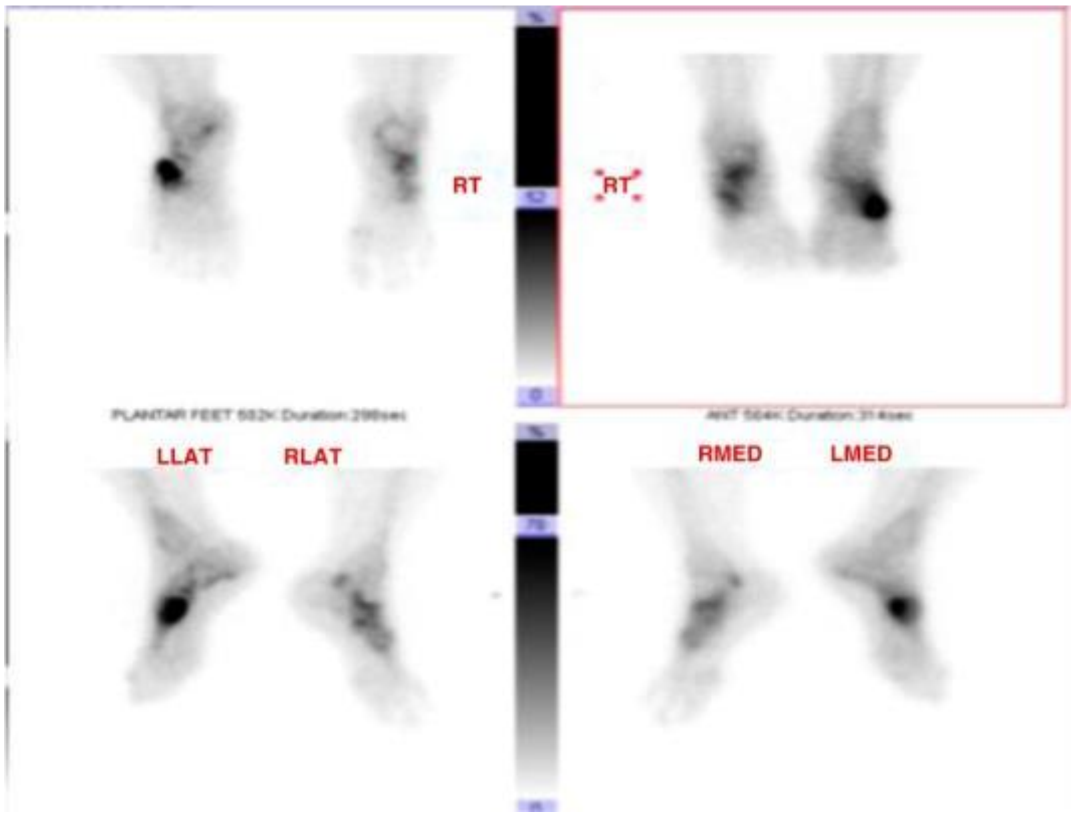
Nuclear Imaging - Bone Scintigraphy

- The three-phase bone scan using Technetium-99m-Medronic Acid Bisphosphonate provides a two-dimensional image of areas in bone with active bone turnover.
- For diabetic foot osteomyelitis, bone scans have a sensitivity of 80–90% but a specificity of less than 50%.
- The poor specificity relates to inability of the bone scan to distinguish osteomyelitis from other inflammatory or traumatic conditions involving the bone, such as Charcot neuroarthropathy joint disease, bone metastasis, gout, fracture, or even recent surgery.
- It must also be noted that it is difficult to delineate the exact anatomical location or extent of infection with a bone scan.

- Malhotra R, *Diabetic Foot Ankle 2014*

Nuclear Imaging - Bone scintigraphy

Nuclear Imaging - Bone scintigraphy



Additional Radiological Investigative Modalities

- Single photon emission computerized tomography (SPECT):
  - Combines bone scan with computerized tomography to improve the anatomical–functional correlation since it provides three-dimensional images of the foot.
  - However, the technology is still not widely available and its diagnostic potential for diabetic foot osteomyelitis is still being researched.

- Malhotra R, *Diabetic Foot Ankle 2014*

Additional Radiological Investigative Modalities

- White blood cell (WBC) scan:
  - Leukocytes can also be removed from the patient, tagged with a radioactive tracer and re-infused into the patient where they accumulate at an infected focus.
  - WBC scans have a sensitivity of at least 80% and a specificity of at least 70% for diabetic foot osteomyelitis.
  - WBC scanning shows soft tissue infection and is not bone specific and therefore correlation with the results of a bone scan is useful with a sensitivity and specificity of 80–90% .
  - This combination, however, would be time consuming, expensive and perhaps best conducted when a MRI is contraindicated.

- Malhotra R, *Diabetic Foot Ankle 2014*

Additional Radiological Investigative Modalities

- Positron emission tomography (PET):
  - Evolving modality for evaluating osteomyelitis in the diabetic foot.
  - PET scan images radioactive fluorine attached to 2-fluoro-2deoxy-D-glucose, which accumulates at sites of increased intracellular glucose metabolism such as infection, inflammation, or malignancy.
  - Its sensitivity ranges from 80 to 100% while its specificity has been reported as 93%.
  - Combining PET with computerized tomography improves the anatomical detail available.

- Malhotra R, *Diabetic Foot Ankle 2014*

Haematological Analyses

Full blood picture

- Haemoglobin:
  - Anaemia – Acute vs. Chronic.
- White Cell Count:
  - Inflammation / Infection.
- Platelets:
  - Clotting potential.
- Indices:
  - Mean Cell Volume.
  - Packed Cell Volume.

Urea and electrolytes

- Sodium.
- Potassium.
- Urea.
- Creatinine / eGFR:
  - CTA / MRA scanning.
  - Angiogram.
  - Antibiotics.
- Other electrolytes:
  - Calcium.
  - Magnesium.

Coagulation screen

- Prothrombin Time (PT).
- Activated Partial Thromboplastin Time (APTT):
  - Heparin.
- International Ratio (INR):
  - Warfarin.

C-reactive protein

- Inflammation / Infection.
- Trends / Progress.

Risk factor analysis

- Fasting Glucose.
- Fasting Lipid Profile.

Risk factor analysis

- Fasting Glucose.
- Fasting Lipid Profile.
- Vasculitis Screen.
- Thrombophilia screen.
- Thyroid Function Tests.

Treatment Goals

Treatment Goals

Clinical Treatment Goals

- **Improve Functional Status**
  - Improve Symptoms
  - Improve Quality of Life
  - Improve Exercise Capacity
- **Preserve the Limb**
  - Decrease Need for Revascularization
- **Prevent Progression of Atherosclerosis**
- **Reduce Cardiovascular Morbidity and Mortality**
  - Reduce Nonfatal Events, such as MI and Stroke

Why have PAD Guidelines ?

- To enhance the quality of patient care.

- Increasing recognition of the importance of atherosclerotic lower extremity PAD:

  - High prevalence.
  - High cardiovascular risk.
  - Poor quality of life.

- The evidence base has become increasingly robust, data-driven care guidelines are now possible.

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TASC II

Inter-Society Consensus for the Management of PAD

Editors: Lars Norgren and William R Hiatt
Associate Editors: John A Dormandy and Mark R Nehler
Contributing Editors: Kenneth A Harris and F Gerry R Fowkes
Consulting Editor: Robert B Rutherford

Journal of Vascular Surgery 2007;45:1S-67S,
European Journal Vascular & Endovascular Surgery 2007;33:S1-S75

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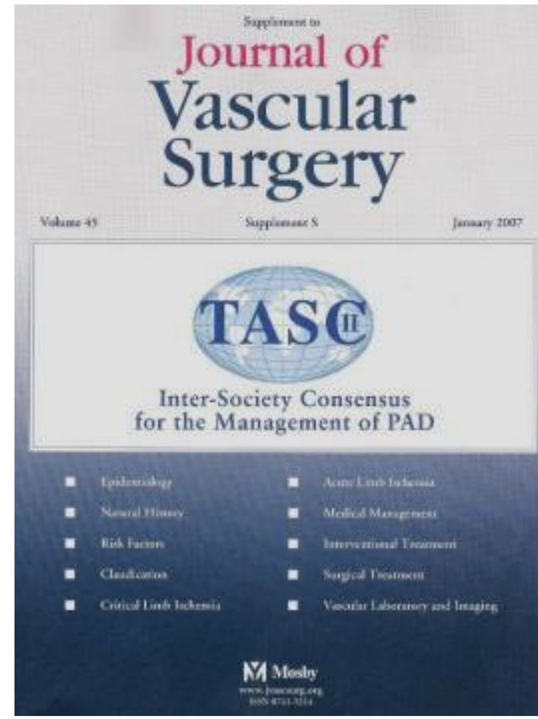
TASC II Guidelines

- Epidemiology of PAD.
- Management of CV risk factors and co-existing disease.
- Intermittent claudication.
- Chronic critical limb ischemia.
- Acute limb ischemia.
- Revascularisation.
- Non-invasive vascular laboratory and imaging.



Levels of Evidence

- **IA** Evidence from meta-analysis of randomized controlled trials.
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- **IV** Evidence from expert committee reports or opinions or clinical experience of respected authorities, or both.

Grades of Recommendation

- Grade A
  - Based on the criterion of a least one randomised, controlled clinical trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation.
- Grade B
  - Based on well-conducted clinical studies but no good quality randomised clinical trials on the topic of recommendation.
- Grade C
  - Based on evidence obtained from expert committee reports or opinions and / or clinical experiences of respected authorities.

Conservative

Modifiable Risk Factors

Gender reassignment

Stop smoking

Improved survival

Treat hypertension & stress

Smoking Cessation

- All patients who smoke should be strongly and repeatedly advised to stop smoking. **A**

- All patients who smoke should receive a program of physician advice, group counselling sessions and nicotine replacement. **A**

- Cessation rates can be enhanced by the addition of antidepressant drug therapy (buproprion) and nicotine replacement. **A**

Exercise Rehabilitation

- Supervised exercise should be made available as part of the initial treatment for all patients with PAD. **A**
- The most effective programs employ treadmill or track walking that is of sufficient intensity to bring on claudication, followed by rest, over the course of a 30-60 minute session. **A**
- Exercise sessions should be typically conducted three times per week for three months. **A**

Medical

Antiplatelet Therapy

- All symptomatic PAD patients with or without a history of other cardiovascular disease should be prescribed an antiplatelet drug long term to reduce the risk of cardiovascular morbidity and mortality. **A**

- Aspirin is effective in patients with PAD who also have clinical evidence of other forms of cardiovascular disease (coronary or carotid). **A**

- Clopidogrel is effective in reducing cardiovascular events in a subgroup of patients with symptomatic PAD, with or without other clinical evidence of cardiovascular disease. **B**

Why Prescribe Aspirin?

Why Prescribe Aspirin?

- Antithrombotic Trialists' Collaboration reported that antiplatelet therapy was associated with a 23% reduction in non-fatal MI, non-fatal stroke and vascular death in patients with PAD.

- The clopidogrel versus aspirin in patients at high risk of ischaemic events trial (CAPRIE) showed that clopidogrel reduced the relative risk of major vascular events by 8.7% compared to aspirin.

Antithrombotic Trialists' Collaboration BMJ 2002

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- Remember dual antiplatelet therapy in infrainguinal procedures, complex or redo surgeries.

