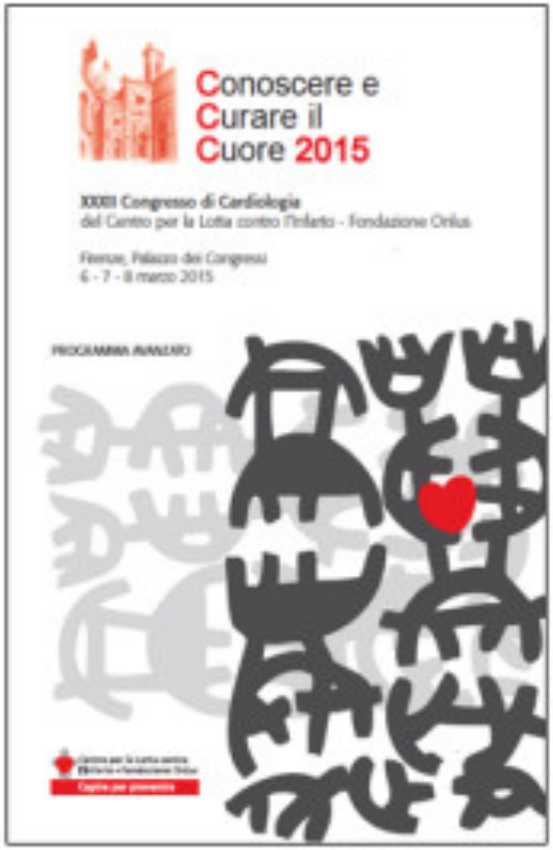
Conoscere e Curare il Cuore 2015

IL SALVATAGGIO DEL PIEDE DIABETICO

Luca Dalla Paola

Chief Diabetic Foot Unit
Visiting Professor Harvard Medical School
Maria Cecilia Hospital
GVM Care & Research



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www.piedediabetico.eu

DIABETES: ONE OF THE MOST CHALLENGING HEALTH PROBLEMS IN THE 21ST CENTURY

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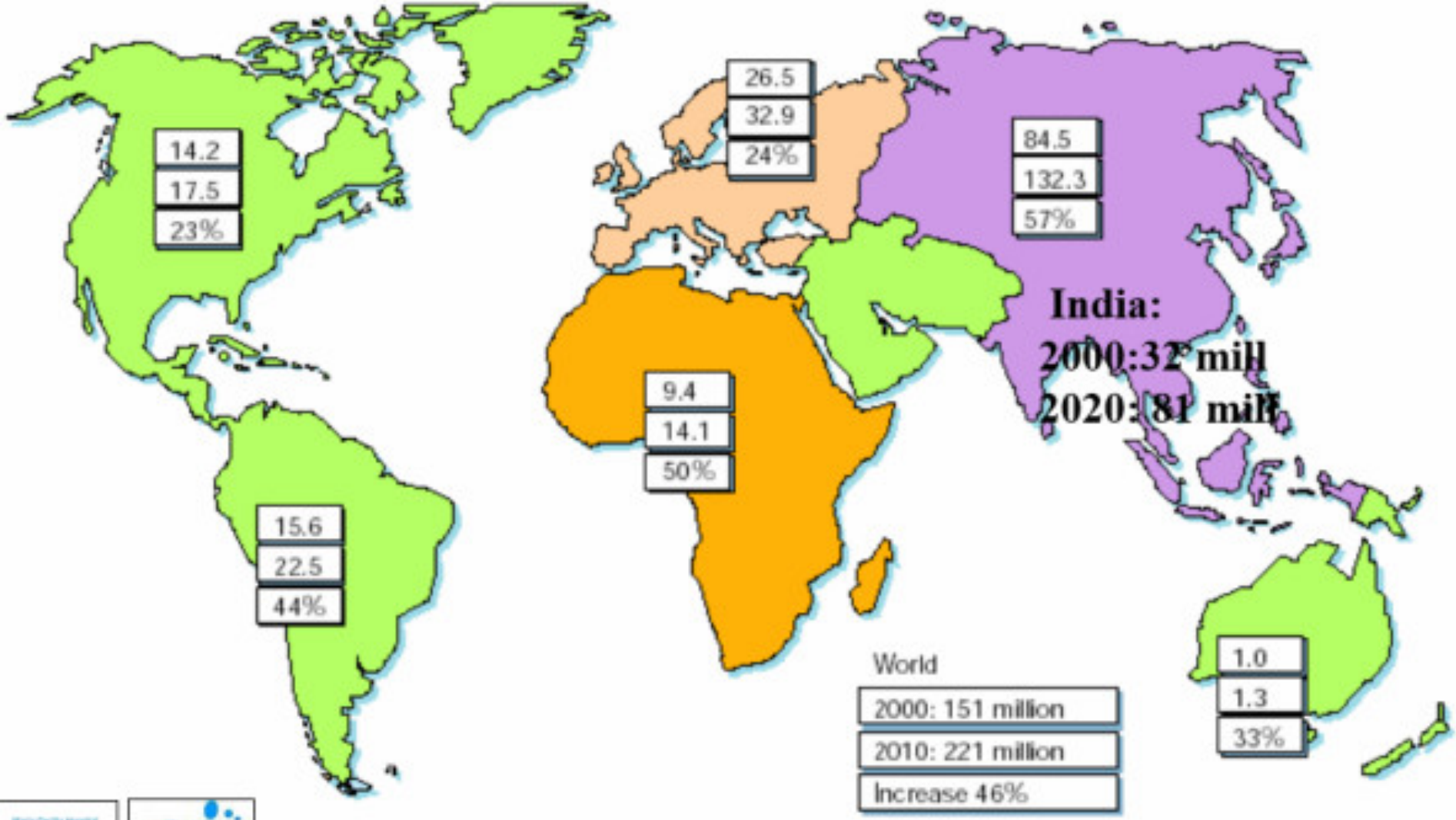
World wide epidemic



EPIDEMIOLOGY

- The Diabetic foot constitutes a tremendous challenge for patients, caregivers and health care systems
- The diabetic foot treatment expenses absorb about 40% of overall hospital budget for diabetes
- During their lifetime one in seven diabetic patients develops foot ulcers which are highly susceptible to infection
- 85% of amputations are preceeded by an ulcer
- 15-46 fold higher lower limb amputation risk in diabetic population in comparison with general population

Lavery L.A. et al., Diabetes Care, 19:48, 1996

PAPER

Major Lower Extremity Amputation

Outcome of a Modern Series

Bernadette Aulivola, MD; Chantel N. Hile, MD; Allen D. Hamdan, MD; Malachi G. Sheahan, MD; Jennifer R. Veraldi, BA; John J. Skillman, MD; David R. Campbell, MD; Sherry D. Scovell, MD; Frank W. LoGerfo, MD; Frank R. Pomposelli, Jr, MD

Arch Surg. 2004;139:395-399

- An amputation increases the risk of subsequent LLA and mortality of patients
- Mortality within the first month after LLA is 8.5% of patients and in 5 years period reaches 68%
- Complications of cardiac nature, such as miocardial infarction, arrhytmias and congestive heart failure were the most common and were documented in 25.8% of cases

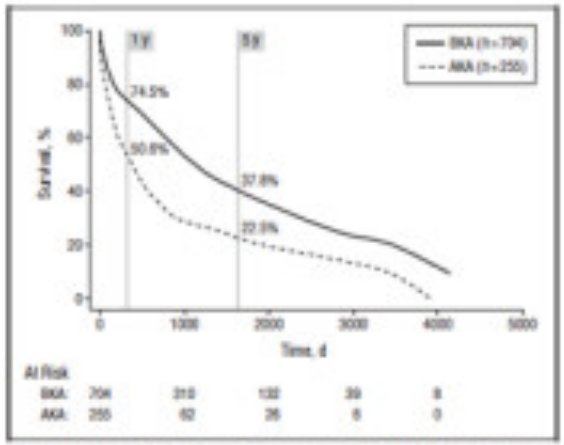


Figure 1. Actuarial survival in below-knee amputation (BKA) patients vs above-knee amputation (AKA) patients ($P<.001$).

The main action in reducing social and economic costs in diabetic foot management should be reduction of major amputations

Apelqvist J.

***Clin Podiatr Med Surg*.1998 Jan; 15(1):21-39**

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PLOS | ONE

Lower Extremity Amputations in Persons with and without Diabetes in Italy: 2001–2010

Flavia L. Lombardo[1], Marina Maggini[1], Alessandra De Bellis[2], Giuseppe Seghieri[2], Roberto Anichini[2]*

1 National Centre for Epidemiology, Surveillance and Health Promotion, National Institute of Health, Roma, Italy, 2 Diabetes Unit and Diabetic Foot Unit, Department of Internal Medicine General Hospital Pistoia, Pistoia, Italy

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Table 1. Rate of amputees (top) and hospitalization for amputation (bottom) in persons with and without diabetes, Italy 2010.

