2018 MID-ATLANTIC
CONFERENCE

8th ANNUAL CURRENT CONCEPTS IN
VASCULAR THERAPIES

2018

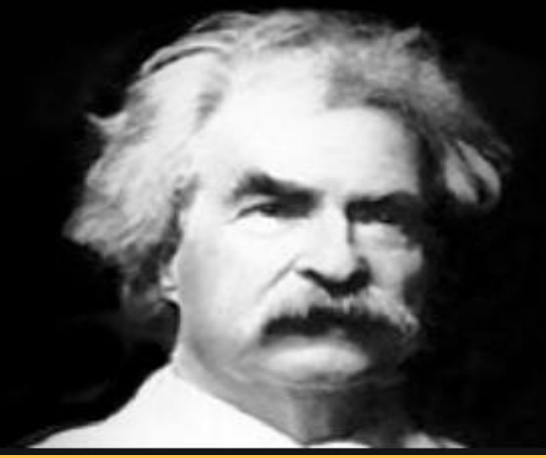
Michael E Landis
MD FACS

Screening for Carotid disease

EASTERN VIRGINIA MEDICAL SCHOOL
1973

GET YOUR FACTS FIRST
THEN YOU CAN DISTORT THEM
AS YOU PLEASE

Mark Twain



EASTERN VIRGINIA MEDICAL SCHOOL
1973

Why Screen?

- *"... If detected early, they stand a reasonable chance of being cured, whereas if not diagnosed until the patients come to the hospital with clear-cut symptoms they may be incurable. ... it would seem that the practice of screening for disease would be widespread. That it is not so to the extent that might be expected is due to a number of factors, among them the cost of screening, and the tendency of the medical profession to wait for patients rather than actively look for disease in the population. Another factor undoubtedly is inadequate knowledge of the principles and practice of screening for disease."*