Antithrombotic Trialists' Collaboration BMJ 2002

Hyperlipidaemia

- All symptomatic PAD patients should have their low-density lipoprotein (LDL) cholesterol lowered to <2.59mmol/l (<100mg/l). **A**

- A further reduction of LDL cholesterol down to <1.81mmol/l (<70mg/l) in patients with vascular disease in additional sites. **B**

- All asymptomatic patients with PAD should have their LDL cholesterol lowered to <2.59mmol/l (<100mg/l). **C**

Hyperlipidaemia

- Dietary modification should be the initial intervention to control abnormal lipid levels. **B**
- In symptomatic PAD patients, statins should be the primary agent to lower LDL cholesterol levels to reduce cardiovascular events. **A**
- Fibrates and / niacin should be considered in PAD patients with abnormal high density lipoprotein cholesterol and triglyceride levels. **B**

Why Prescribe Statins ?

Why Prescribe Statins ?

- Medical Research Council (MRC) recommended statin therapy for all patients with PAD where simvastatin 40mg daily resulted in a 22% relative risk reduction in rates of MI, stroke and revascularisation in patients with PAD with a cholesterol level >3.5mmol/L.
- Walking performance improvements.
- Potential reduction in plaque volume.

Heart Protection Study *Lancet 2002*

Diabetes

- Patients with diabetes and PAD should have aggressive control of blood sugar levels with a haemoglobin A1c (HbA1c) goal of <7.0% or as close to 6% as possible. **C**

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PAD Specific Pharmacotherapy

- A three to six month course of cilostazol should be first-line pharmacotherapy for the relief of claudication symptoms, as evidence shows both an improvement in treadmill exercise and quality of life. **A**

- Naftidrofuryl (Praxilene®) can also be considered for the treatment of claudication symptoms. **A**

- No recommendation for the use of pentoxifylline.

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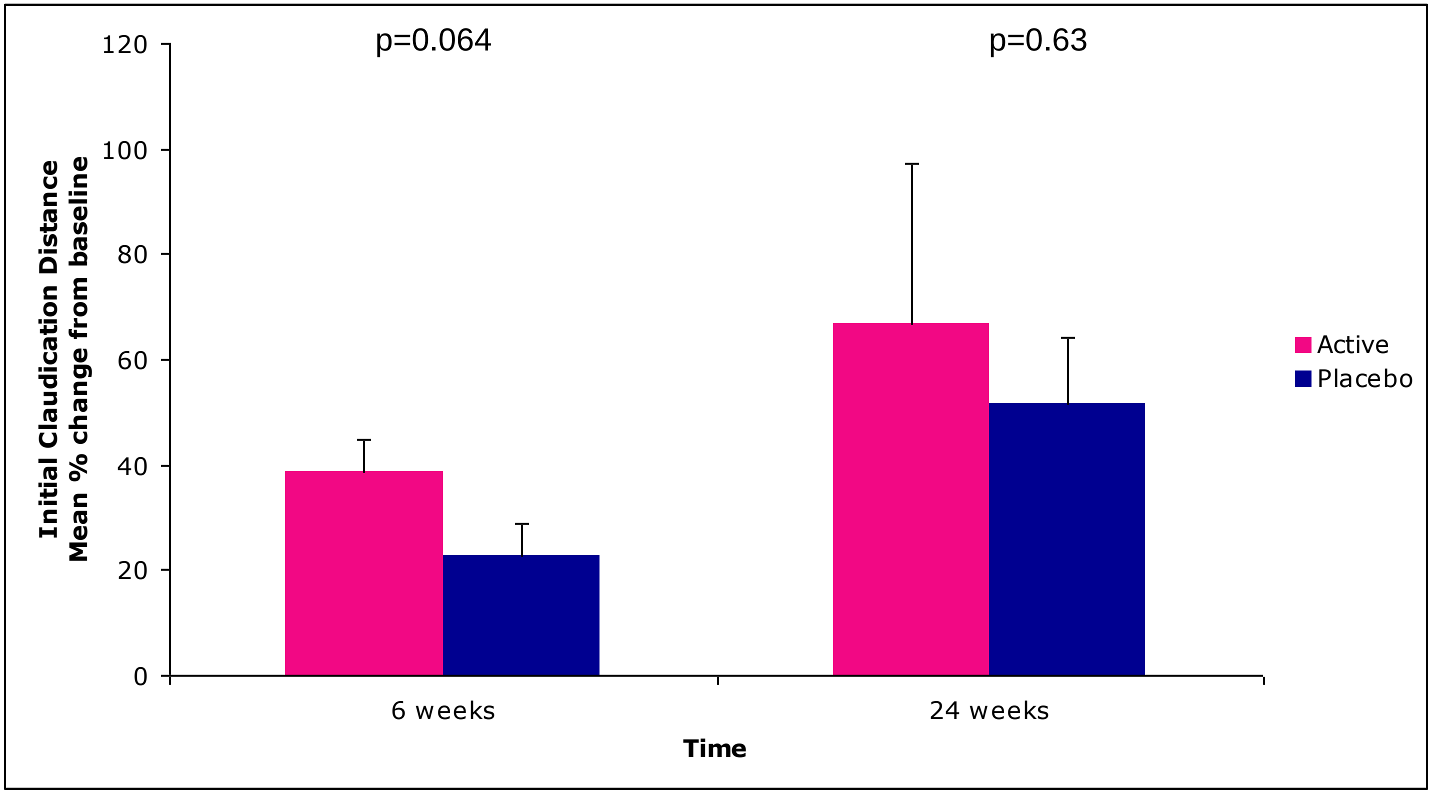
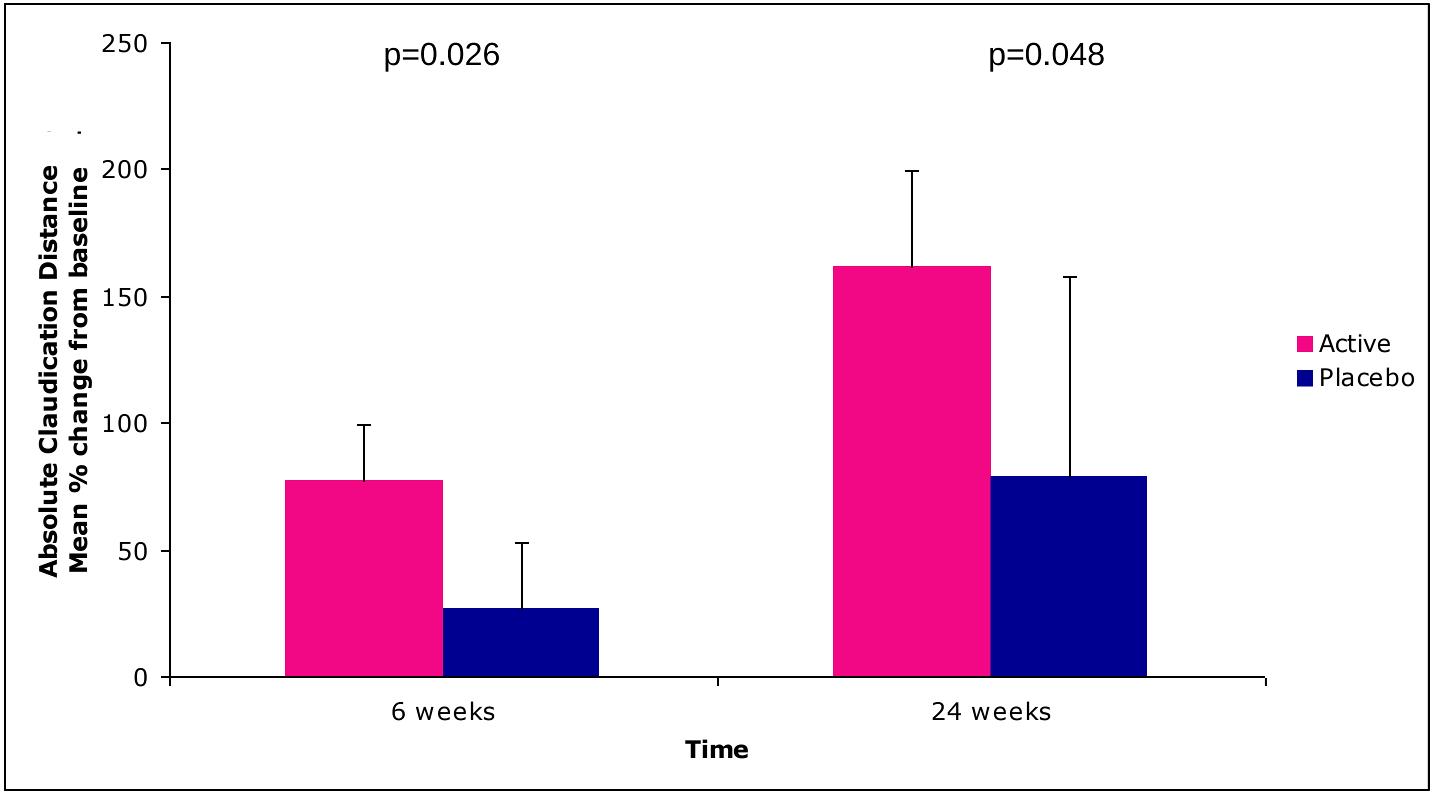
Initial Claudication Distance - Cilostazol



*MWU test

Absolute Claudication Distance - Cilostazol



*MWU test

PAD Specific Medical Therapies

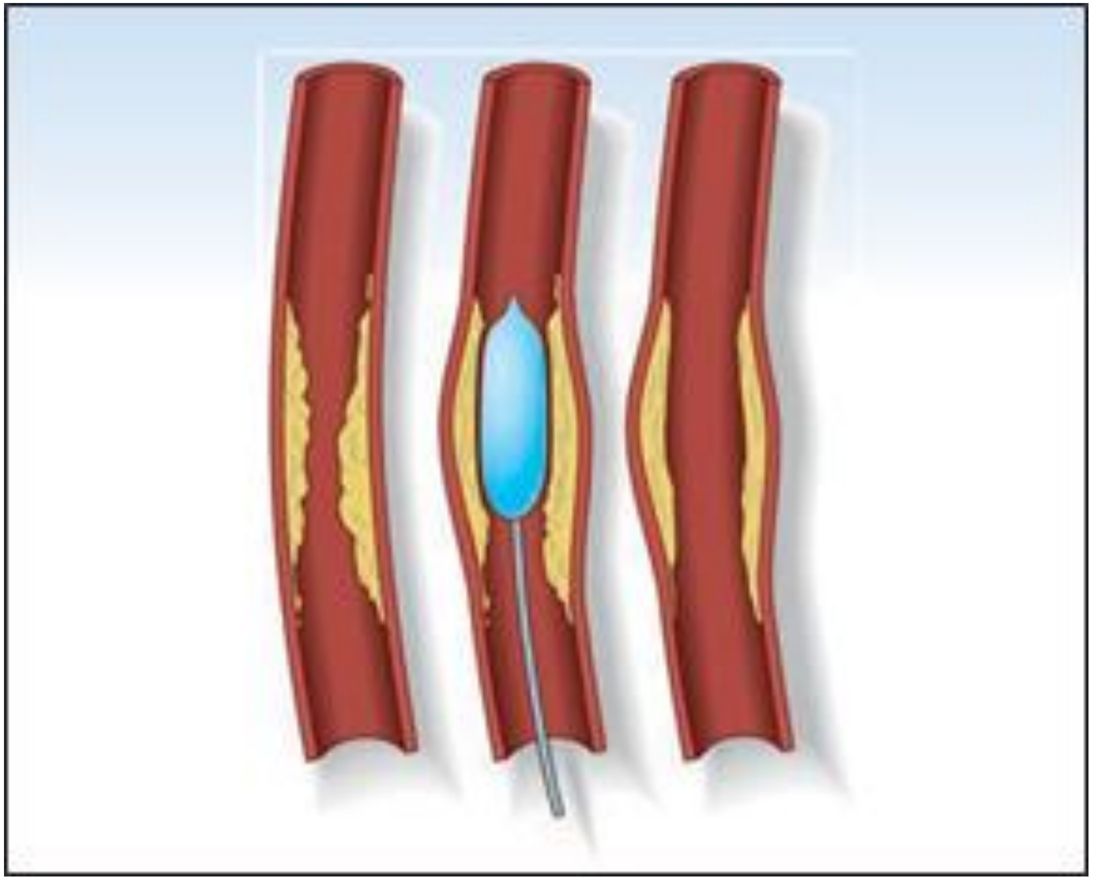
- Cilostazol.
- Naftidrofuryl.
- Pentoxifylline.
- Carnitine.
- Prostanoids.
- Ginkgo Biloba.
- Verapamil.
- Inositol Nicotinate.
- Buflomedil.
- Gene Therapy.
- Stem Cell Therapy.
- Other drugs not in active use.
- Venoactive Therapies.