	With diabetes	Without diabetes
Amputees		
Number	7,373	4,922
Crude amputee rate (per 100,000)^	247.2	8.6
Male to female rate ratio	2.7	1.6
Age* (mean±sd)	71.1±11.1	73.2±17.9
Hospitalizations for LEAs		
Number[§]	8,857	5,339
Crude hosp. rate (per 100,000)^	297.0	9.3
Minor to major ratio	2.5	1.0

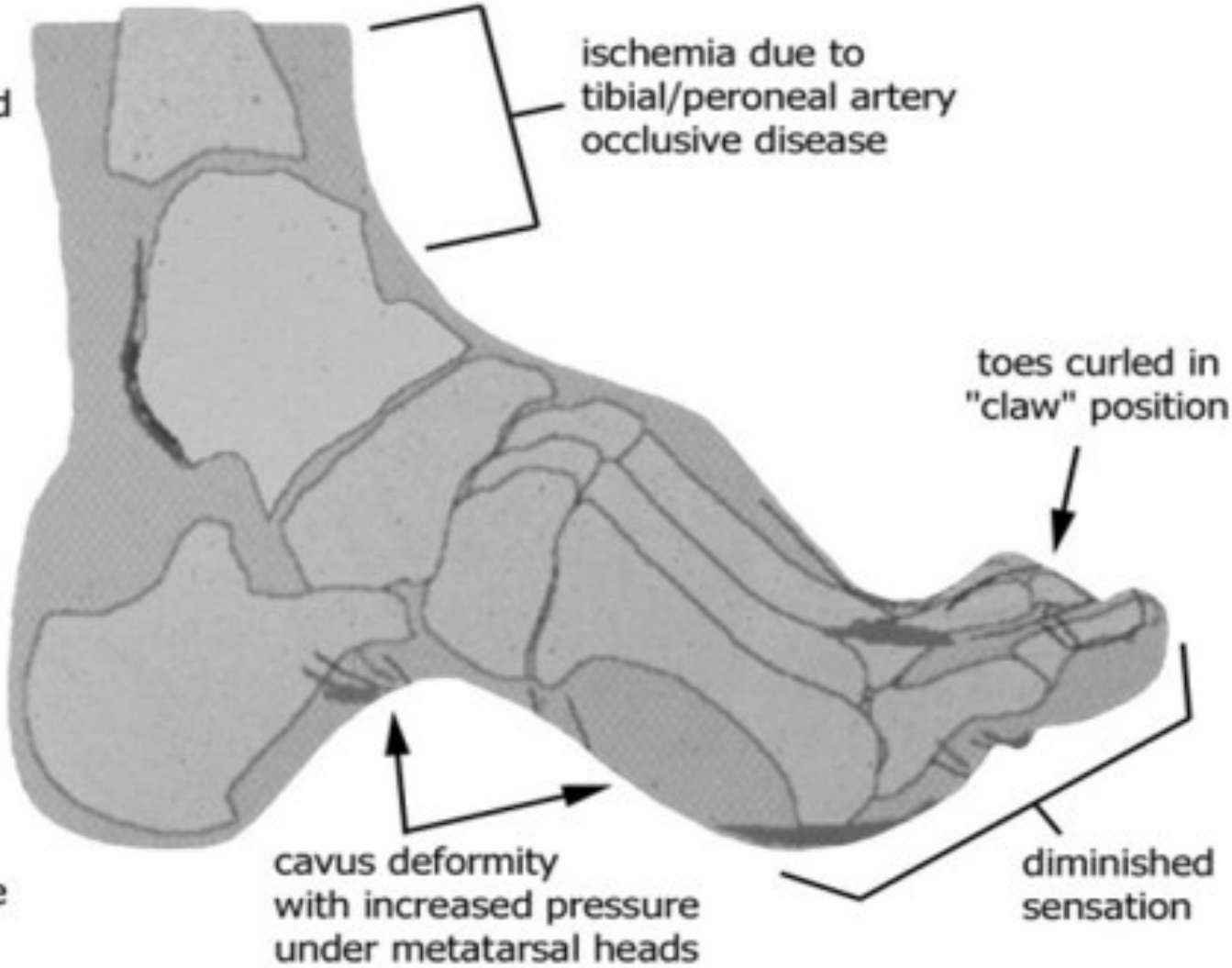
[§]All discharges for amputation (i.e. major, minor and not specified level).
^Rates are expressed per 100,000 000 persons with and without diabetes respectively.
*Age at first amputation.

DIABETIC NEUROPATHY

"PAIN-God's greatest gift to mankind"

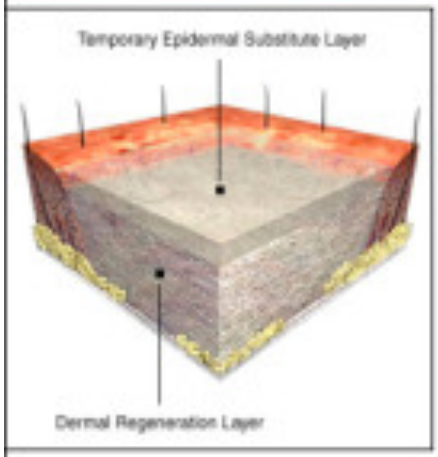
Paul Brand

- Microneurovascular dysfunction with loss of nociceptive reflex and inflammatory response
- Vasomotor dysfunction with AV shunting
- Capillary basement membrane thickening with altered capillary exchange
- Glycosylation of matrix proteins
- Loss of apocrine/eccrine gland function



Marta Cecilia Hospital
Cartagena

GVM


Temporary Epidermal Substitute Layer
Dermal Regeneration Layer

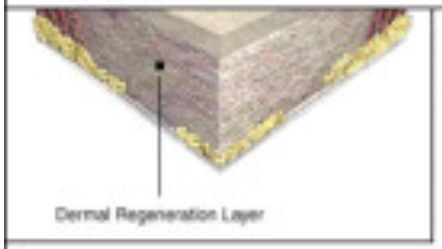
SOCIETY FOR VASCULAR SURGERY® DOCUMENT

The role of interdisciplinary team approach in the management of the diabetic foot

A Joint Statement from the Society for Vascular Surgery and the American Podiatric Medical Association

Bauer E. Sumpio, MD, PhD,[a] David G. Armstrong, DPM, PhD,[b] Lawrence A. Lavery, DPM, MPH,[c] and George Andros, MD[d] (the SVS/APMA writing group), *New Haven, Conn; Tucson, Ariz; Dallas, Tex; and Van Nuys, Calif*

The Society for Vascular Surgery (SVS) and the American Podiatric Medical Association (APMA) recognize the beneficial impact of a multidisciplinary team approach on the care of patients with critical limb ischemia, especially in the diabetic population. As a first step in identifying clinical issues and questions important to both memberships, and to work together to find solutions that will benefit the shared patient, the two organizations appointed a representative group to write a joint statement on the importance of multidisciplinary team approach to the care of the diabetic foot. (J Vasc Surg 2010;51:1504-6.)



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The costs of diabetic foot: The economic case for the limb salvage team

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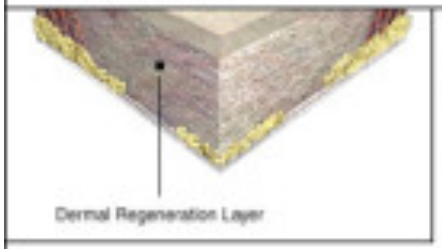
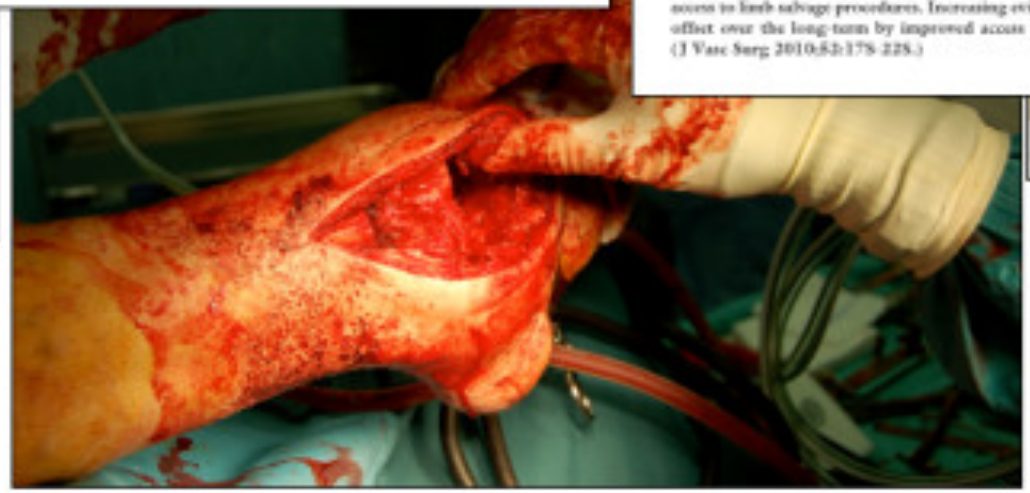
Background: In 2007, the treatment of diabetes and its complications in the United States generated at least $116 billion in direct costs; at least 33% of these costs were linked to the treatment of foot ulcers. Although the team approach to diabetic foot problems is effective in preventing lower extremity amputations, the costs associated with implementing a diabetic foot care team are not well understood. An analysis of these costs provides the basis for this report.