Wilson, WHO Public Health Paper, 1968

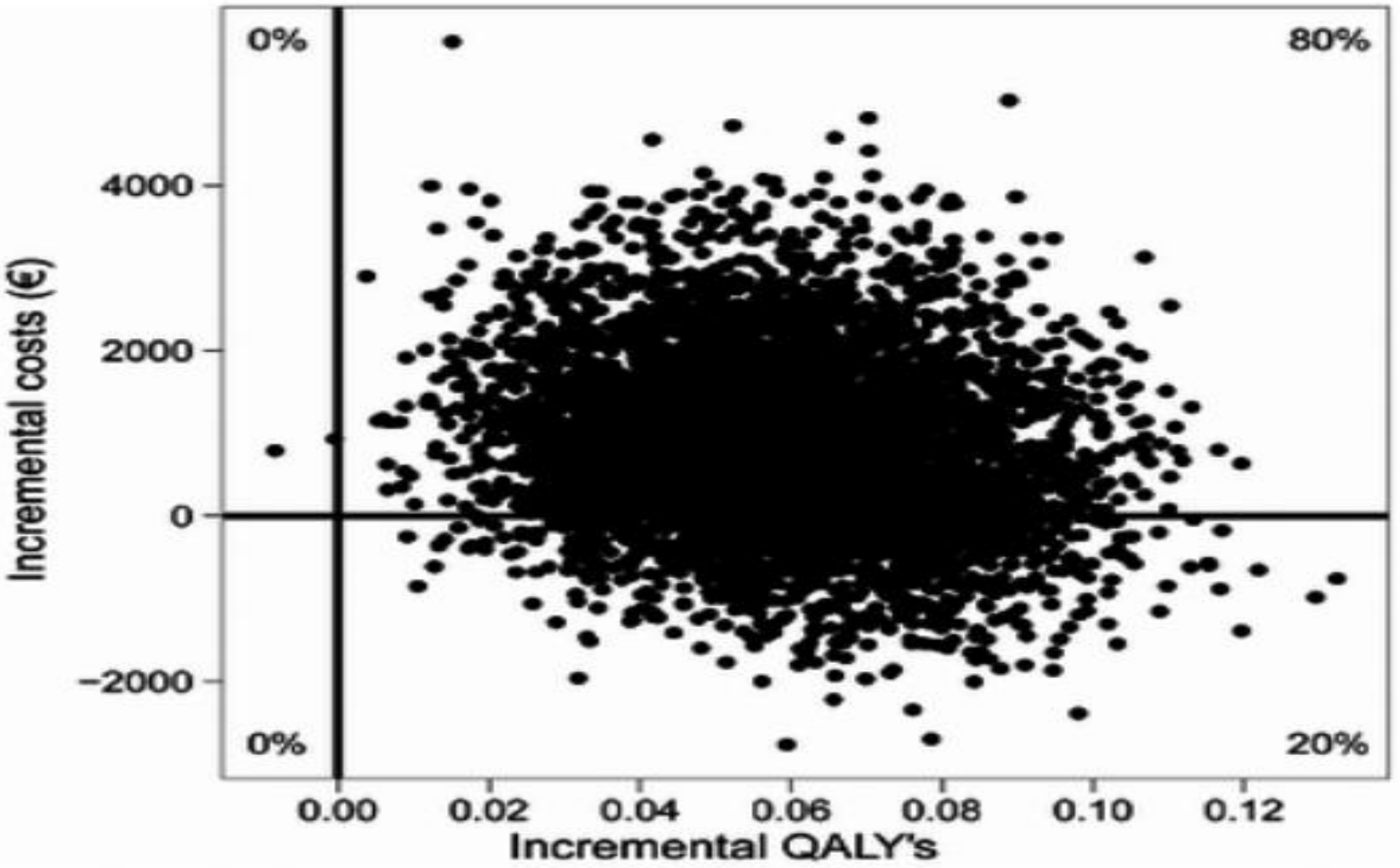
Principles of screening

- The screening program should respond to a recognized need.
- The objectives should be defined at the outset
- There should be a defined target population.
- There should be scientific evidence of screening program effectiveness
- The natural history of the disease should be understood, and an agreed policy on who to treat.
- **“The total cost of finding a case should be economically balanced in relation to medical expenditure as a whole.”**

WHO, Princ of Screen, 2008

Cost-effectiveness

- “Cost-effectiveness analysis is a method for assessing the gains in health relative to the costs of different health interventions. The basic calculation involves dividing the cost of an intervention in monetary units by the expected health gain measured in natural units, such as number of lives saved.”


0%
80%
4000
2000
0
−2000
0%
20%
Incremental costs (€)
0.00
0.02
0.04
0.06
0.08
0.10
0.12
Incremental QALY's

Medicare Part B screening

- **Abdominal aortic aneurysm**
  - You have a family history of abdominal aortic aneurysms.
  - You're a man age 65 to 75 and have smoked at least 100 cigarettes in your lifetime.
- **Mammography**
- **Prostate cancer**
- **Lung cancer**

  - They're 55-77.
  - They're asymptomatic (they don't have signs or symptoms of lung cancer).
  - They're either a current smoker or have quit smoking within the last 15 years.
  - They have a tobacco smoking history of at least 30 "pack years" (an average of one pack a day for 30 years).

WHO, Princ of Screen, 2008

Why not screen for carotid artery disease?

Stroke Incidence

- 750,00 CVA/year: 20-30% associated with extracranial CAS
- 3rd most common cause of death.[1]
- Leading cause of disability.[1]
- 5 year survival 56% for men, and 64% for women.[2]

SENTARA

[1] Sacco, *Ischemic Stroke* 1994
[2] Sacco, *Stroke* 1982

Stroke Cost

- Stroke responsible for 500,000+ hospitalizations annually.
- Estimated 6,000,000+ stroke survivors in the U.S.
- Recurrent stroke risk 4 – 15% at 1 year, and 25% at 5 years.
- Annual health care cost estimated at $68 billion.
- Ancillary and emotional costs associated with lifelong disability cannot be calculated.