Procedural Intervention

Consent

- General Local Complications;
  - Pain, Bruising, Bleeding, Wound infection.
- Systemic Complications;
  - Cardiovascular, Respiratory, Thromboembolic.
- Procedural Specific Complications;
  - Graft sepsis.
  - Graft occlusion and distal ischaemia.
  - Limb loss.
  - Nerve injury.
  - Failure to improve symptoms.

Endovascular Treatment



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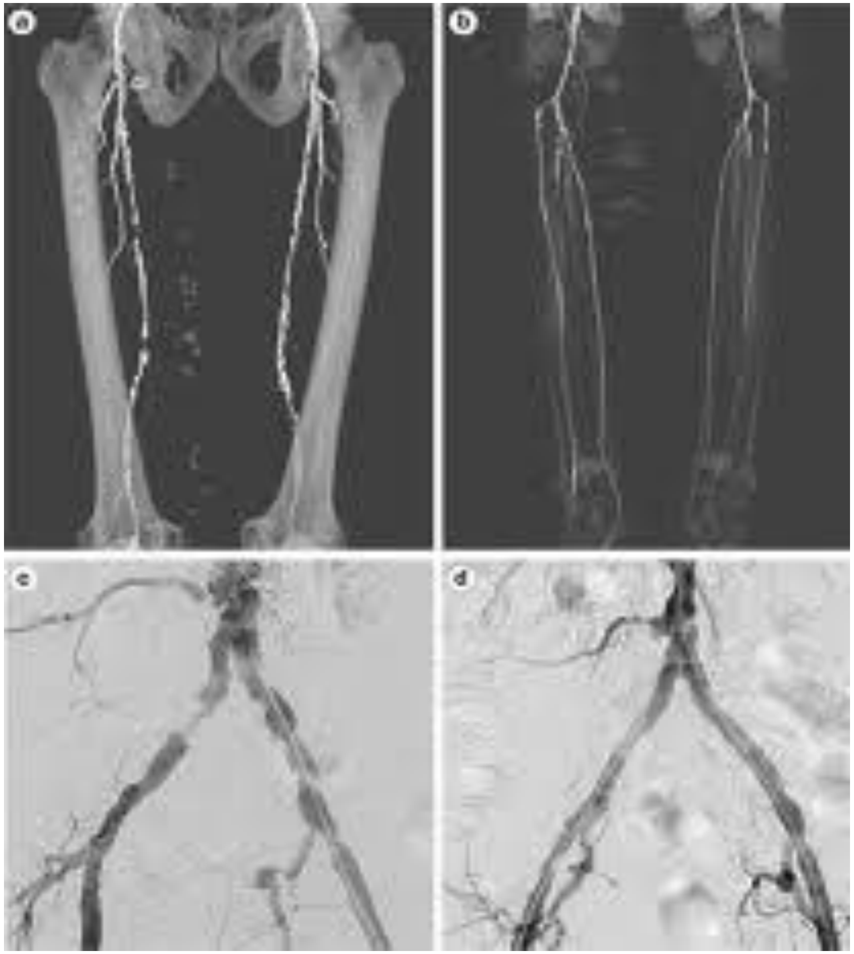
Endovascular Treatment



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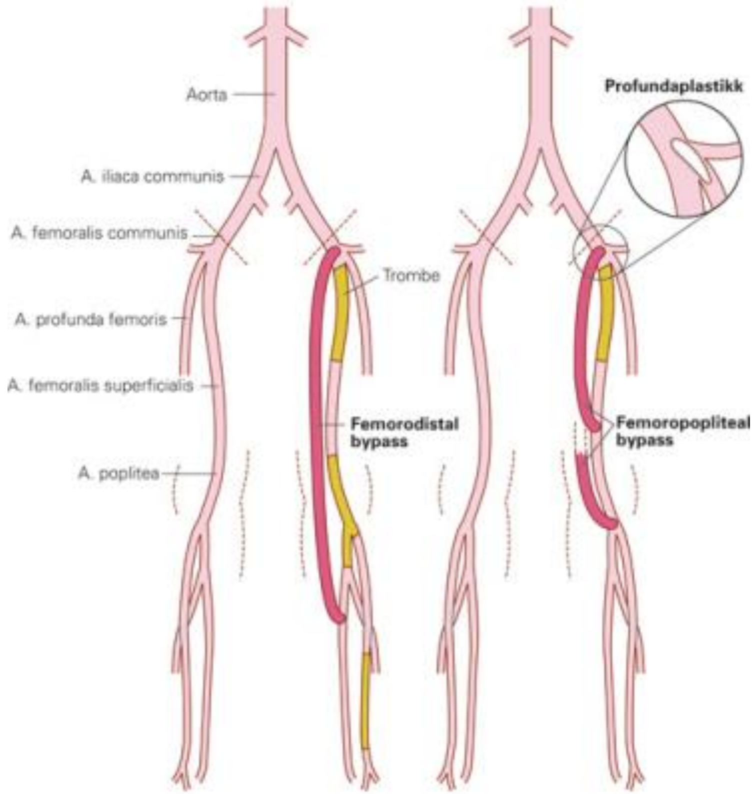
Acute Limb Ischaemia

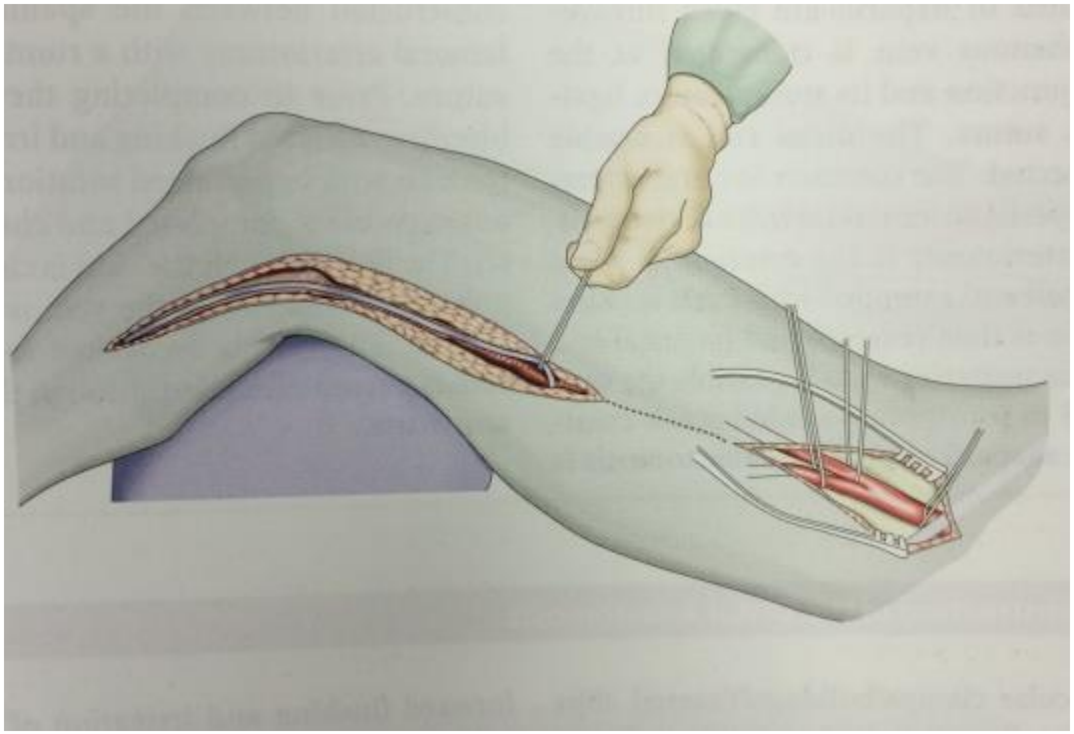
- Associated with significant morbidity and mortality.
- Clinical assessment is paramount – 6 P’s.
- Remember;
  - Evaluate the contralateral limb.
  - Administer heparin early.
  - If you think about a fasciotomy – DO IT !!!!

