Evaluation Of The Diabetic Foot and Evidence For Hyperbaric Oxygen

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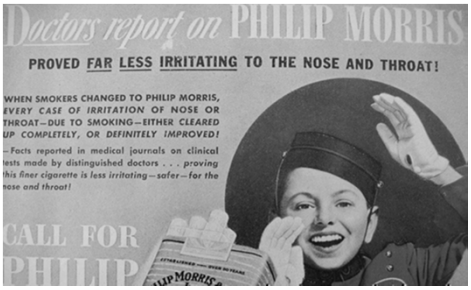
Outline

- Diagnosis and epidemiology of diabetes
  - Emphasis on Bexar County, Texas (San Antonio)
- Evaluation of the diabetic foot
- Evidence for the use of hyperbaric oxygen in the management of the diabetic foot
- Update on a new review of HBO for radiation injuries



How can we prevent this?

Diagnosis of Type II Diabetes

- Fasting plasma glucose (FPG) ≥ 126 mg/dl (7.0 mmol/l) **OR**
  Symptoms (such as polyuria, polydipsia, unexplained weight loss) **AND**
  a casual plasma glucose ≥ 200 mg/dl (11.1 mmol/l) **OR**
  Plasma glucose ≥ 200 mg/dl (11.1 mmol/l) 2 hours after a 75g glucose load **OR**
  A1C ≥ 6.5%.

Pre-diabetes

- Impaired fasting glucose (IFG) (fasting plasma glucose (FPG) levels): 100 - 125mg/dl (5.6 - 6.9mmol/l); **OR**
  Impaired glucose tolerance (IGT) (2-h values in the oral glucose tolerance test (OGTT)): 140 mg/dl - 199 mg/dl (7.8 - 11.0 mmol/l); **OR**
  A1C: 5.7 - 6.4%.

Diabetes prevalence

- **Total:** 25.8 million children and adults in the United States—8.3% of the population—have diabetes.
- **Diagnosed:** 18.8 million people
- **Undiagnosed:** 7.0 million people
- **Pre-diabetes:** 79 million people
- **New Cases:** 1.9 million new cases of diabetes diagnosed in people aged 20 years and older in 2010.

Prevalence In The US

- Adjusting for population age difference, 2007–2009 national survey data for people ages 20 years or older indicate:
- 7.1 percent of non-Hispanic whites
- 8.4 percent of Asian Americans, 11.8 percent of Hispanics/ Latinos
- 12.6 percent of non-Hispanic blacks had diagnosed diabetes.
- Among Hispanics/Latinos
  - 7.6 percent for both Cuban Americans and for Central and South Americans
  - 13.3 percent for Mexican Americans
  - 13.8 percent for Puerto Ricans.
- Diabetes rates vary among Alaska Natives (5.5 %) to American Indians in southern Arizona (33.5%)

Prevalence by Age

- **Under 20 years of age**
  - 215,000, or 0.26% of all people in this age group have diabetes
  - About 1 in every 400 children and adolescents has diabetes
- **Age 20 years or older**
  - 25.6 million, or 11.3% of all people in this age group have diabetes
- **Age 65 years or older**
  - 10.9 million, or 26.9% of all people in this age group have diabetes
- **Men**
  - 13.0 million, or 11.8% of all men aged 20 years or older have diabetes
- **Women**
  - 12.6 million, or 10.8% of all women aged 20 years or older have diabetes

Prevalence in Texas

Texas, Diagnosed:	1.7 million people (or 9.3% of the total Texas population)
Texas, Undiagnosed:	Approximately 440,468 Texans remain undiagnosed
Bexar County, Diagnosed:	137,009 people or 11.8% of the population

Obesity in San Antonio

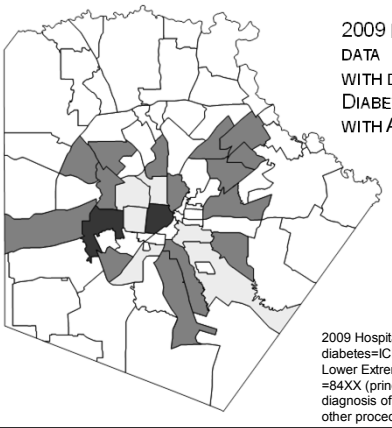
- The 2004-2005 BRFSS results estimate that 69 percent of the Bexar County adult population is overweight
  - Overweight 34 percent
  - Obese 35 percent