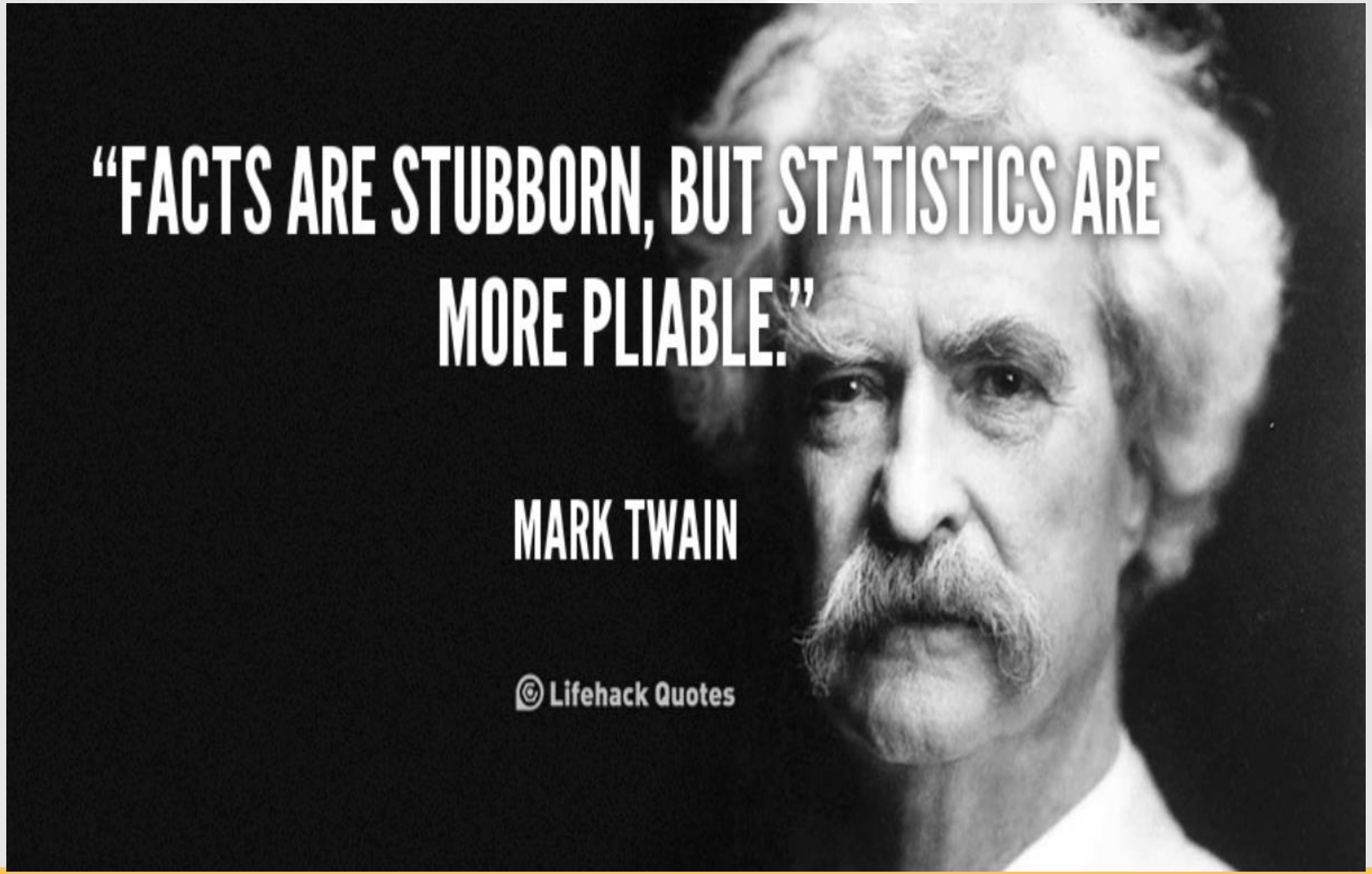
2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/ SAIP/SCAI/SIR/SNIS/SVM/SVS Guideline on the Management of Patients With Extracranial Carotid and Vertebral Artery Disease

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American Stroke Association, American Association of Neuroscience Nurses, American Association of Neurological Surgeons, American College of Radiology, American Society of Neuroradiology, Congress of Neurological Surgeons, Society of Atherosclerosis Imaging and Prevention, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society of NeuroInterventional Surgery, Society for Vascular Medicine, and Society for Vascular Surgery

Developed in Collaboration With the American Academy of Neurology and Society of Cardiovascular Computed Tomography

Indications for Carotid Duplex

- Cervical bruit in an asymptomatic patient
- Follow-up of known stenosis (>50%) in asymptomatic individuals
- Vascular assessment in a patient with multiple risk factors for atherosclerosis
- Stroke risk assessment in a patient with CAD or PAD
- Amaurosis fugax
- Hemispheric TIA
- Stroke in a candidate for carotid revascularization
- Follow-up after a carotid revascularization procedure
- Intraoperative assessment during CEA or stenting


"FACTS ARE STUBBORN, BUT STATISTICS ARE MORE PLIABLE."
MARK TWAIN
© Lifehack Quotes

CLINICAL GUIDELINE | Annals of Internal Medicine

Screening for Asymptomatic Carotid Artery Stenosis: U.S. Preventive Services Task Force Recommendation Statement

Michael L. LeFevre, MD, MSPH, on behalf of the U.S. Preventive Services Task Force*

Description: Update of the 2007 U.S. Preventive Services Task Force (USPSTF) recommendation on screening for carotid artery stenosis.