Surgical Intervention

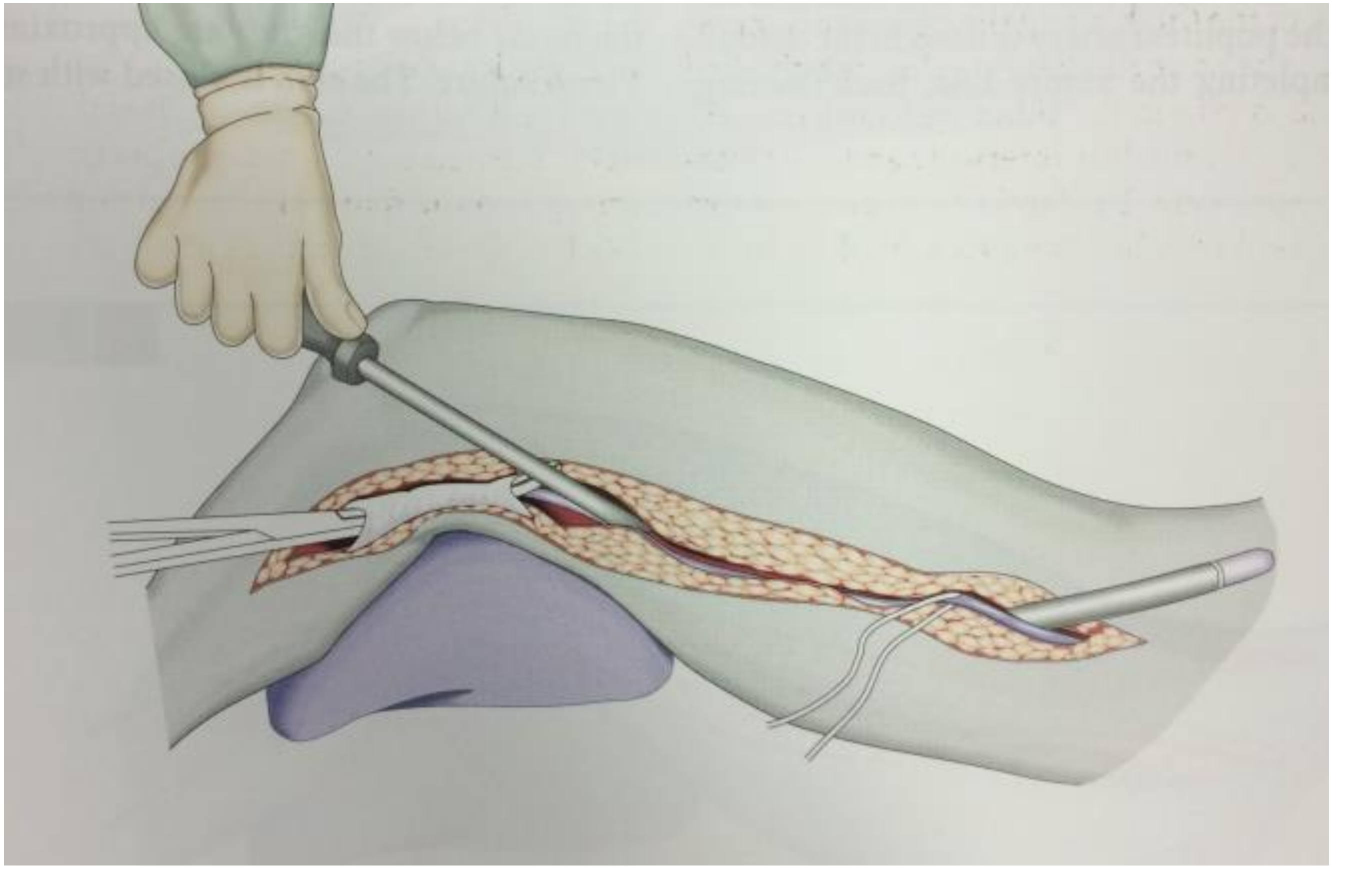


Surgical Bypass

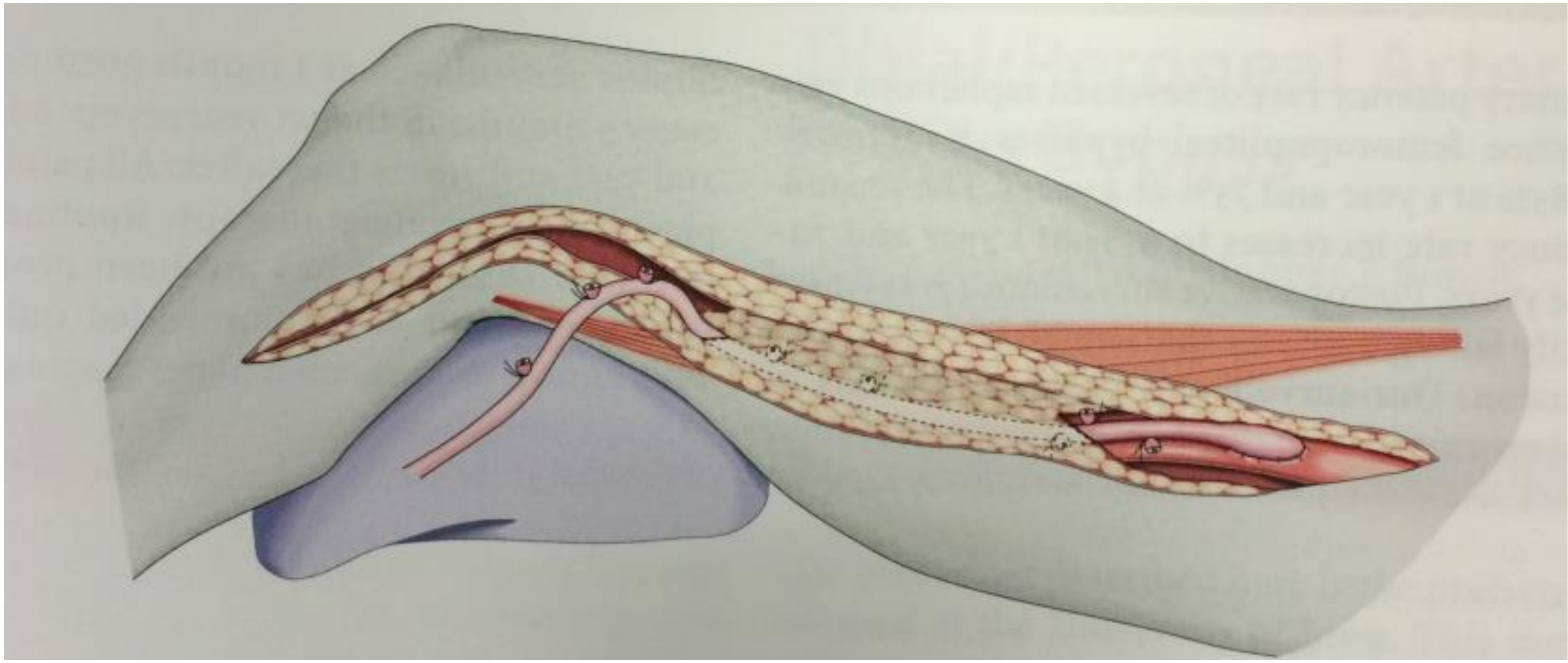
Vein Harvest



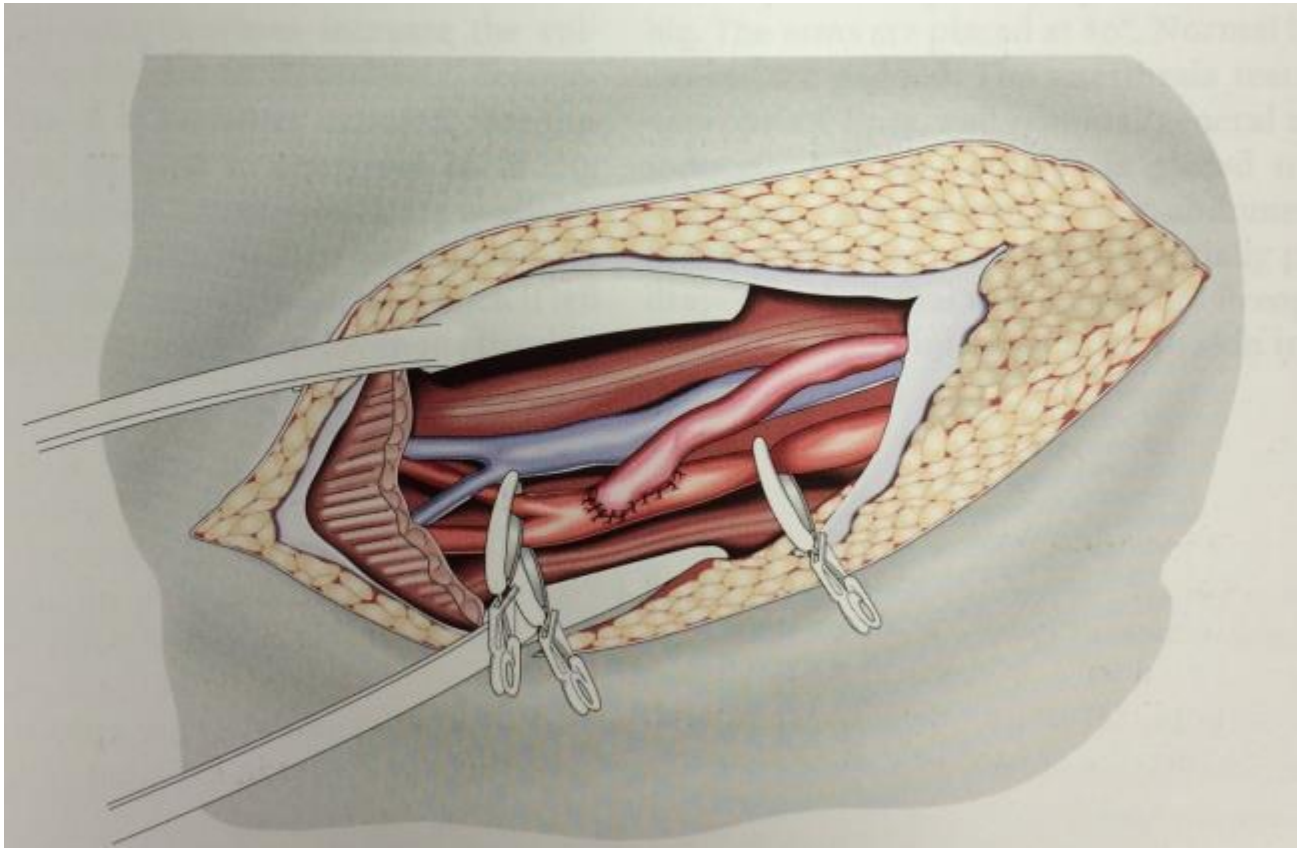
Subfascial Tunnel Creation



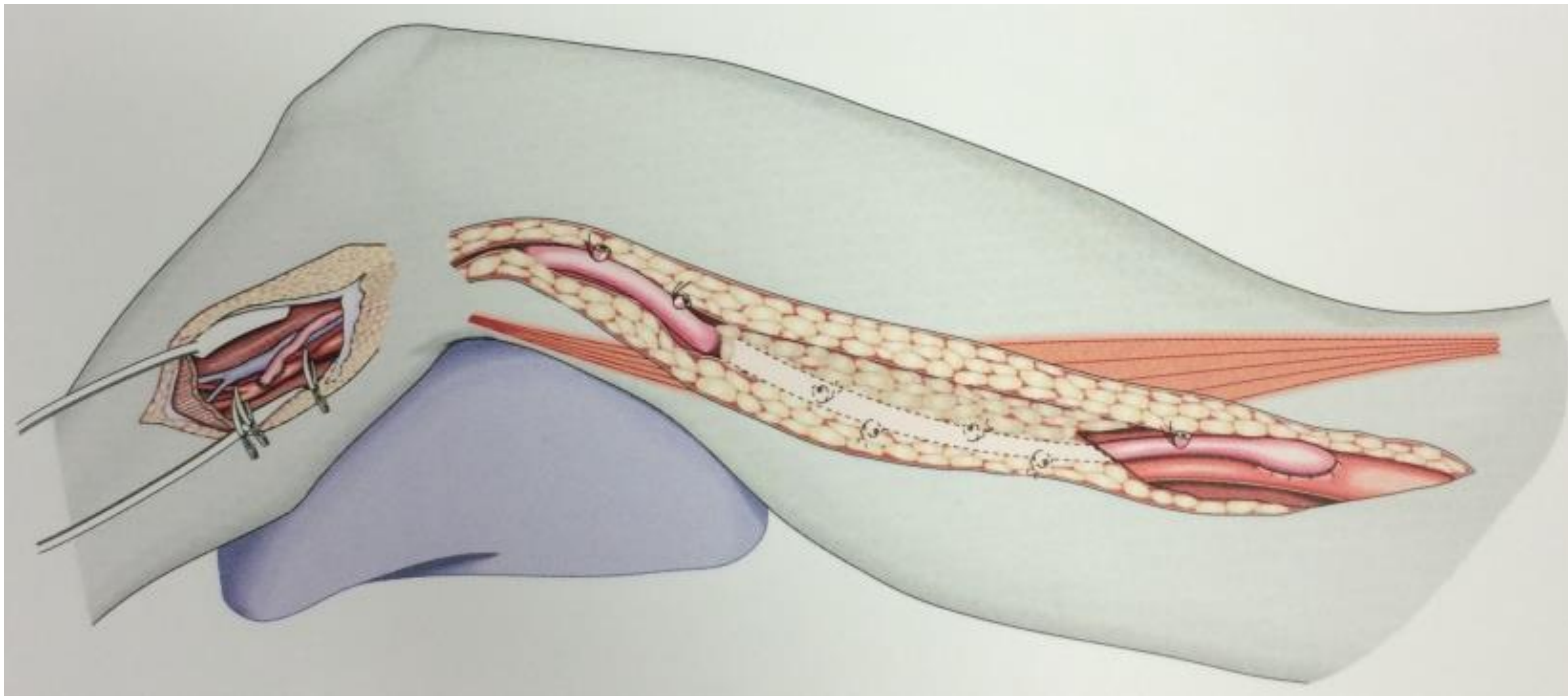
Proximal Anastomosis



Distal Anastomosis



Completion



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Why Treat Diabetic Foot Disease ?