Results: Diabetic foot problems impose a major economic burden, and costs increase disproportionately to the severity of the condition. Compared with diabetic patients without foot ulcers, the cost of care for patients with a foot ulcer is 5.4 times higher in the year after the first ulcer episode and 2.8 times higher in the second year. Costs for the treatment of the highest-grade ulcers are 8 times higher than for treating low-grade ulcers. Patients with diabetic foot ulcers require more frequent emergency department visits, are more commonly admitted to hospital, and require longer length of stays. Implementation of the team approach to manage diabetic foot ulcers within a given region or health care system has been reported to reduce long-term amputation rates from 82% to 62%. Limb salvage efforts may include aggressive therapy, such as revascularization procedures and advanced wound healing modalities. Although these procedures are costly, the team approach gradually leads to improved screening and prevention programs and earlier interventions, and thus seems to reduce long-term costs.

Conclusions: To date, aggressive limb preservation management for patients with diabetic foot ulcers has not usually been paired with adequate reimbursement. It is essential to direct efforts in patient-caregiver education to allow early recognition and management of all diabetic foot problems and to build integrated pathways of care that facilitate timely access to limb salvage procedures. Increasing evidence suggests that the costs for implementing diabetic foot teams can be offset over the long-term by improved access to care and reductions in foot complications and in amputation rates. (J Vasc Surg 2010;52:178-228.)





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Team Approach Toward Lower Extremity Amputation Prevention In Diabetes

ROBERT G. FRYKBERG, DPM, MPH*

Through a discussion of the etiology and pathology of diabetic foot lesions with particular emphasis on ulceration and osteoarthropathy, the author will develop a plan for treatment and prevention using a multidisciplinary approach to such problems. Underlying risk factors including neuropathy, ischemia, infection, and, especially high pressures must be evaluated and appropriately ameliorated in order to promote resolution and avoidance of recidivism. Accordingly, conservative management with pressure-relieving devices, topical therapies, and prophylactic surgery on structural deformities plays an integral part in the overall podiatric management of the high-risk foot in diabetes mellitus.

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ADVANCES IN THE MANAGEMENT OF CRITICAL LIMB ISCHEMIA

J CARDIOVASC SURG 2012;53:605-16

Body of knowledge around the diabetic foot and limb salvage

M. EDMONDS

Diabetic Foot Clinic
King's College Hospital, London, UK

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Current Diabetes Reviews, 2006, 2, 431-447 431

Treatment of Diabetic Foot Ulcer: An Overview Strategies for Clinical Approach

Luca Dalla Paola* and Ezio Faglia†

**Diabetic Foot Department, Foot & Ankle Clinic, Leonardo Foundation, Abano Terme Hospital, Padova, Italy*
†Diabetic Foot Unit- IRCCS Multimedica, Sesto San Giovanni, Milan, Italy

Abstract: Diabetic foot disease is a major health problem, which concerns 15% of the 200 million patients with diabetes worldwide. Major amputation, above or below the knee, is a feared complication of diabetes. More than 60% of non-traumatic amputations in the western world are performed in the diabetic population. Many patients who undergo an amputation, have a history of ulceration. Major amputations increase morbidity and mortality and reduce the patient's quality of life. Treatment of foot complications is one of the main items in the absorption of economic and health resources addressed to the diabetic population. It is clear that effective treatment can bring about a reduction in the number of major amputations.

Over recent years, we have seen a significant increase in knowledge about the physiopathological pathways of this complication, together with improvements in diagnostic techniques, but above all a standardized conservative therapeutic approach, which allows limb salvage in a high percentage of cases. This target has been achieved in specialized centers.

An important prelude to diabetic foot treatment is the differing diagnosis of neuropathic and neuroischemic foot. This differentiation is essential for effective treatment.

Ulceration in neuropathic foot is due to biomechanical stress and high pressure, which involves the plantar surface of toes and metatarsal heads. Treatment of a neuropathic plantar ulcer must correct pathological plantar pressures through weight bearing relief. Surgical treatment of deformities, with or without ulcerations, is effective therapy. A neuropathic ulcer that is not adequately treated can become a chronic ulcer that does not heal. An ulcer that does not heal for many months has a high probability of leading to osteomyelitis, for which treatment with antibiotics is not useful and which usually requires a surgical procedure. Charcot neuroarthropathy is a particular complication of neuropathy which may lead to fragmentation or destruction of joints and bones. A well-timed diagnosis of Charcot neuroartropathy is essential to avoid deformities of chronic evolution.

In the diabetic population peripheral vascular disease (PVD) is the main risk factor for amputation. If peripheral vascular disease is ignored, surgical treatment of the lesion cannot be successful. In diabetic patients, PVD is especially distal, but often fully involves the femoral, popliteal and tibial vessels. It can be successfully treated with either open surgical or endovascular procedures.

Infection is a serious complication of diabetic foot, especially when neuroischemic: phlegmon or necrotizing fasciitis are not only limb-threatening problems, but also life-threatening ones. In this case, emergency surgery is needed.

Primary and secondary prevention of foot ulceration is the main target. Prevention programs must be carried out to highlight risk factors, lowering amputation incidence.

Keywords: Diabetic foot, Amputation, Diabetic ulceration, Critical limb ischemia, Diabetic foot surgery, Revascularization.

INTRODUCTION

Diabetic foot must be considered a syndrome. Two aspects are recognised: neuropathic foot and neuroischemic foot [1]. Both entities have different pathophysiological moments, diagnostic-therapeutic phases and outcomes. These two distinct entities involve two time-frames, justifying a methodologically integrated but essentially different approach. In 1990, Pecoraro outlined the pathways that take a diabetic subject with neuropathic and ischemic complications through the chain of defined events to develop an infective progression that consequently leads to an elevated risk of having to undergo amputation [2]. It is useful to clarify the importance of defining essential steps in diagnostic and therapeutic strategies when treating diabetic foot aimed at saving the limb. It is only by recognising the factors capable of negatively influencing prognosis and correcting them (e.g. critical ischemia and revascularization, osteomyelitis and its surgical treatment, compartmental syndrome, emergency surgery) that we can reduce the number of amputations in the target diabetic population. The objective of this review is therefore to define therapeutic strategies in the various types of diabetic foot syndrome.

Various classification systems have been proposed to classify diabetic foot ulcers. The most popular classification systems have long been the Wagner and Texas University Classifications [3,4].

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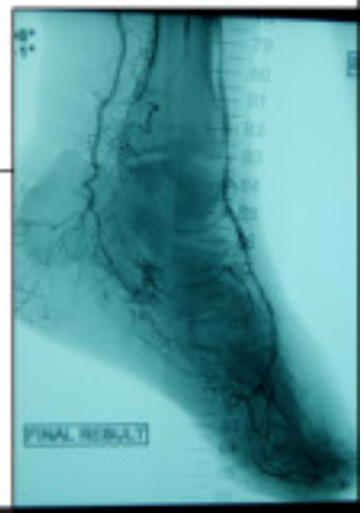
Keypoints for avoiding amputations

- Relief of plantar pressure in the treatment of neuropathic plantar ulcer
- Revascularisation procedures
- Emergent treatment of acute diabetic foot
- Surgery of the chronic diabetic foot
- **New options**