Methods: The USPSTF commissioned a systematic review to synthesize the evidence on the accuracy of screening tests, externally validated risk-stratification tools, the benefits of treatment of asymptomatic carotid artery stenosis with carotid endarterectomy (CEA) or carotid angioplasty and stenting (CAAS), the benefits from medications added to current standard medical therapy, and the harms of screening and treatment with CEA or CAAS.

Population: This recommendation applies to adults without a history of transient ischemic attack, stroke, or other neurologic signs or symptoms.

Recommendation: The USPSTF recommends against screening for asymptomatic carotid artery stenosis in the general adult population. (D recommendation)

Ann Intern Med. 2014;161:356-362. doi:10.7326/M14-1333 www.annals.org

For author affiliation, see end of text.

* For a list of USPSTF members, see the **Appendix** (available at www.annals.org).

This article was published online first at www.annals.org on 8 July 2014.

GRADE D RECOMMENDATION!

USPSTF recommendations

- Methodology appears biased – "*the benefits from medications added to current medical therapy,* ***and the harms with screening or treatment with either CEA or CAAS***."
- *"Asymptomatic CAS causes a relatively small number of strokes."*
- *"Ultrasonography yields many false positive results in the general population."*
- Assume the incidence of disease in the general population is <1%, yet do not stratify for risk.
- None of the board members are physicians who care for patients with stroke.

Prevalence and risk factors for atherosclerotic carotid stenosis and plaque

A population-based screening study

Shin Young Woo, RN, MPH,[a] Jin Hyun Joh, MD, PhD,[b,*] Sang-Ah Han, MD, PhD,[b] and Ho-Chul Park, MD, PhD[b]

- Population based screening study from Korea; 3030 patients over the age of 50.
- Incidence of moderate to severe CAS was 1.1%
- Risk factors; age >80 (OR 8.1), male sex (OR 2.1), HTN (OR 1.72), dyslipidemia (OR 1.84).

Medicine, 2017

Who should be screened?

Carotid stenosis Incidence

- Framingham Study: >50% stenosis in pts older than 66; 7% in women and 9% in men.
- 1991 Swedish study showed a 3% incidence of stenosis greater than 50% in patients over the age of 60.
- University of Washington study from 1984 showed an 8% incidence of significant disease in pts referred to the vascular lab.
- Meta analyses estimates a 5% incidence in patients over the age of 60.

SENTARA

Carpenter, et al JVS 1998

A model for predicting occult carotid artery stenosis: screening is justified in a selected population☆

Presented at the Thirty-first Annual Meeting of the Society for Clinical Vascular Surgery, Miami, Fla, Mar 5-9, 2003.

Glenn R Jacobowitz, MD, Caron B Rockman, MD, Paul J Gagne, MD, Mark A Adelman, MD, Patrick J Lamparello, MD, Ronnie Landis, RN, Thomas S Riles, MD

- Prospective study analyzing patients > age 60, with a h/o smoking, heart disease, HTN, and dyslipidemia.
- Hemodynamically significant disease found in 9.6%.

No. of risk factors	0	1	2	3	4
No. of patients	54	156	133	48	3
% carotid stenosis	1.8	5.8	13.5	16.7	66.7

JVS, 2003

Conventional Carotid duplex

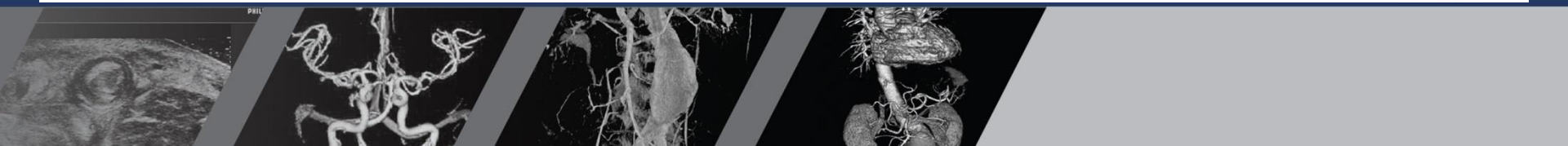
- ‘Gold Standard’
- Cost – $3 -500/study
- Exam time 1 hour, and requires trained specialists to perform and interpret
- Readily available in most hospitals.
- Sensitivity and specificity of over 90%