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Why Treat Diabetic Foot Disease ?

Amputations - Epidemiology

- Peripheral arterial disease accounts for the majority of lower limb amputations in the Western World.
  - Greater than 80% due to vascular disease in UK.
  - Six times higher in insulin dependent diabetic patients.
  - Epicentres based on location and population demographics eg. South Western USA & Navajo population.

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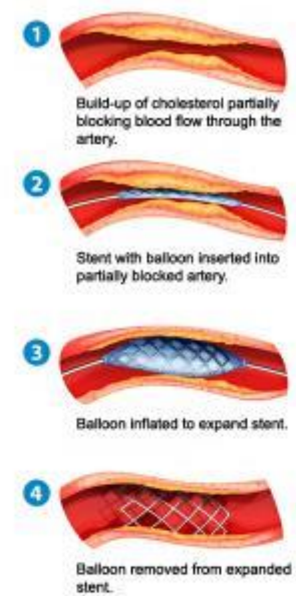
- National Amputee Statistical Database reported that dysvascularity responsible for 70% of all lower limb prosthetic referrals in 2006-07.
  - 4574 referrals post-lower limb amputation.
  - 53% transtibial.
  - 39% transfemoral.

Impact of Modern Surgery

- Danish National Amputation Register demonstrated a 27% fall in major limb amputations due to increased utilisation of infra-inguinal bypass operations.

- Similar reports from Finland, United States and other Western Countries.

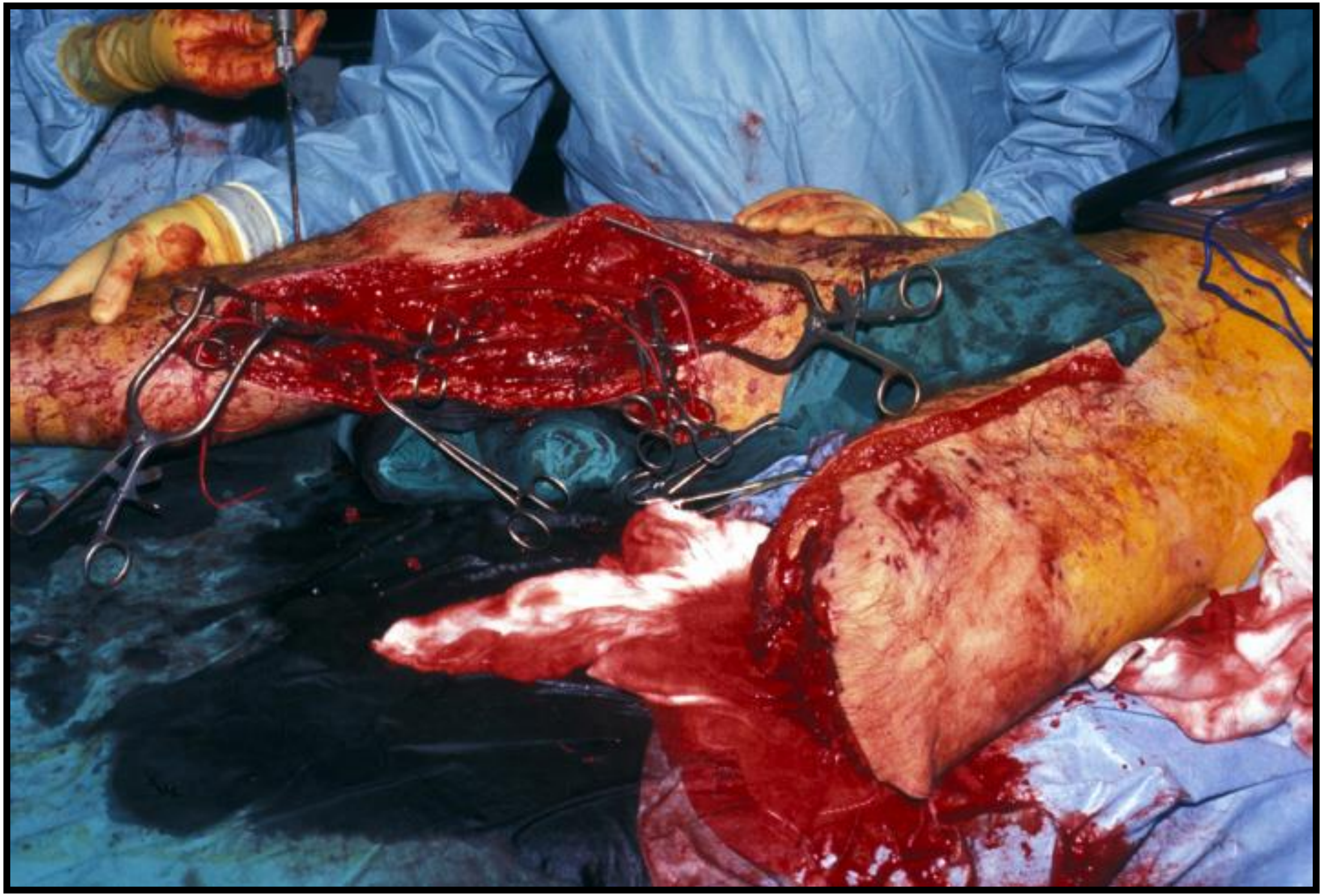


Survival following Major Limb Amputation

- Survival rates post-amputation remain bimodal.

Survival following Major Limb Amputation

- Survival rates post-amputation remain bimodal.
  - If patient survives initial traumatic episode long-term survival is good.



Outcomes following Major Limb Amputation

- Mortality rates post-amputation remain bimodal.
    - For PAD patients, mortality rates are significantly affected by their underlying cardiovascular disease burden.

Vascular Disease – What Lies Beneath !!

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Outcomes following Major Limb Amputation

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  - **30-day mortality between 9% and 15%.**

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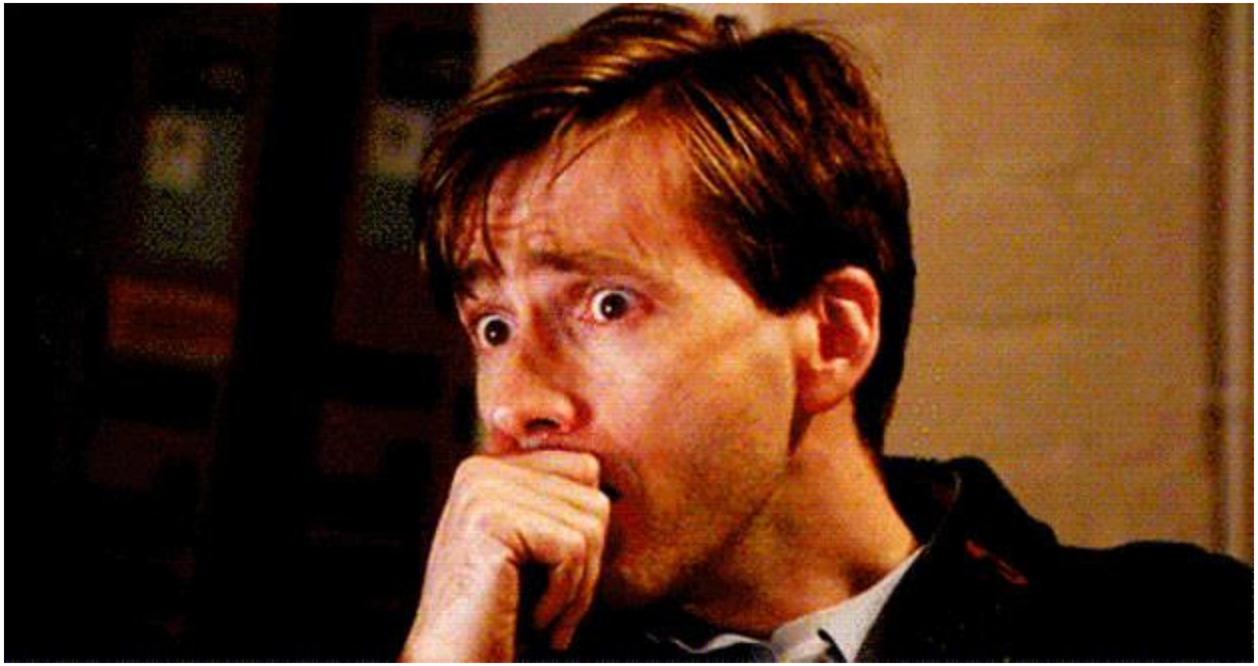
Outcomes following Major Limb Amputation

- Mortality rates post-amputation remain bimodal.
    - For PAD patients, mortality rates are significantly affected by their underlying cardiovascular disease burden.
    - 30-day mortality between 9% and 15%.
- Long-term survival rates deteriorate;
    - **60% at one year.**
    - **42% at three years.**
    - **35% - 45% at five years.**

Surgical Philosophy

- Emergent status.
- Spectrum of disease severity;
  - No tissue loss extending to gross macroscopic destruction.
- Patient co-morbidities.
- Revascularisation possible.
- Rehabilitation potential.

Vascular Amputation – The Horror !!!!



Surgical Considerations

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- Oversize flaps initially then trim and avoid dog-ears.
- Protect good quality skin and cover stump without tension.
- Bone edges should be bevelled and smoothed out.
- Think of stump shape for future prosthetic use.
- Tourniquet usage as per surgeon preference.

Optimisation of Wound Healing

- Appropriate patient work-up including MRSA screening.
- Antibiotic prophylaxis in accordance with local protocols.
- Patient physiology:
  - Normothermia.
  - Maintenance of glucose homeostasis.
- Operative technique:
  - Pre-operative patient washing ??
  - Anatomical marking.
  - Aseptic technique and precise tissue handing.
  - Theatre sterility and laminar air-flow.