Dalla Paola L., Faglia E.
Curr Diabetes Rev 2006 Nov; 2(4): 431-47

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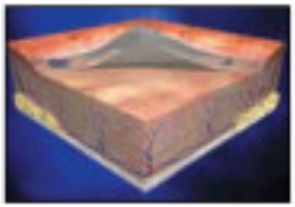
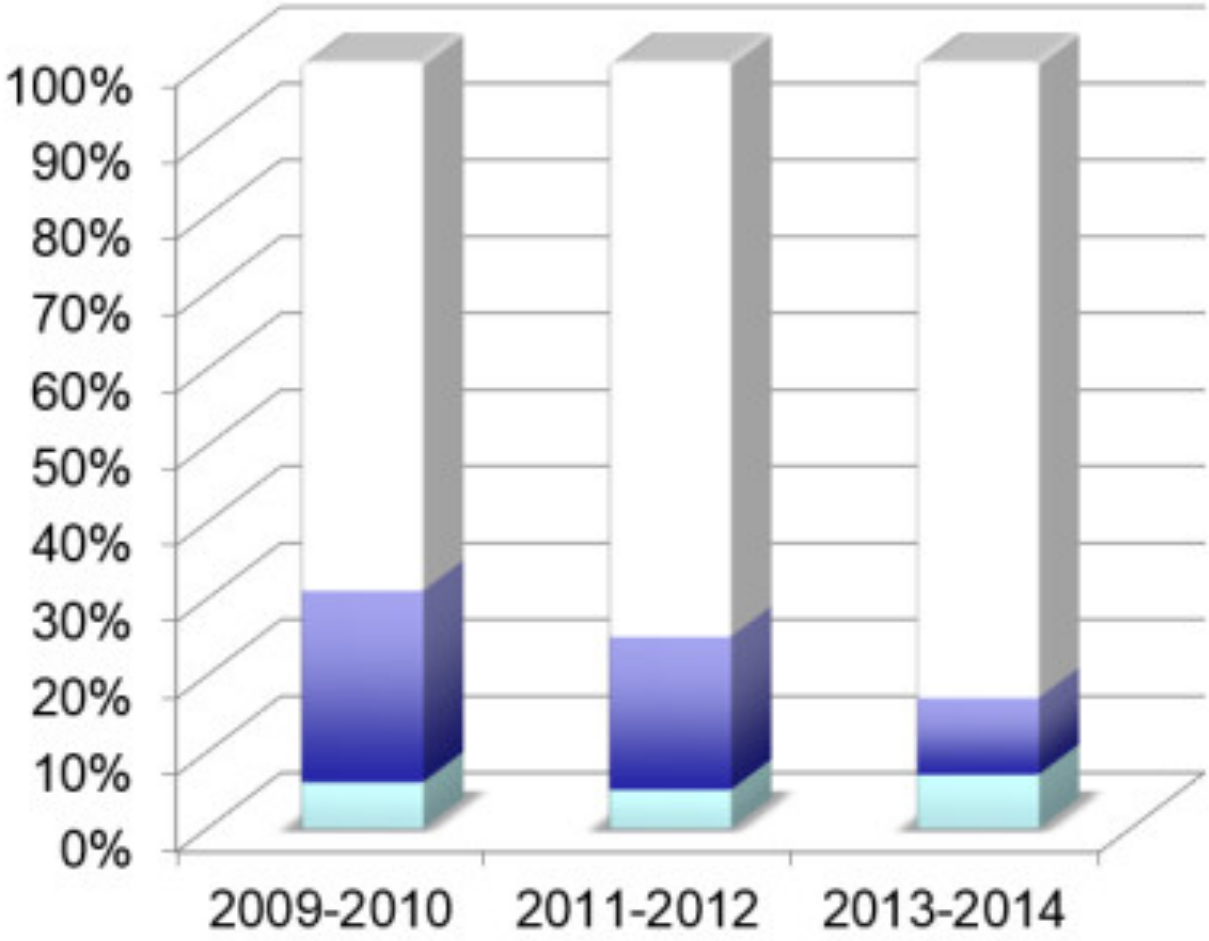
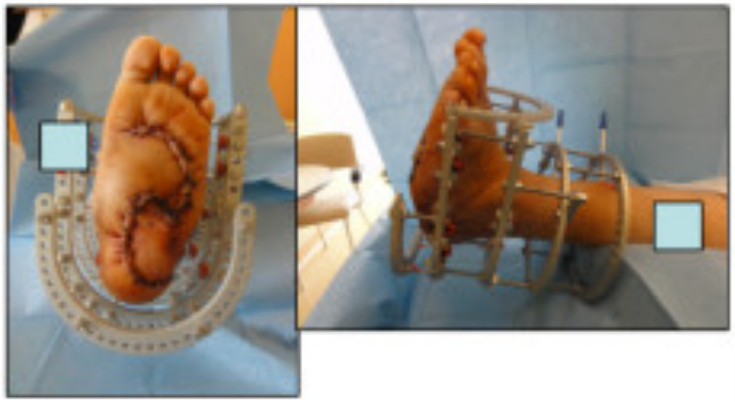
New tools

- **New antiseptic agents**
- **hydroknives**
- **New debridement devices**
- **NPWT with instillation**
- **Bioengineered tissues**
- **Ex Fix**



TREND OF AMPUTATION IN DFU MCH





TOE/RAY/CONSERV
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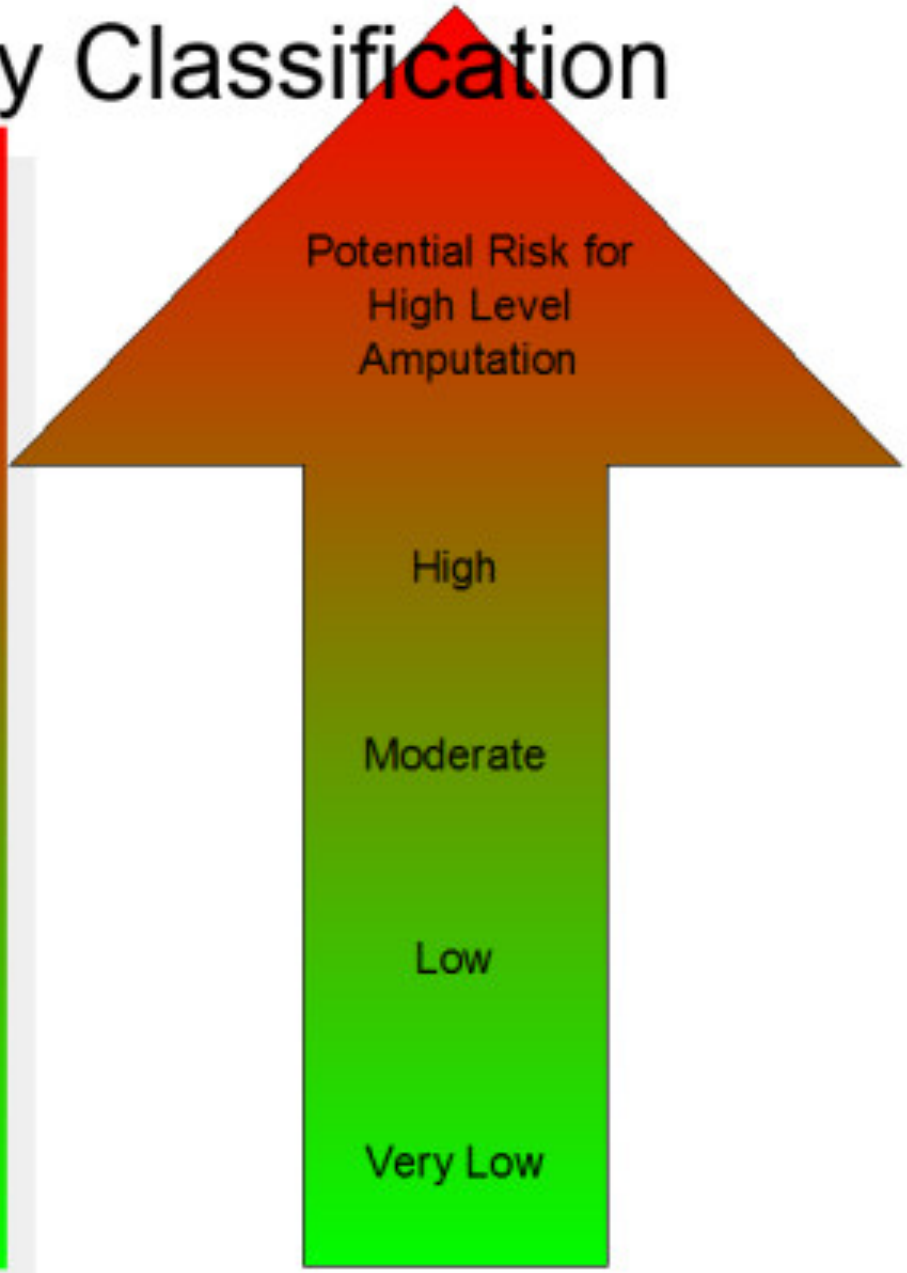
Diabetic Foot Surgery Classification

Diabetic Foot Surgery Class	Description
Class IV: Emergent	Procedure performed to limit progression of acute infection
Class III: Curative	Procedure performed to assist in healing open wound
Class II: Prophylactic	Procedure performed to reduce risk of ulceration or reulceration in person with loss of protective sensation but without open wound
Class I: Elective	Procedure performed to alleviate pain or limitation of motion in a person without loss of protective sensation