LIFE LINE SCREENING®
The Power of Prevention

Life Line Screening

- Commercial vascular screening:
  - Carotid ultrasound, AAA ultrasound, PAD ankle brachial index, ECG for AF
- Screened 8M people in USA, UK and Ireland
- USA
  - Started in 1993
  - Screen ~750,000 adults per year
- UK & Ireland
  - Started in 2007
  - Screen ~50,000 adults per year

http://www.lifelinescreening.co.uk/



LIFE LINE SCREENING®
The Power of Prevention

- 'Vascular package' - $109. Covers PAD, aortic aneurysm, and carotid artery screening.
- Testing takes less than 1 hour. Results usually available within 1 – 3 weeks.
- Small, non-randomized studies have shown correlation with conventional duplex US.

LIFE LINE SCREENING®

The Power of Prevention

- ‘For profit company’
- No physician on site. Technologists are registered or ‘eligible’
- No established oversight, or standardized quality control measures.
- May give patients a false sense of security.

‘Limited’ carotid duplex

- Designed as a rapid, cost effective approach to assess the carotid bifurcation.
- Assess for PSV > 125 cm/s
- 1014 vessels studied
- Average exam time of 3.2 m
- Sensitivity 86%, Specificity 98%
- PPV 95%
- Limited screening studies recommended for high risk patients.

Carsten, et al AJS 1999

DVX

- Authors based their study/device on the presumption of a 5% incidence of CAS in the over 65 age group, a standard carotid duplex cost of $210, and a calculated cost of $4,200 to identify one significant lesion.
- They proposed a low cost screening device that would identify hemodynamically significant disease, that would subsequently be referred for a conventional CD (analogous to screening mammography).
- Device identifies velocities in the region of the carotid bifurcation that are greater than 140 cm/s.
- Can be done in the office. No specialized training necessary.
- 15 minute exam, with a cost of less than $15.
- Estimated cost of finding a greater than 50% stenosis was $1,530.