2009 Hospital Discharge data with diagnosis of Diabetes and Diabetes with Amputations

	2009 Bexar Co. Population	Dx of Diabetics	Rate per 1000	Dx of Diabetics Amputations	Rate per 100k
Total	1,651,448	39,376	24	1,528	93
Hispanic	962,600	24,188	25	1,122	117
White non-Hisp	516,932	10,042	19	277	54
African Am.	111,859	3,204	29	83	74

San Antonio Hispanics have twice the rate of Diabetic Amputations as White non Hispanics

2009 Hospital Discharge, Diagnosis of diabetes=ICD9 code 250XX, Non-traumatic Lower Extremity Amputations ICD9 code =84XX (principal diagnosis or other diagnosis of diabetes) (principal surgical or other procedure)

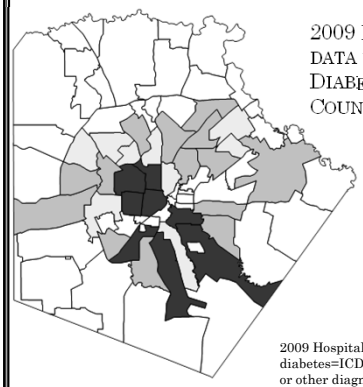


2009 Hospital Discharge data with diagnosis of Diabetes and Diabetes with Amputations

of Amputations per zip code

- 75 to 101
- 50 to 74
- 25 to 49
- 0 to 24

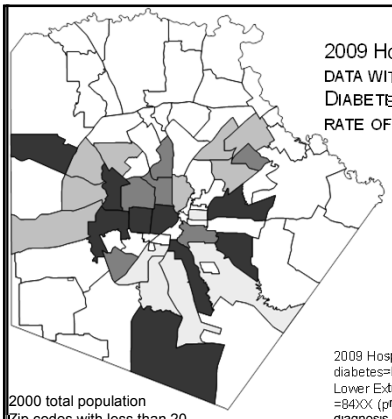
2009 Hospital Discharge, Diagnosis of diabetes=ICD9 code 250XX, Non-traumatic Lower Extremity Amputations ICD9 code =84XX (principal diagnosis or other diagnosis of diabetes) (principal surgical or other procedure)



2009 Hospital Discharge data with diagnosis of Diabetes by zip code-Bexar County

- 1,180 to 2,060
- 770 to 1,179
- 530 to 769
- 0 to 529

2009 Hospital Discharge, Diagnosis of diabetes=ICD9 code 250XX, (principal diagnosis or other diagnosis of diabetes)



2009 Hospital Discharge data with diagnosis of Diabetes and Diabetes with rate of Amputations

Rate Amputations per 1000 by zip code

- 1.8 plus
- 1.4 to 1.8
- 1 to 1.4
- 0.4 to 1

2000 total population
Zip codes with less than 20 amputations were not included

2009 Hospital Discharge, Diagnosis of diabetes=ICD9 code 250XX, Non-traumatic Lower Extremity Amputations ICD9 code =84XX (principal diagnosis or other diagnosis of diabetes) (principal surgical or other procedure)

Diabetes Complications

- **Amputation**
  - More than 60% of non-traumatic lower-limb amputations occur in people with diabetes.
  - In 2006, about 65,700 non-traumatic lower-limb amputations were performed in people with diabetes.

Deaths From Diabetes

- Diabetes was the seventh leading cause of death based on U.S. death certificates in 2007. This ranking is based on the 71,382 death certificates in 2007 in which diabetes was the underlying cause of death. Diabetes was a contributing cause of death in an additional 160,022 death certificates for a total of 231,404 certificates in 2007 in which diabetes appeared as any-listed cause of death.
- Overall, the risk for death among people with diabetes is about twice that of people of similar age but without diabetes.