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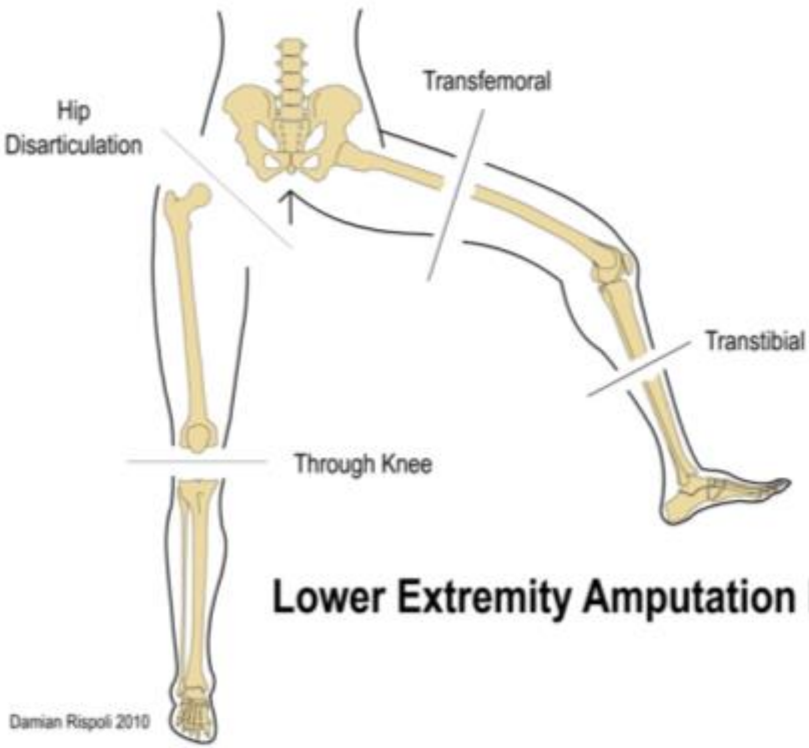
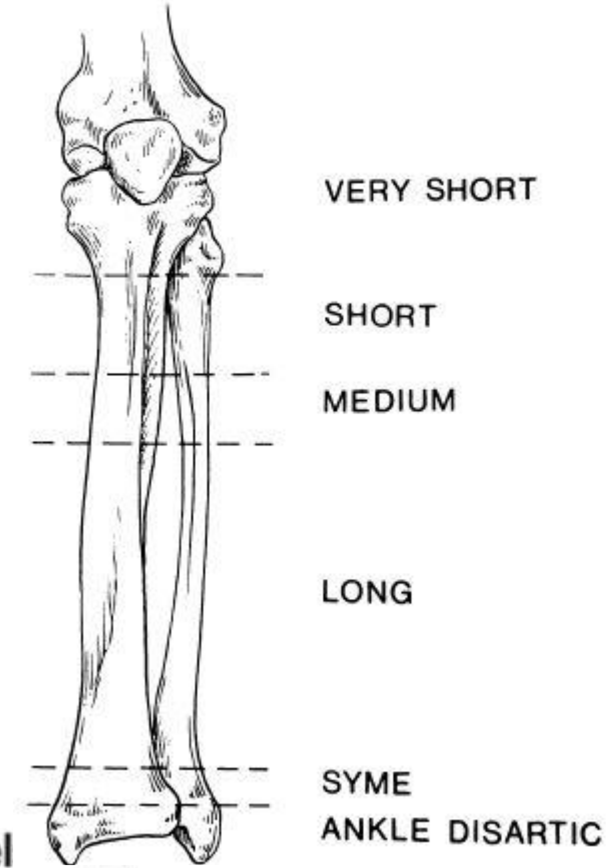
Lower Extremity Amputation Level





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How are we doing ????

ELHT Amputation Annual Case Load

	ELECTIVE	EMERGENCY
2011	64	74
2012	84	57
2013	80	67
2014	83	57
2015	90	76
2016	90	56

ELHT Procedural Specific Case Volume

	Procedural Volume
Above Knee	163
Through Knee	3
Below Knee	136
Transmetatarsal	87
Great Toe	63
Other Toes	156

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National Vascular Registry - MOD

Amputation Procedure

Record Status	Number of Records
All records	58
Submitted records	55
Submitted records with discharge date	55

Time Period: Start 01/01/2012 End (based on discharge date): 08/02/2017 Run

Activity

Procedure Type	Elective	Non-Elective
Above/Thru knee amputation	5	15
Below knee amputation	3	7
Foot amputation	1	6
Toe(s) amputation	4	14
All	13	42

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National Vascular Registry - MOD

Demographics

Variable	All Cases	Cases with Patient Data	Average Age	% Male	% Diabetes
Above/Thru knee amputation	20	20	73.29	75	30
Below knee amputation	10	10	62.54	40	90
Foot amputation	7	7	64.54	100	86
Toe(s) amputation	18	18	73.31	89	89
All	55	55	70.23	76	67

Outcomes

Variable	All Cases	Cases with Outcome Data	Return to theatre	Median LOS	% Referred to rehab/limb fitting *	In Hospital Deaths	Crude Mortality Rate
Above/Thru knee amputation	20	20	0	23	90	2	0.1
Below knee amputation	10	10	0	26	80	2	0.2
Foot amputation	7	7	4	39	100	0	0
Toe(s) amputation	18	18	1	22	44.44	6	0.33
All	55	55	5	25	74.55	10	0.18

*Referred to rehab/limb fitting uses a data item that was introduced in January 2014 and this percentage will be only accurate for tables based on procedures carried out after 01/01/2014.

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UK National Vascular Registry – 2014 to 2015

	Below knee	%	Above knee	%
Procedures	3,190		2,128	
Age group (years)				
Under 60	832	26.2	343	16.1
60 to 64	367	11.5	205	9.6
65 to 69	455	14.3	292	13.7
70 to 74	444	13.9	328	15.4
75 to 79	467	14.6	347	16.3
80 and over	622	19.5	613	28.8
Men	2,367	74.2	1,458	68.5
Women	823	25.8	670	31.5
Smoking				
Current	833	26.2	721	34.0
Ex-	1,548	48.6	1,056	49.8
Never	802	25.2	345	16.3
Presenting problem				
Acute limb ischaemia	313	9.8	481	22.6
Chronic limb ischaemia	596	18.7	481	22.6
Neuropathy	64	2.0	19	0.9
Tissue loss	1,271	39.9	754	35.5
Uncontrolled infection	933	29.3	368	17.3
Aneurysm	50	0.2	24	1.1
Previous ipsilateral limb procedure	2,001	62.8	1,311	61.7

UK National Vascular Registry – 2014 to 2015

	Below knee	%	Above knee	%
Procedures	3,190		2,128	
Age group (years)				
Under 60	832	26.2	343	16.1
60 to 64	367	11.5	205	9.6
65 to 69	455	14.3	292	13.7
70 to 74	444	13.9	328	15.4
75 to 79	467	14.6	347	16.3
80 and over	622	19.5	613	28.8
Men	2,367	74.2	1,458	68.5
Women	823	25.8	670	31.5
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National Vascular Registry – Co-Morbidities

	Below knee	%	Above knee	%
Procedures	3,190		2,127	
ASA grade				
1 Normal	18	0.6	6	0.3
2 Mild disease	404	12.7	133	6.3
3 Severe, not life-threatening	2,222	69.7	1,293	60.8
4-5 Severe, life-threatening, or moribund patient	544	17.0	695	32.7
Comorbidities				
None	263	8.2	210	9.9
Hypertension	1,904	59.7	1,324	62.2
Ischaemic heart disease	1,201	37.7	908	42.7
Diabetes	2,157	67.6	873	41.0
Stroke	297	9.3	322	15.1
Chronic lung disease	444	13.9	551	25.9
Chronic renal disease	709	22.2	398	18.7
Chronic heart failure	268	8.4	230	10.8
Medication				
None	299	9.4	220	10.3
Anti-platelet	2,292	71.9	1,538	72.3
Statin	2,319	72.7	1,496	70.3
Beta blocker	836	26.2	564	26.5
ACE inhibitor/ARB	1,086	34.0	672	31.6

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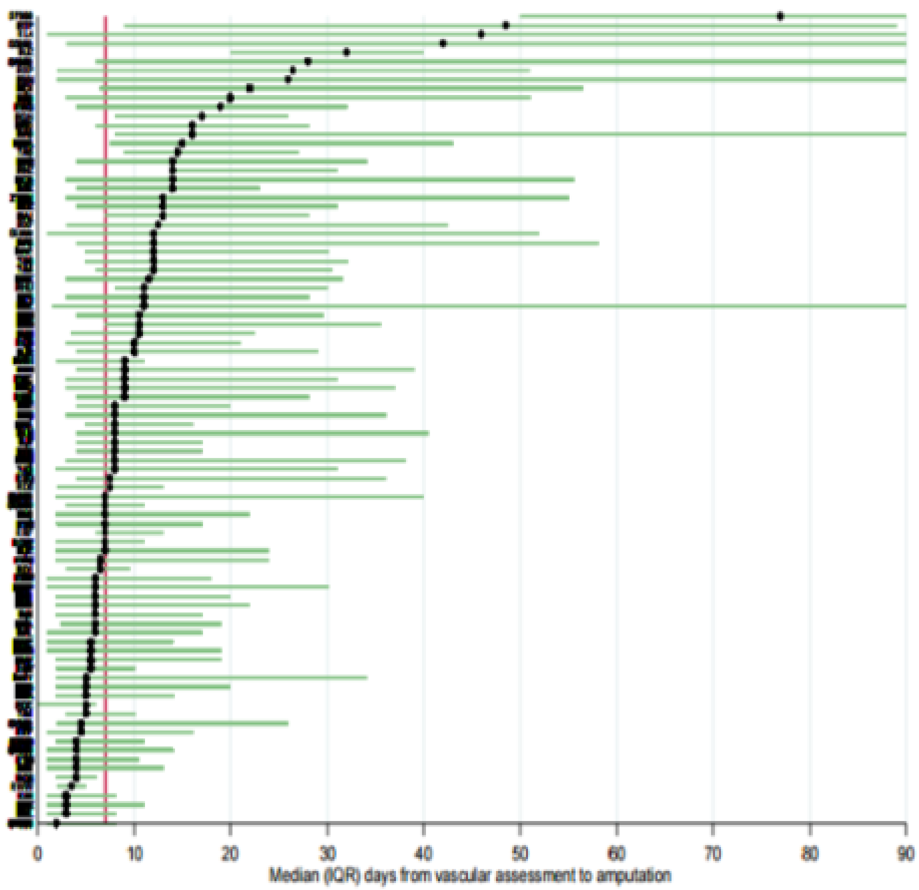
National Vascular Registry – Time to Surgery