Armstrong, Frykberg, Diabetic Medicine, 2003

emergent surgery

curative surgery

Maria Cecilia Hospital
Cotignola

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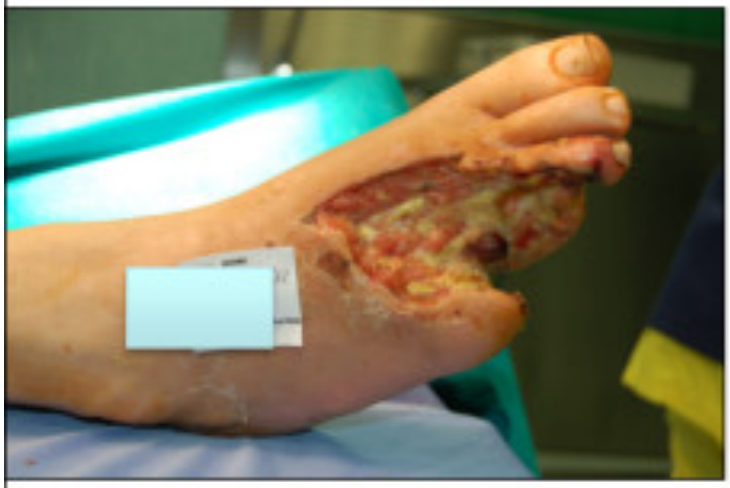
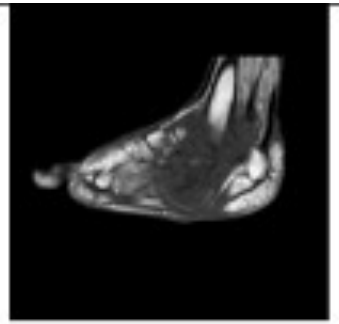


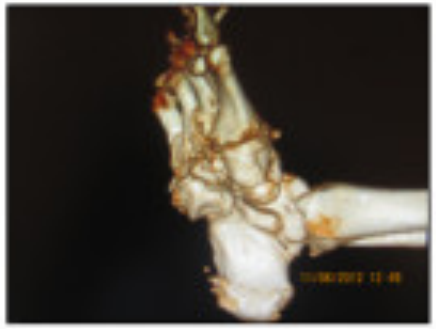
Reconstructive surgery

Maria Cecilia Hospital
Cotignola

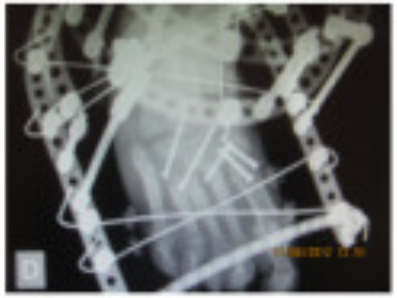
GVM



Charcot surgery



Charcot surgery



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Review

Confronting a Dramatic Situation: The Charcot Foot Complicated by Osteomyelitis

The International Journal of Lower Extremity Wounds
1–16

DOI: 10.1177/1534734614545875
ijlw.sagepub.com
SAGE

Luca Dalla Paola, MD[1]

Abstract
Charcot osteoarthropathy is a serious complication of diabetic neuropathy. Its prevalence in the diabetic population varies in the literature in relation to certain variables, such as the method of assessment, clinical or instrumental; the population studied; and the scope of the selection. This article is intended as a review of the recent literature concerning Charcot osteoarthropathy in its evolution and complications characterized by the development of ulceration and subsequent bone infection. Diagnosis and treatment strategies—either medical or surgical—are discussed both for Charcot arthropathy and osteomyelitis.

- **DIABETIC FOOT SURGERY IS A COMPLEX TREATMENT PROJECT THAT OFTEN NEEDS MORE THAN 2 OR 3 PROCEDURES TO OBTAIN LIMB SALVAGE**

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CASE 2
Male 42 yrs old
Wet gangrene 4th left ray
Necrotizing fascitis of the leg
CLI (PTA BTK of posterior and anterior tibial artery)
MRSA Serratia
PCI Cdx

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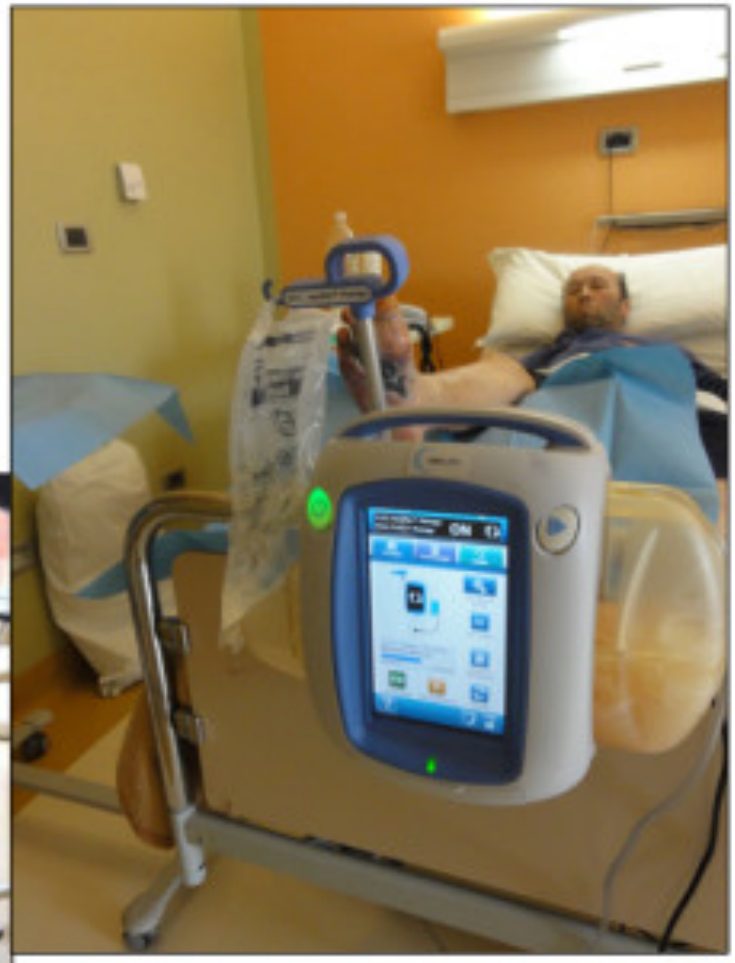

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Vascular Approach to Diabetic Foot Lesions

1967

Death of

" small vessel disease in diabetic patients"

(by Margaret C. Conrad Ph.D)

MEDICAL INTELLIGENCE

CURRENT CONCEPTS

VASCULAR AND MICROVASCULAR DISEASE OF THE FOOT IN DIABETES

Implications for Foot Care

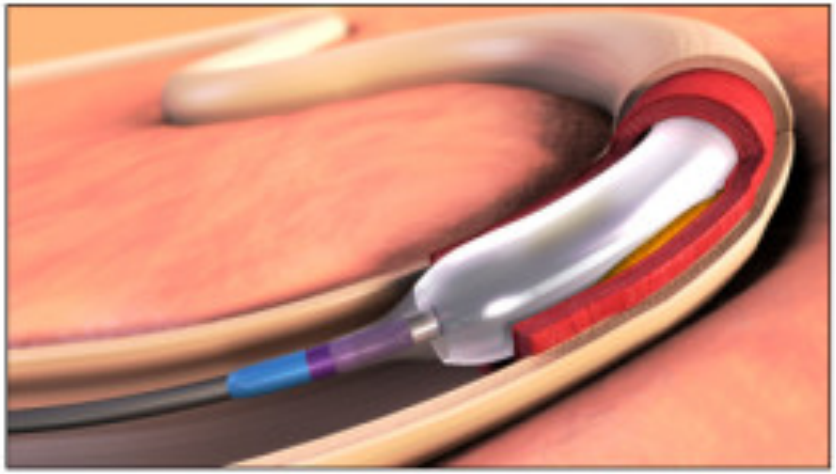
FRANK W. LOGERFO, M.D., AND JAY D. COFFMAN, M.D.

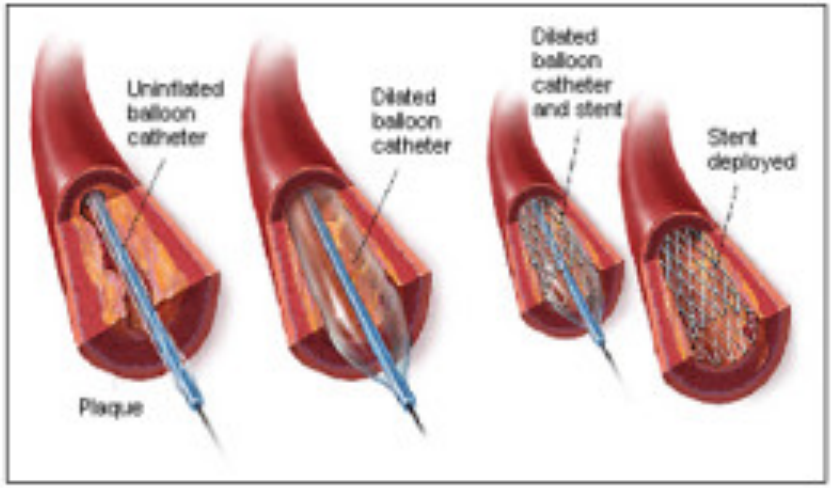
Frank W. LoGerfo 1984

"When atherosclerosis occurs the in lower extremities of patients with diabetes mellitus, it is most common in the femoropopliteal segment, as it is also in nondiabetic patients"

"..in diabetic patients there is a high propensity toward atherosclerotic occlusion of the tibial and peroneal arteries…"