Cost of Diabetes - US

Total costs—direct and indirect	$174 billion
Direct medical costs	$116 billion—after adjusting for population age and sex differences, average medical expenditures among people with diagnosed diabetes were 2.3 times higher than what expenditures would be in the absence of diabetes
Indirect costs	$58 billion—disability, work loss, premature mortality

Cost of Amputations - San Antonio

Costs of amputations and other diabetic complications by race ethnicity
2009 San Antonio Hospital Discharge, Diagnosis of diabetes

	Dx. Diabetic Amputations	Total Cost	$ per person
Total	1,541	$ 109,274,520	$ 70,911
Hispanic	1,128	$ 74,581,948	$ 66,119
Non Hispanic White	283	$ 23,022,512	$ 81,352
African Am.	83	$ 6,428,785	$ 77,455

	Dx. Diabetic	Total Cost	$ per person
Total	39,820	$ 1,608,592,595	$ 40,397
Hispanic	24,371	$ 946,613,564	$ 38,842
Non Hispanic White	10,248	$ 430,175,398	$ 41,977
African Am.	3,229	$ 117,585,476	$ 36,415

(principal surgical or other procedure Nontraumatic Lower Extremity Amputations)
ICD9 code 250XX, Non-traumatic Lower Extremity Amputations ICD9 code =84XX

Etiology of the Diabetic Foot

- Complex and Multifactorial
- Hard to know which components are key
  - Neuropathy
  - Muscle Atrophy
  - Charcot Neuroarthropathy
  - Diabetic Foot Infections

Neuropathy

- Four types of diabetic neuropathy:
- Peripheral
- Autonomic
  - Affects GI and GU tracts and cardiovascular system
    - Bloating, diarrhea, constipation, erectile dysfunction, increased heart rate, dizziness on standing, among many others
- Proximal
  - Often unilateral pain in thigh or buttocks
- Focal
  - Can result in sudden dysfunction such as diplopia, eye pain, localized severe pain

Peripheral Neuropathy

- Tingling
- Burning
- Decreased sensation including numbness of the foot

Muscle Atrophy

- Begins with distal intrinsic muscles of the foot then later to larger extrinsic muscles of the leg
- Intrinsic muscles weaken, becomes difficult to stabilize the proximal phalanges
- Larger and more powerful flexors and extensors of the toes gain a mechanical advantage
- Leads to:
  - Hammer
  - Mallet
  - Contracted
  - Curly toe deformities

Muscle Atrophy

- With deformity, dorsal, digital, and interdigital pressures increase from shoe to bone and bone to bone contact
- Increases pressure and shear forces to the skin
- Loss of toe function also causes increased shear pressure of the metatarsal heads as the gait changes

Glycosylation of foot tissue

- Causes an adverse effect on all the connective tissue of the foot
- Toe capsules and tendons become stiff
- Achilles' tendon becomes stiffer
- Posterior muscles lose flexibility
- All result in less dorsiflexion of the ankle with subsequent forefoot pressure

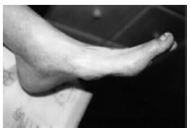
Loss of posterior tibial function

- Lose the ability to resist pronation
- Causes arch collapse
- This then leads to mid-foot collapse and dorsal mid-foot interosseous compression syndrome

Muscle Atrophy

- Begins with distal intrinsic muscles of the foot then later to larger extrinsic muscles of the leg

Charcot neuroarthropathy



Charcot Foot-Three Theories of etiology

- Neurovascular
  - Breakdown of the skeletal structure is weakening of the bones from osseous hyperemia as a result of diabetic neuropathy
- Neurotraumatic
  - Mechanical caused by microfractures produced by mechanical overload. Lack of pain from peripheral diabetic neuropathy
- Combined

Autonomic neuropathy

- Significant effect on the skin
- Sweat and apocrine glands decrease secondary as autonomic dysfunction increases
  - Decreases ability to fight infections
- Dry skin cracks and decreased fatty content allows easier bacterial and fungal infections
- Skin will ulcerate
  - Bacteria invade and colonize the impaired host

Callous and Blister formation

- Callouses cause an increase in pressure on dermal and subcutaneous tissues
- Develop interdermal and subdermal hemorrhages
  - Fluid accumulation between tissues layers and below tissue layers
  - These small accumulations lead to tissue maceration and blister formation
- If weight bearing area, this fluid constantly compressed, dissects to surrounding tissue
  - Dissection then to intermetatarsal space of medial and lateral foot resulting in large bullae