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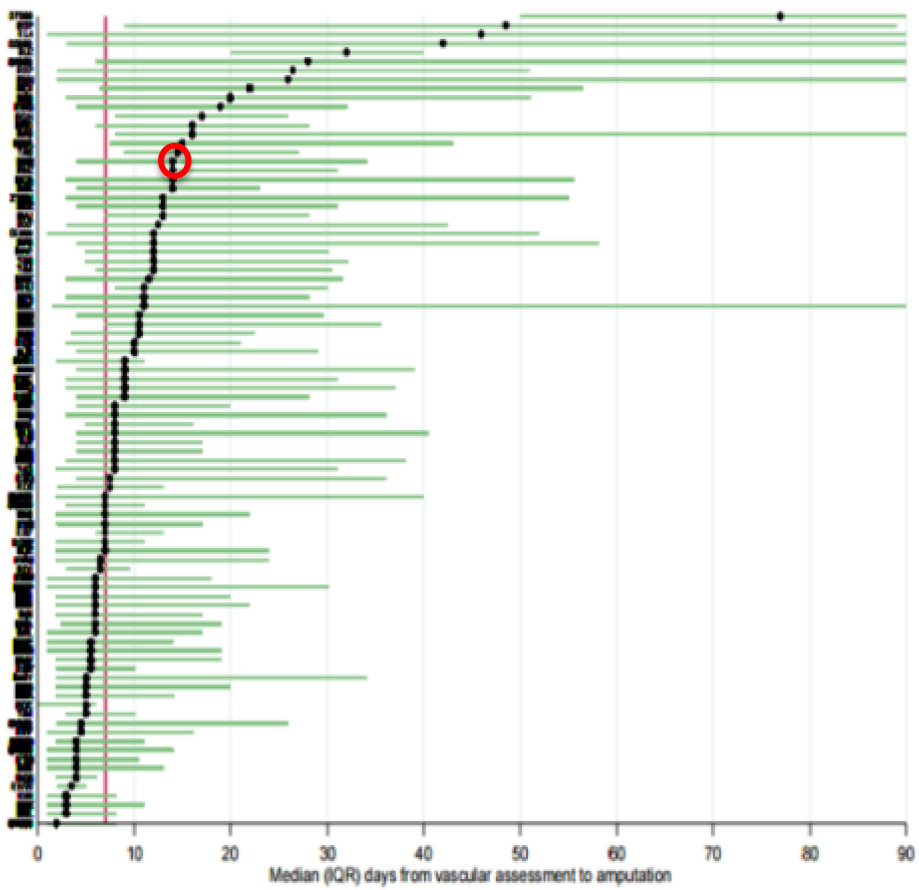
National Vascular Registry – Time to Surgery



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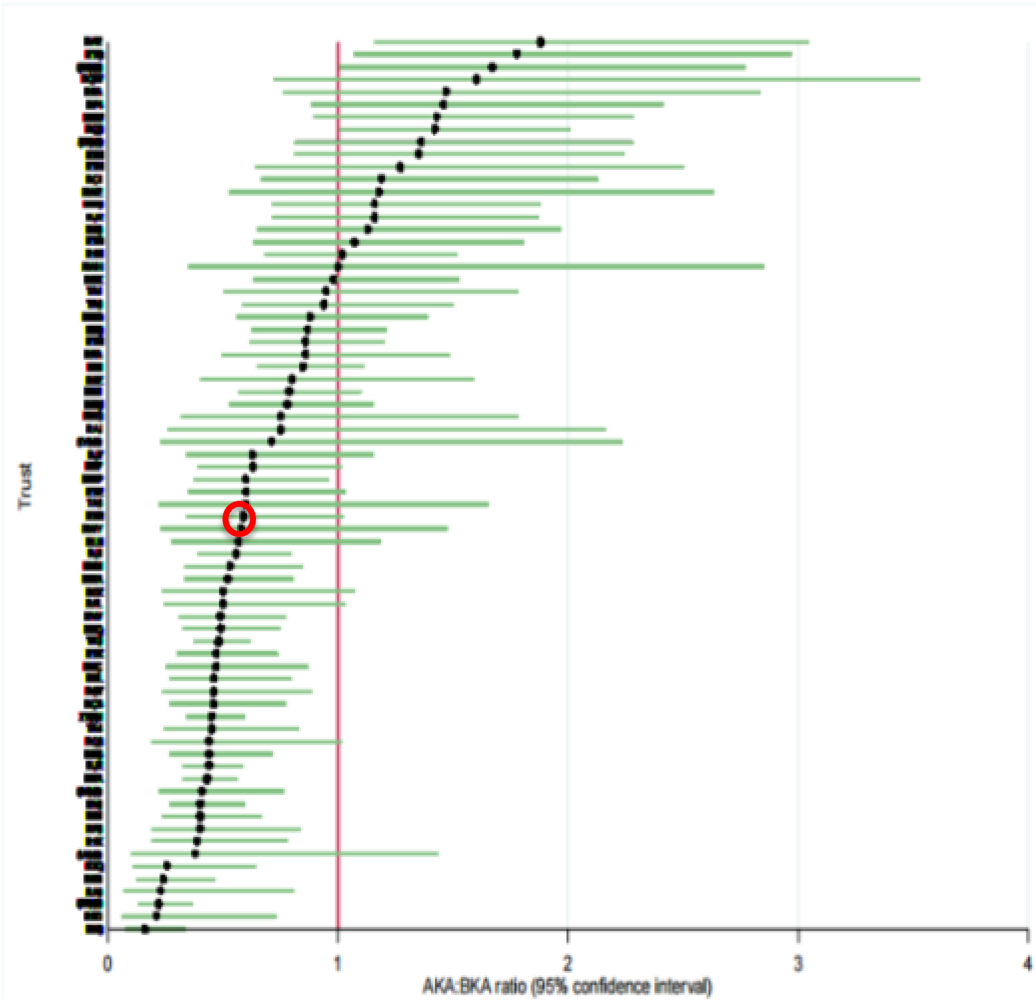
National Vascular Registry – AKA: BKA Ratio



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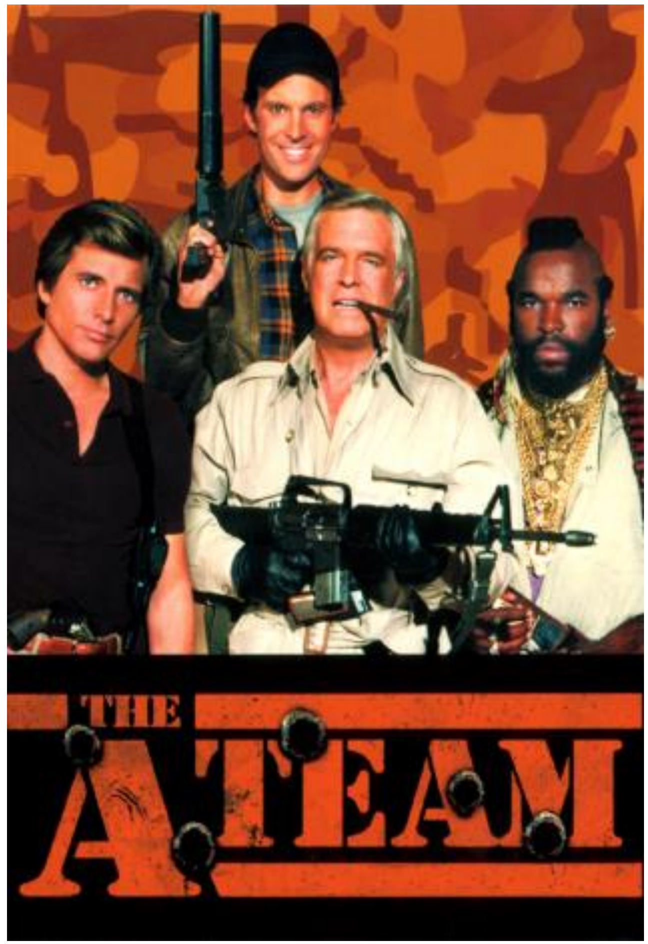
What are we doing about it ????



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Foot nurses at Royal Blackburn Hospital help diabetics

Gill Lomax and Kath Eccles are part of a specialist team

Two nurses at the Royal Blackburn Hospital are helping hundreds of diabetic people stay on their feet.

Kath Eccles and Gill Lomax have helped make the town the area with the lowest level of diabetes-related limb amputation in the UK.

They developed the Blackburn Boot, a padded covering used to protect ulcerated feet and prevent further damage.

Patients credit them with saving not just their legs but their lives.

Diabetics can have neuropathy, where nerves don't feel pain. If the feet then get damaged, from something as simple as a shoe rubbing,

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BBC Health: Diabetes

ELSEWHERE ON THE WEB
Royal Blackburn Hospital

LASER Team Conception

- Multidisciplinary Team Approach.
  - Specialised Vascular Services, NHS England 2014.
- Specialised Care Providers **with Passion**.
- Recognition of Patient Flow.
- Open Communication.
- Ability to influence management quickly.

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LASER Team Recruitment

- Senior Podiatry Staff; Gill Lomax, Carl Kenright and Peter Reston.

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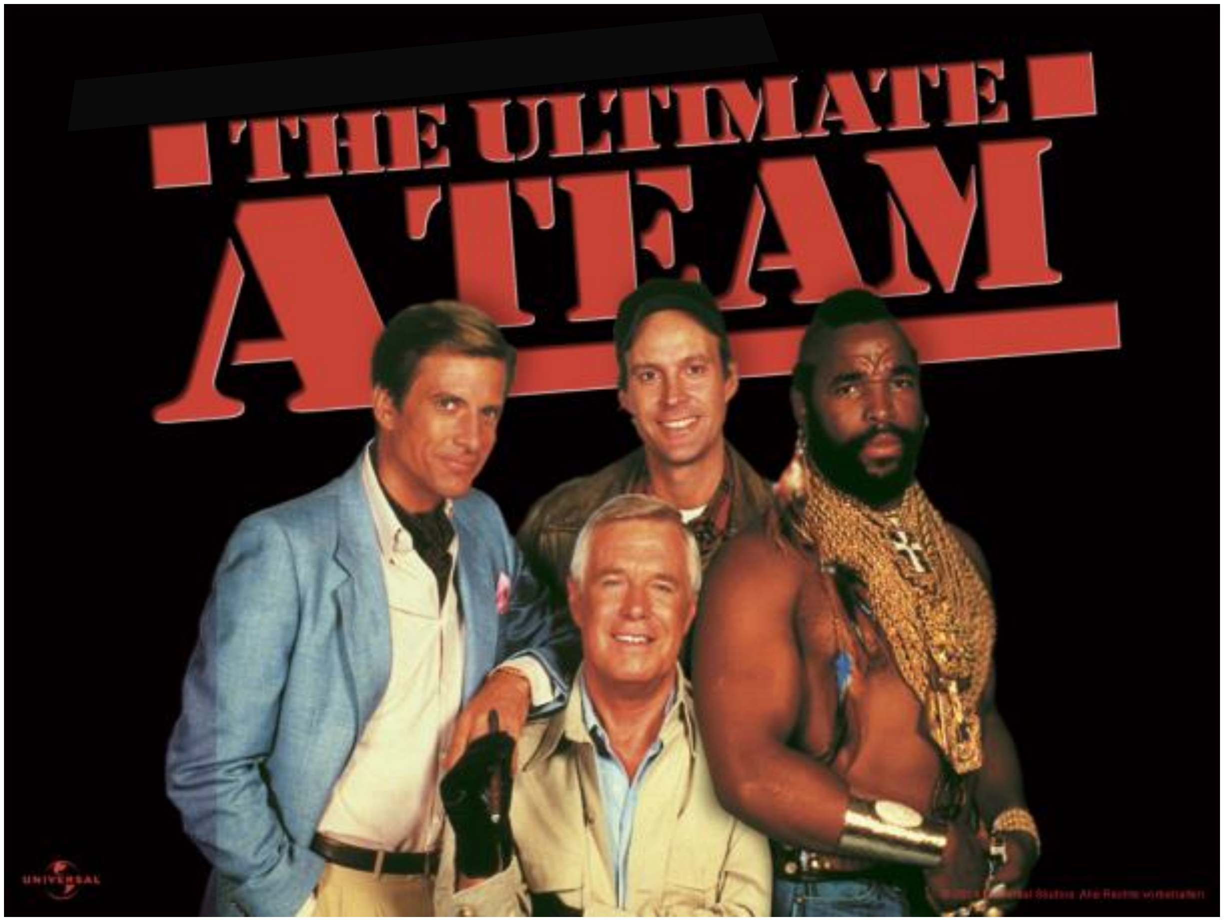
- Orthopaedic Surgeon with a Diabetic Foot Interest; Mr Jim Barrie.
- Vascular Surgeon with an Interest in Limb Salvage; Professor Mark O'Donnell.
- Microbiologist; Dr Ruth White.