New England Journal of Medicine 1984




Uninflated balloon catheter
Dilated balloon catheter
Dilated balloon catheter and stent
Stent deployed
Plaque

WHY VASCULAR SPECIALIST NEEDS TO RECOGNIZE ACUTE DIABETIC FEET

- Patient is at high risk for limb or life loss
- Revascularization must be postponed and the patient has to be treated with emergent surgical debridement
- Controlling the infection allows to improve local microcirculation and macrocirculation
- Revascularization without infection control does not control the risk of amputation

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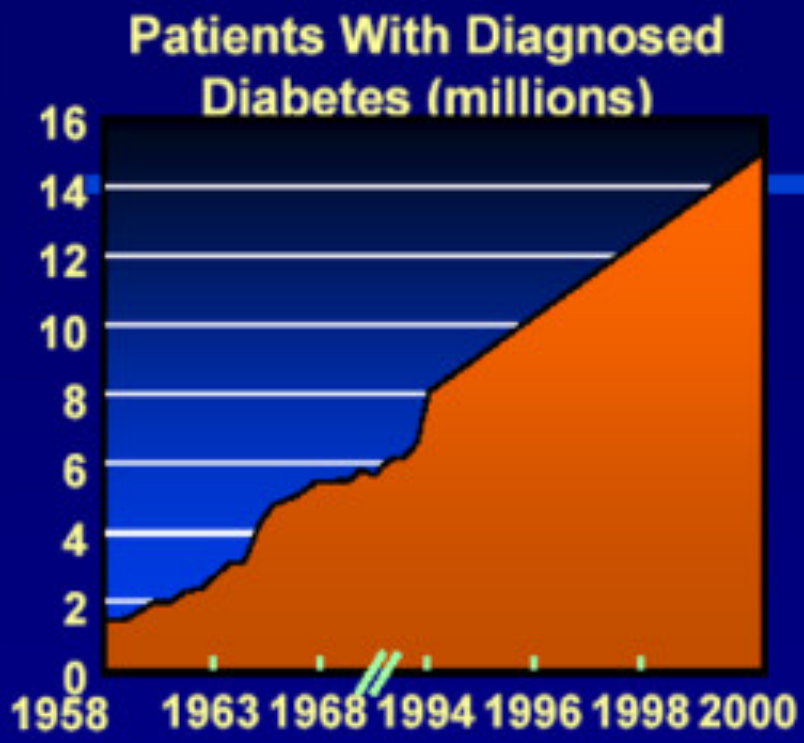
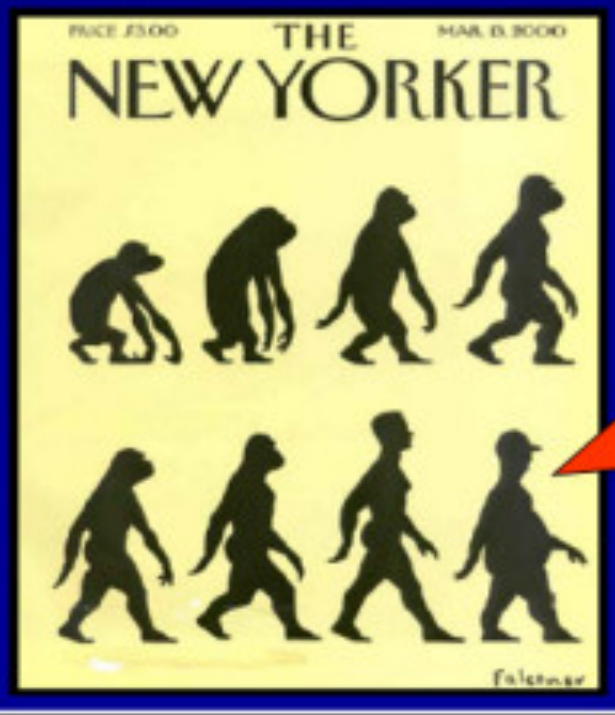
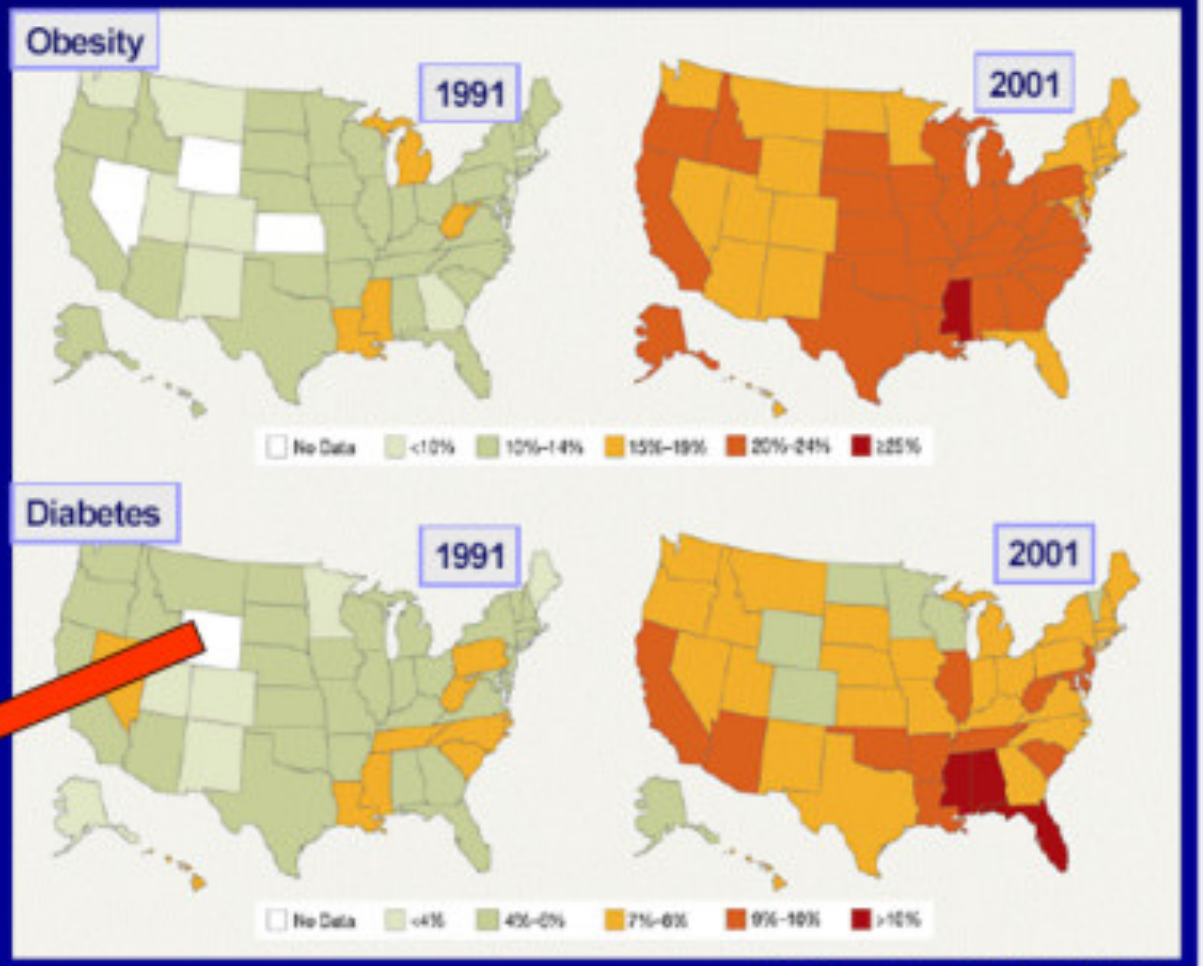


70% of the patients seen by a cardiologist will have *DM* <u>or</u> *undiagnosed DM* <u>or</u> *IGT* <u>or</u> *IFG* <u>or</u> *Metabolic Syndrome*





R. Nesto, TCT 2003

DIABETES AND MORTALITY

- **Cardiovascular diseases are cause of death up to 70-80%, AMI up to 50%.**(Ann Epidemiol 1993;3:27.34)
- **In diabetics with CVD seven year mortality is 45% and ten year mortality is 75%.**(N Engl J Med. 1998;339:229-234)
- **Evolution in AMI is worse, with an increased mortality rate at 1 month to 58%, and with a 50% of mortality rate after 5 years.**(Diabetes Care.1998;21:69-75; Diabet Med.1998;15:308-314)
- **Mortality from stroke is twofold compared to general population.**(Am J Epidemiol.2001;154:635-641; Stroke.1996;27:210-215)

Diabetes Care 35:2021–2027, 2012

Epidemiology/Health Services Research

ORIGINAL ARTICLE

Long-Term Prognosis of Diabetic Foot Patients and Their Limbs

Amputation and death over the course of a decade

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Heike Furchert[1]
Ute Groblinghoff, MD[1]
Herbert Hoffmeier[1]
Kerstin Kersten, MD, MSc[1]
Gerd-Thomas Klauke, MD, MSc[2]
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Zulfiqarali G. Abbas, MMed, DTMH&H[7,8]
Manish Bhabra, PhD[9]
David G. Armstrong, DPM, MD, PhD[9]

for a 10-year period (6–8). One of these studies described cumulative amputation rate and mortality after amputation; the other reported mortality among patients with a history of foot ulceration (without specific description of amputation status). The purpose of our study is therefore to report risk factors associated with first major

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Table 1—*Demographic data, risk factors, and comorbidities of the study population*

n	247
Age (years)	68.8 ± 10.9
Diabetes duration (years)	15.7 ± 10.5
Male	145 (58.7)
Nursing home resident	14 (5.7)
Living alone	49 (19.8)
Type 2 diabetes	216 (87.5)
Insulin treatment	164 (66.4)
Neuropathy	213 (86.2)
Charcot foot syndrome	29 (11.7)
History of coronary events (CHD)	51 (20.7)
History of stroke	54 (21.9)
PAD	137 (55.5)
CRI	49 (19.8)
Dialysis	9 (3.6)
Active smokers	52 (21.1)
Former smokers	94 (38.1)
Previous minor amputation	51 (20.7)
First-ever foot lesion	114 (46.2)

Data are means ± SD or *n* (%). CHD, coronary heart disease.