Callous and blister formation

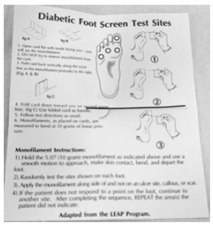
- Bullae rupture and are quickly invaded by bacteria
- Bacteria then can invade deep tissue-formation of proteolytic enzymes
- Pus accumulates, dissects further especially when there is continued weight bearing in an insensate foot
- A benign appearing callous can easily become a limb threatening infection

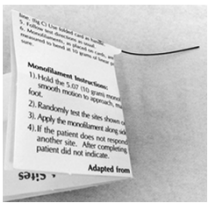
Diabetic foot infections

Neuropathy

Evaluation of the Diabetic Foot

- Peripheral Neuropathy Assessment
  - Semmes-Weinstein monofilament



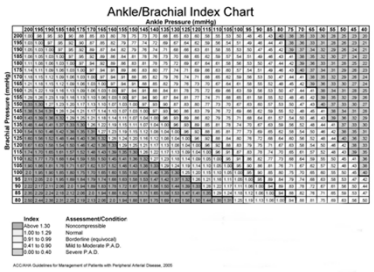


Evaluation of the Diabetic Foot

- All should get plain films
  - Foreign Body
  - Charcot Foot
  - Gas in the Tissue
- Probing to bone means osteomyelitis
  - We still get an MRI

Evaluation of the Diabetic Foot

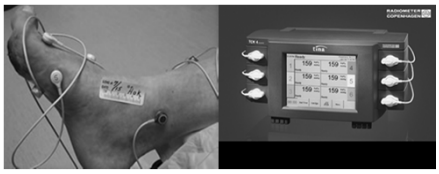
- Non-invasive arterial studies
  - Ankle-Brachial Index



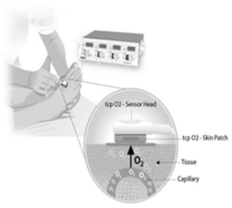
Evaluation of the Diabetic Foot

- ABI gives a general indication of global pedal perfusion
- Healing is really dependent upon cutaneous circulation
- Assess cutaneous circulation with:
  - Transcutaneous Oxygen Tension (TcPO2)
  - Cutaneous laser Doppler velocimetry

Transcutaneous Oximetry



Transcutaneous Oximetry



- The electrode heats the underlying tissue to create a local hyperemia, which intensifies the blood perfusion, increasing the oxygen pressure.
- The heat will dissolve the lipid structure of the dead, keratinized cells in the epidermal layer making the skin permeable to gas diffusion.

Transcutaneous Oximetry

- Tissue hypoxia is defined as a PtcO2 <40 mm Hg
- Patients with critical limb ischemia (ankle systolic pressure of < or =50 mm Hg or toe systolic pressure of < or =30 mm Hg) breathing air will usually have a PtcO2 <30 mm Hg;
- PtcO2 <40 mm Hg obtained while breathing normobaric air is associated with a reduced likelihood of amputation healing
- If the baseline PtcO2 increases <10 mm Hg while breathing 100% normobaric oxygen, this is at least 68% accurate in predicting failure of healing post-amputation
- In-chamber testing values < 400 mm Hg are predictive of failure
- TcPO2 can be used for mapping amputation sites and predicting failure of amputation site failure.

Classification of Diabetic Foot Lesions-Wagner Classification

Grade 1: Superficial Diabetic Ulcer
Grade 2: Ulcer extension. Involves ligament, tendon, joint capsule or fascia. No abscess or osteomyelitis
Grade 3: Deep ulcer with abscess or osteomyelitis
Grade 4: Gangrene to portion of forefoot
Grade 5: Extensive gangrene of foot

Wagner Grade I

WAGNER III

WAGNER IV

WAGNER V

SEMINAL HBO AND DIABETIC FOOT ULCER STUDY

- Faglia E, et al. Diabetology Center, Niguarda Hospital, Milan, Italy.
  Diabetes Care. 1996 Dec;19(12):1338-43.
- Basis for Medicare payment for HBO for diabetic foot ulcers.