LASER Team Evolution

- Microbiology Pharmacist;
  - Ms Jennifer Oakley with Consultant Microbiology support.

- Training / Education;
  - Orthopaedic Specialist Nurses.
  - Endocrinology Trainees.
  - Medical Trainees.
  - Vascular Surgery Trainees.
  - Nursing staff education.


THE ULTIMATE
A TEAM
UNIVERSAL

What do we actually do???

- Patient Identification.
- Prioritisation Logistics.
- Clinical Review at Bedside – NOT AROUND A DESK.
- Expedited Care Management.
- Expert Review.

What do we actually do???

- Patient Identification;
  - Point of contact referral from podiatry / specialist nurse / vascular laboratory.
  - Real-time email correspondence.
  - Ward referral.

What do we actually do???

- Patient Identification.

- Prioritisation Logistics;
  - Most at risk patients.
  - LASER round ward attendance flow.

What do we actually do???

- Patient Identification.
- Prioritisation Logistics.

- Clinical Review;
  - Limb exposure.
  - Diabetic medical review and optimisation of co-morbidities.
  - Orthopaedic clinical and radiological evaluation.
  - Vascular assessment including bedside Doppler.

What do we actually do???

- Patient Identification.
- Prioritisation Logistics.
- Clinical Review.

- Expedited Care Management;
  - Bedside dressing optimisation / wound debridement / offloading.
  - Microbiological sampling – tissue and bone.
  - Pharmacological optimisation.
  - Same day vascular laboratory evaluation.
  - Radiological / surgical intervention within 24 hours.

- Expert Review.

What do we actually do???

- Patient Identification.
- Prioritisation Logistics.
- Clinical Review.
- Expedited Care Management.

- Expert Review;
  - Email summary of decision processes.
  - Vascular MDT discussion.
  - Diabetic / orthopaedic pathway.
  - Diabetic / vascular pathway.
  - Cross-over frequent.

Review of LASER Practice

Patient Demographics and Co-Morbidities

- 127 patients had 198 assessments performed between October 2015 and March 2017;
  - Male=99, Female=28.
  - Mean age 69 (range 36-102) years.
  - Mean LASER assessments 2.25 (range 1 – 5).

- Patient co-morbidities included;
  - Diabetes 93.4% (n=185).
  - Hypertension 56.1% (n=111).
  - Hypercholesterolaemia 22.2% (n=44).
  - Smoking 14.1% (n=28).

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Investigations

- Mean haematological indices included;
  - Haemoglobin 10.9g/L.
  - White cell count 10.8 x10^9/L.
  - Creatinine 122 µmol/L.
  - C-reactive protein 77.5mg/L.

- All patients had a bed-side doppler assessment.

- Formal vascular laboratory testing was completed in 148 assessments (74.7%) with a mean ankle brachial index of 0.59 in the affected limb.

- 26 patients had osteomyelitis diagnosed via Xray with an additional 3 confirmed via MRI (22.8%)

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Treatment

- Medical;
  - All Kardex's were reviewed.
  - Best medical therapy commenced as required.
  - Antibiotic therapy reviewed and rationalised.

Treatment

- A total of 48 revascularisations were performed;
  - Endovascular=39.
  - Surgical endarterectomy / arterial bypass=3.
  - Combined endovascular / surgical=6.

- Wound Care / Amputation;
  - Seven patients had wound debridement alone.
  - Fifty toe amputations.
  - Twelve major limb amputations.
  - Four patients refused treatment.

Patient Outcome

- 37 (29.1%) patients died throughout the study.
- 24 (18.9%) patients were re-operated on, of which 9 (37.5%) had amputation revision to higher level

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LASER Service Conclusions

- Our initial experience has identified an extremely high-risk patient population presenting with advanced diabetic ischaemia pathology.

- A combined multi-disciplinary approach afforded rapid investigation and subsequent therapeutic intervention in 59% of total assessments, suggesting a labour intensive approach is required to limit limb loss and mortality, which still remains high in this patient population.

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Future Aspirations for LASER Team

- Business Plan.
- Increased frequency of service.
- Education.
- Out-patient / Community expansion.

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Future Aspirations for LASER Team

- Business Plan.
- Increased frequency.
- Education.
- Out-patient / Community expansion.

Fewer Amputations.

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Clinical Cases

Case 1

- 69 year old female diabetic presented to hospital podiatry department due to acute deterioration of right foot ulcer over 72-hours.

- Past Medical History:
  - Well controlled diabetes.
  - Smoking.
  - Exercise limited COPD.

- Foot ulcer:
  - Present for six months.
  - Non-resolving despite maximal conservative treatment.

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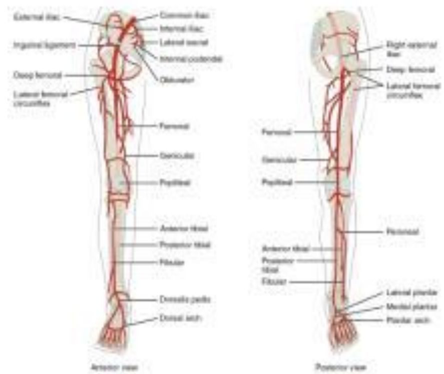
Blood Supply



Septic Load

Blood Supply

- Full history and clinical examination:
  - Capillary return less than 3 seconds.
  - Palpable pulses.
  - Biphasic doppler signals.

Blood Supply

- Full history and clinical examination:
  - Capillary return less than 3 seconds.
  - Palpable pulses.
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- Investigations:
  - Arterial duplex – secondary priority.

Septic Load

- Primary priority:
  - Basic life support measures.
  - Analgesia.
  - Commence appropriate antibiotics – broad spectrum eg. Tazocin and adjust as per later microbiology cultures.

Septic Load

- Primary priority:
  - Basic life support measures.
  - Analgesia.
  - Commence appropriate antibiotics – broad spectrum eg. Tazocin and adjust as per later microbiology cultures.

- Investigations:
  - X-ray.

Action

Action

Outcome

- Unsalvageable.
- Below knee amputation following day after discussion with patient and daughter.

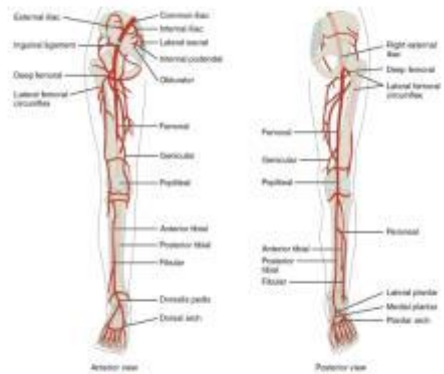
Case 2

- 54 year old female diabetic attends routine podiatry with background foot neuropathy.

- Past Medical History:
  - Non-compliant with all aspects of care.
  - Smoking >40/day.
  - Previous myocardial infarction.

- Foot ulcer:
  - Unsure of duration.
  - Initially refused hospital admission.

Blood Supply



Septic Load

Blood Supply

- Full history and clinical examination:
  - Capillary return poor.
  - Impalpable pulses.
  - Weak monophasic doppler signals.

Blood Supply

- Full history and clinical examination:
  - Capillary return poor.
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- Investigations:
  - Arterial duplex and CT angiogram – within 24-hours.

Blood Supply

- Full history and clinical examination:
  - Capillary return poor.
  - Impalpable pulses.
  - Weak monophasic doppler signals.
- Investigations:
  - Arterial duplex and CT angiogram – within 24-hours.
- Treatment:
  - Contralateral percutaneous access to left femoral artery.
  - Angioplasty and stenting of right common and external iliac artery.

Septic Load

- Protocol based care:
  - Basic life support measures.
  - Analgesia.
  - Commence appropriate antibiotics – broad spectrum eg. Tazocin and adjust as per later microbiology cultures.

Septic Load

- Protocol based care:
  - Basic life support measures.
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- Investigations:
  - X-ray.

Action

- Urgent theatre immediately after angiogram – all under general anaestheisa:
  - Amputation of fifth toe and most of fifth metatarsal.
  - Incision and drainage of plantar abscess.
  - Insertion of yeates drain.
  - Intravenous antibiotics.

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Action

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  - Amputation of fifth toe and most of fifth metatarsal.
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- Prolonged in-patient hospital stay.
  - Larval therapy.
  - Application of negative pressure dressings.
  - Discharged week-10.

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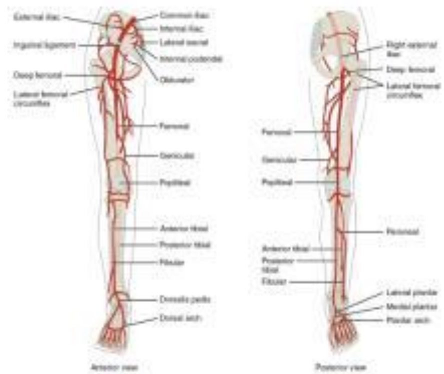
Case 3

- 59 year old male non-diabetic transferred emergently from long-term psychiatry care with severe sepsis left foot.

- Past Medical History:
  - Long-term schizophrenia.
  - Newly diagnosed diabetes.
  - No cardiovascular risk factors.

- Foot ulcer:
  - Horrific – refused examination and theatre on arrival to hospital.
  - Patient advocates / safeguarding team involved.

Blood Supply



Septic Load

Blood Supply

- Full history and clinical examination:
  - Capillary return poor.
  - Palpable posterior tibial pulse.
  - Biphasic PT doppler signals.

Blood Supply

- Full history and clinical examination:
  - Capillary return poor.
  - Palpable posterior tibial pulse.
  - Biphasic PT doppler signals.

- Investigations:
  - Arterial duplex – patent flow.
  - CT angiogram – no evidence of any stenotic lesion.

Septic Load

- Primary priority:
  - Basic life support measures.
  - Analgesia.
  - Commence appropriate antibiotics – broad spectrum eg. Tazocin and adjust as per later microbiology cultures.

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- Investigations:
  - X-ray.

Action

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Action

- Arduous recovery – patient never acknowledged diabetes or foot problem.
- Topical negative pressure dressings.
- Cast immobilisation.
- Gradual onset equinovarus deformity.

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Action

- Arduous recovery – patient never acknowledged diabetes or foot problem.
- Topical negative pressure dressings.
- Cast immobilisation.
- Gradual onset equinovarus deformity.

- One-year later:
  - Still not healed.
  - Never re-gained mobility.
  - Still resides in secure care facility.

Summary

- Global patient evaluation.
- Examination and investigation of the “At-Risk” limb.
- Treatment strategies for limb salvage.
- Specialist unit-based outcomes and multi-disciplinary team approaches to excellence in patient care.
- High risk clinical case reviews.

Questions ?