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Table 2—*Cumulative probabilities (with 95% CI) of first major limb amputation or death*

	Year 1	Year 3	Year 5	Year 10
Major amputation, all patients	8.7 (5.1–12.4)	12.5 (8.0–16.9)	15.9 (10.7–21.0)	22.3 (15.3–29.2)
Death				
All patients	15.4 (10.9–20.0)	33.1 (27.1–39.1)	45.8 (39.4–52.2)	70.4 (64.5–76.4)
Patients without PAD	7.5 (2.5–12.5)	19.7 (12.2–27.3)	30.2 (21.5–39.0)	57.7 (48.2–67.3)
Patients with PAD	21.9 (14.8–29.0)	44.1 (35.5–52.7)	58.8 (50.2–67.4)	81.0 (74.1–88.0)

GVM

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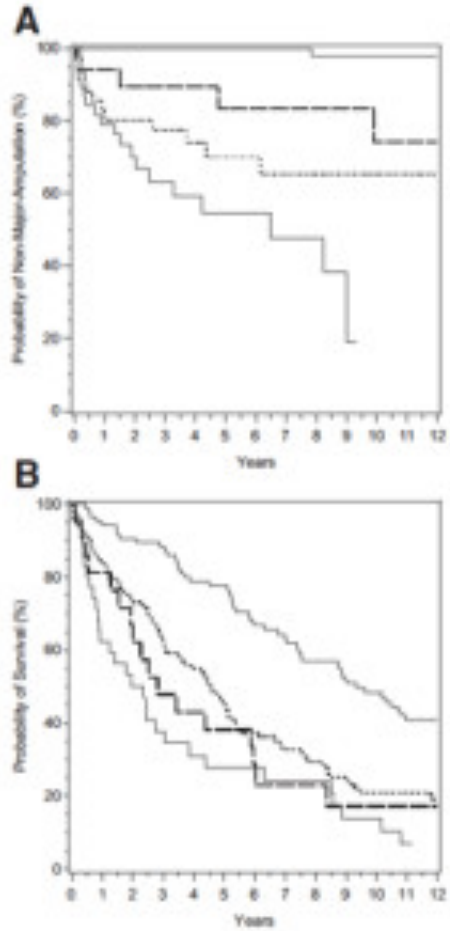

Figure 1—A: *Relevance of the presence and severity of PAD for the cumulative probability of a first major limb amputation. To avoid complexity, PAD not classified because of medial arterial calcification is not shown (n = 8; only 1 event of first major limb amputation). The highest curve represents no PAD, the second curve represents mild PAD, the third curve represents moderate PAD, and the lowest curve represents severe PAD.* B: *Relevance of the presence or absence of PAD, advanced renal disease, or both combined for the cumulative probability of death. The highest curve represents no PAD and no renal disease, the second curve represents renal disease and no PAD, the third curve represents PAD and no renal disease, and the lowest curve represents PAD and renal disease.*

, risk factors, dy population

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Diabetologia (2013) 56:1140–1147
DOI 10.1007/s00125-013-2860-x

ARTICLE

The impact of metabolic control and QTc prolongation on all-cause mortality in patients with type 2 diabetes and foot ulcers

K. Fagher · M. Löndahl

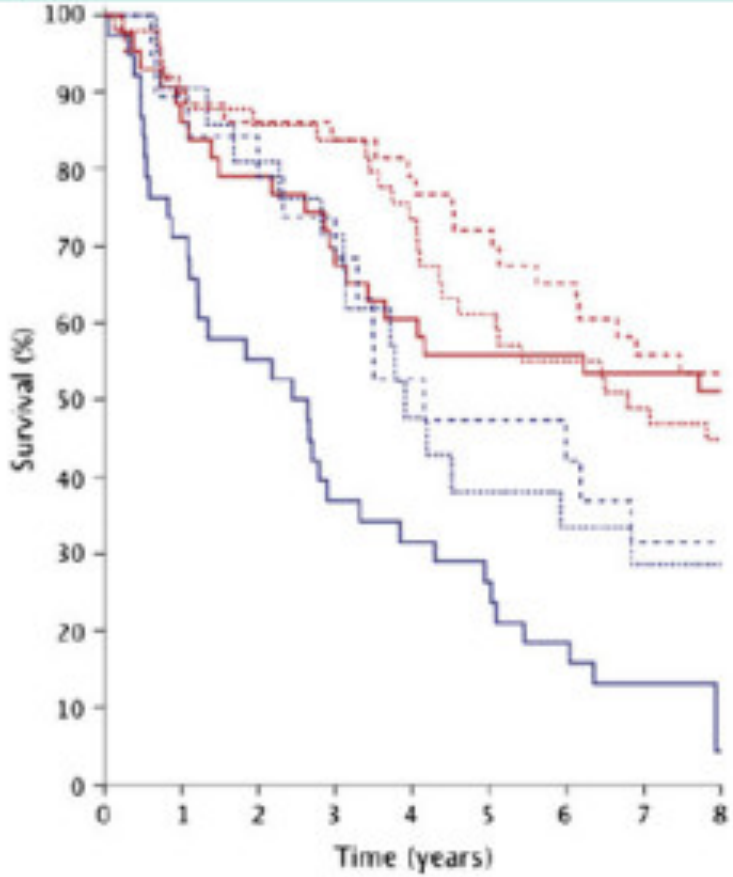
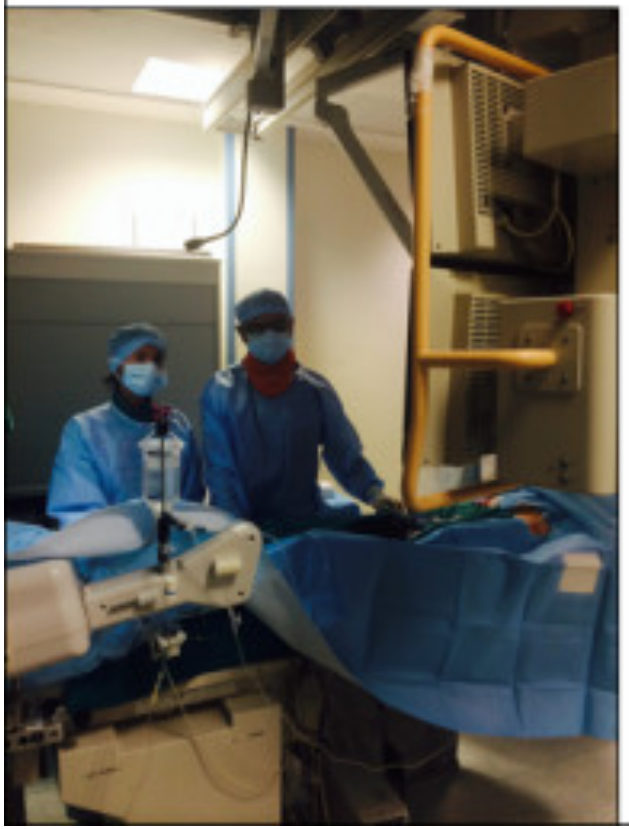
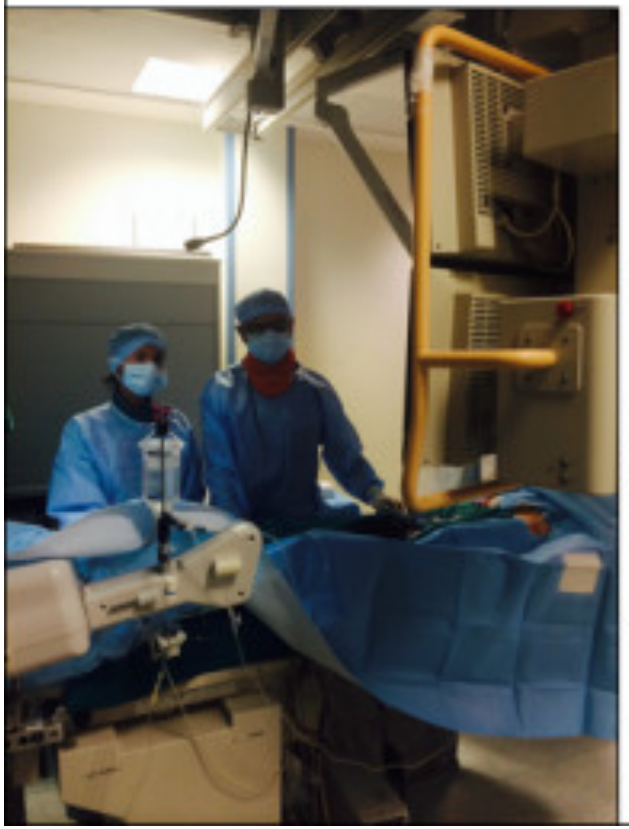
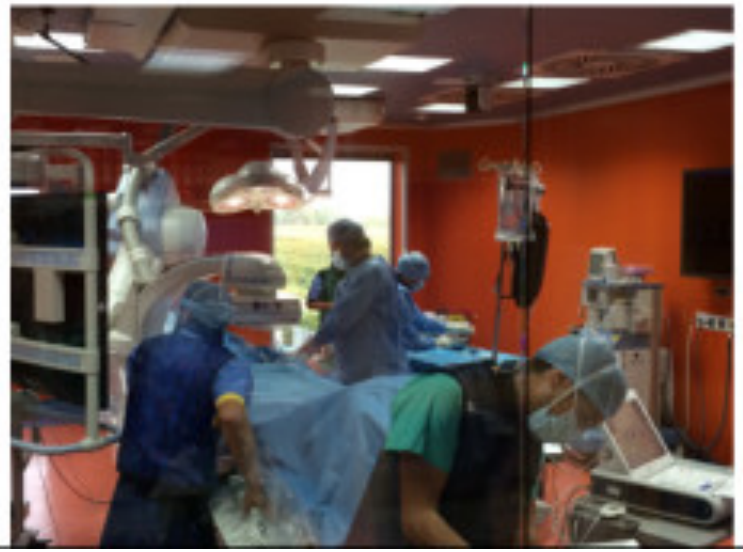
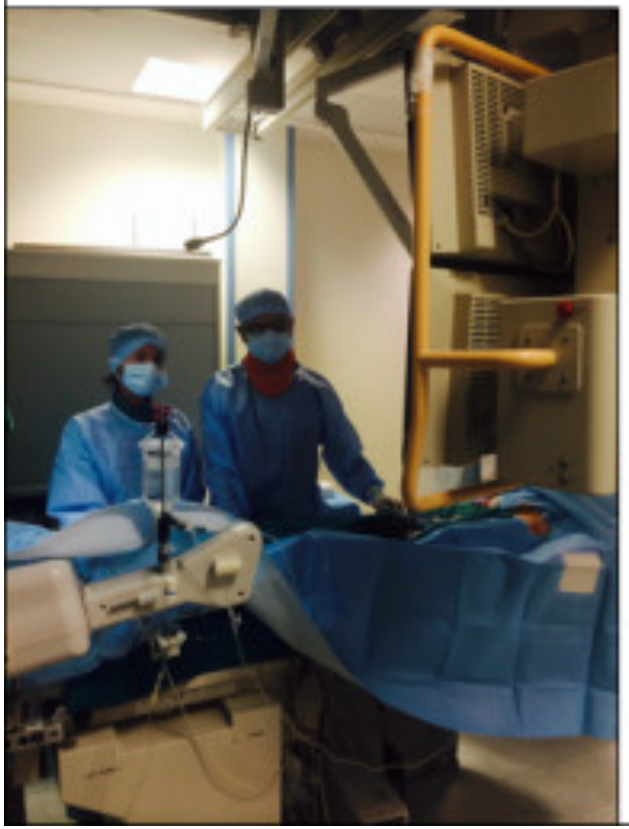