FAGLIA STUDY

- From August 1993 to August 1995, 70 diabetic subjects were consecutively admitted into a diabetologic unit for foot ulcers
- 35 subjects received s-HBOT and another 33 did not. All had aggressive surgical management and antibiotics per established protocol.
- Of the treated group (mean session = 38.8 +/- 8), three subjects (8.6%) underwent major amputation: two below the knee and one above the knee. In the non-treated group, 11 subjects (33.3%) underwent major amputation: 7 below the knee and 4 above the knee. The difference is statistically significant (P = 0.016)
- The relative risk for the treated group was 0.26 (95% CI 0.08-0.84)

Hyperbaric Oxygen Therapy Facilitates Healing of Chronic Foot Ulcers in Patients With Diabetes

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DIABETES CARE, VOLUME 33, NUMBER 5, MAY 201

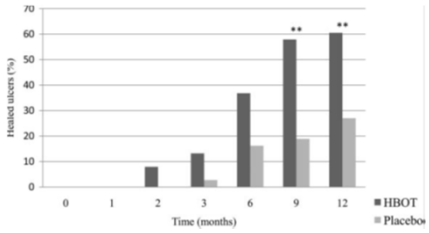
LONDAHL STUDY

Ninety-four patients with Wagner grade 2, 3, or 4 ulcers, which had been present for 3 months, were studied. In the intention-to-treat analysis, complete healing of the index ulcer was achieved in 37 patients at 1-year of follow-up: 25/48 (52%) in the HBOT group and 12/42 (29%) in the placebo group (P = 0.03).

In a sub-analysis of those patients completing >35 HBOT sessions, healing of the index ulcer occurred in 23/38 (61%) in the HBOT group and 10/37 (27%) in the placebo group (P= 0.009).

CONCLUSIONS— The present study supports the concept that adjunctive treatment with HBOT enhances foot ulcer healing in selected patients with diabetes. Accordingly, in our patients with long-standing chronic ulcers at 1-year follow-up, HBOT doubled the number of healed ulcers as compared with adjunctive treatment with hyperbaric air used as placebo.

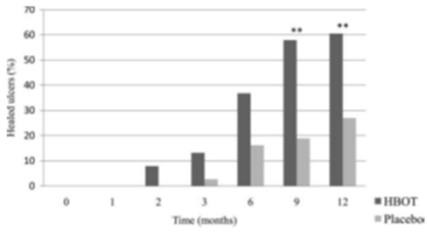
LONDAHL



LONDAHL STUDY

- The issue is inclusion of Wagner 2 diabetic foot ulcers
  - HBO is not used for Wagner 2
- Decreases the actual n that should have been analyzed from 49 and 45 to 37 and 33

LONDAHL



RADIATION INJURY AND HBO

Hyperbaric oxygen therapy for late radiation tissue injury in gynecologic malignancies

P. Craighead, et.al

Current Oncology—Volume 18, Number 5

HBO FOR GYNECOLOGICAL RADIATION INJURIES

The recommendations are based on
- a modest quality of evidence that supports the use of HBO2 for late radiation tissue injury (lrti),
- review by external content experts, and
- the expert consensus opinion of the Alberta Gynecologic Oncology Provincial Tumor Team.

- HBO2 is effective for lrti, particularly that of head, neck, anus, and rectum. That is, there is an emerging field of evidence, with contributions from specific and diverse areas of clinical study, of positive outcomes in patients with lrti involving head, neck, anus, or rectum.
- Among women with lrti secondary to radiation for gynecologic malignancies, the main indication for the use of HBO2 therapy is the management of treatment-refractory chronic radiation injury.

There is evidence for symptomatic benefit with the use of HBO2 therapy in certain clinical settings (cystitis, soft-tissue necrosis, or osteonecrosis) after radiotherapy for cervical cancer. The small number of case series and the low patient numbers limit the construction of more specific recommendations; however,

HBO2 should be considered for women in whom conservative care fails. In patients being considered for surgical removal of necrosis, limited but consistent evidence supports the use of HBO2 to reduce the complications of gynecologic oncology surgery, purported to occur through the stimulation of small-vessel angiogenesis

REFERENCES

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  - http://diabetes.niddk.nih.gov/index.aspx
- Kindwall E, Whalen H, Hyperbaric Medicine Practice 3rd ed., Best Publishing 2008.
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- Faglia E, et al. Adjunctive systemic hyperbaric oxygen therapy in treatment of severe prevalently ischemic diabetic foot ulcer. A randomized study. *Diabetes Care. 1996 Dec;19(12):1338-43.*