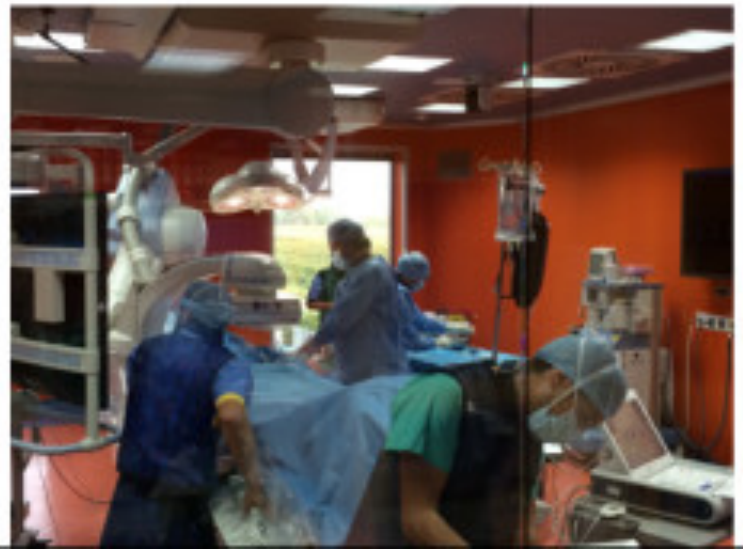
Fig. 2 Kaplan–Meier survival curve showing 8 year mortality in patients grouped according to HbA_{1c} levels and presence of QTc prolongation, defined as QTc time >440 ms. $p<0.0001$ for pooled comparison. For separate comparisons: QTc prolongation and HbA_{1c}<7.5% (<58 mmol/mol) vs all three groups with normal QTc-time separately $p<0.0001$; vs group with QTc prolongation and HbA_{1c} 7.5–8.9% (58–74 mmol/mol) $p=0.023$; and vs group with QTc prolongation and HbA_{1c} >8.9% (>74 mmol/mol) $p=0.015$. QTc prolongation and HbA_{1c} 7.5–8.9% (58–74 mmol/mol) vs normal QTc time and HbA_{1c}>8.9% (>74 mmol/mol), $p=0.025$. All other comparisons NS. Blue lines, patients with QTc prolongation; red lines, patients without QTc prolongation; solid line, HbA_{1c}<7.5% (<58 mmol/mol); dotted line, HbA_{1c} 7.5–8.9% (58–74 mmol/mol); dashed line, HbA_{1c}>8.9% (>74 mmol/mol)

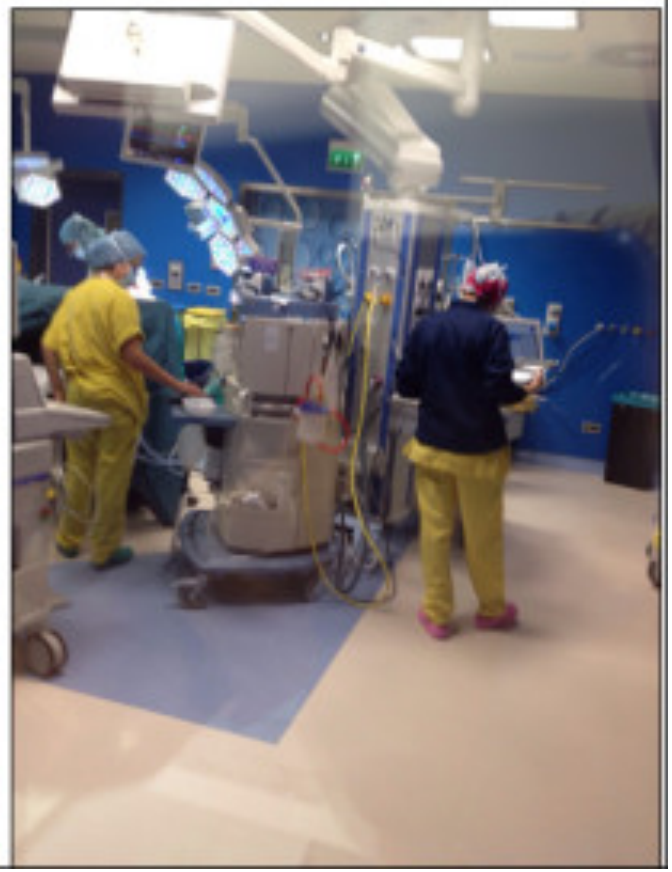












Take Home Message

- Amputation is a marker of quality of care with regard to the diabetic foot
- A decrease (40-79%) in the major amputation rate can be achieved
- A multidisciplinary management strategy has been associated with an improved healing rate and a reduction of the amputation rate
- Diabetic foot patients have an elevated cardiac morbility that explains high mortality rate
- Cardiologists should take part in therapeutic stategies
- Limb Center must be accompanied by cardiologist

Thank you for your attention