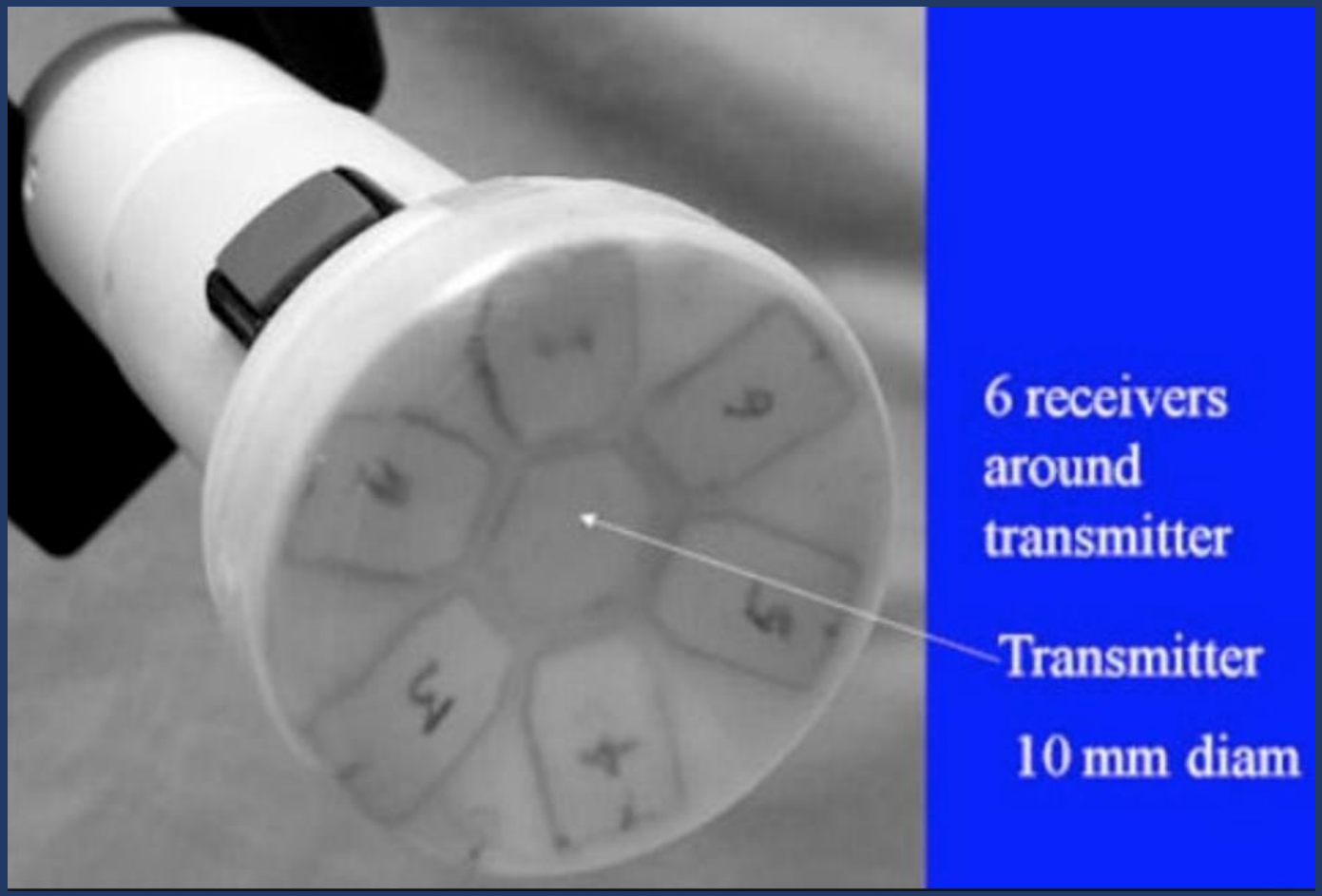
Vilkomerson, Proc SPIE 2005

DVX

- 898 patients studied over an 18 month period.
- 23% referred for conventional duplex
- 16% were found to have >50% stenosis.
- Exam time 4.3 ± 1.8 minutes

Vilkomerson, Proc SPIE 2005

DVX probe



DVX

CarotidScan DVX,LLC

Escape

Start Scan

Scan Done

File Name: Patient1

Date: 01-07-05

Index: 7

New Patient

Scan Period: 3

Samp Rate: 10000

Next File: C:\CarotidData\Patient1_01-07-05-7

Vel: 98

Vel stdev: .02

Ind	Vel	Status
1	093	OK
2	094	OK
3	109	OK
4	111	OK
5	112	OK
6	098	OK

Machine Status

Click Button To START

Data Status: OK

NOTES: Scanning up carotid--bifurcation

Conventional Data

LEFT RIGHT

CCA

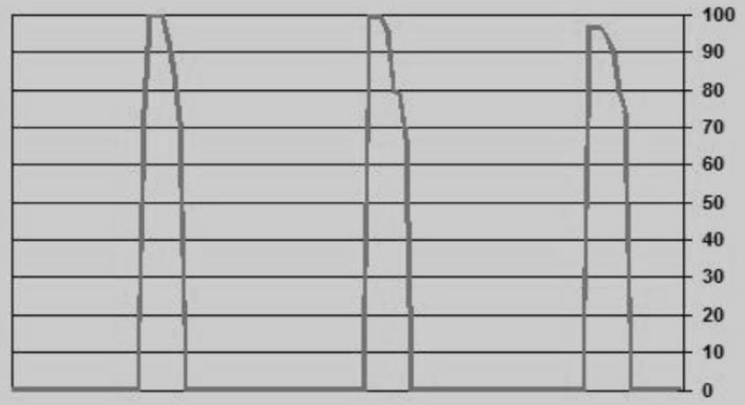
Max V

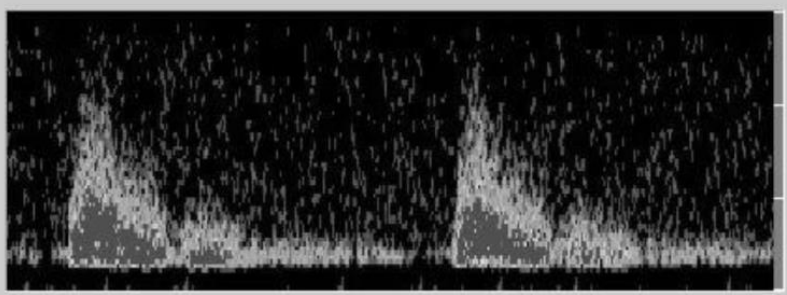
CCA

Max V

Scanning Right Side

VELOCITY GRAPH





Start Spectrum | Stop Spectrum | Set Scroll | Set Wipe

sl := in1

NMAX :=

C:\CarotidData\PatientLog.csv

DVX

- 1,000 screened patient's at $15/study = $15,000.
- 23% referral rate – 230 x $210/CUS + $48,300.
- 29 patients who subsequently underwent CEA for >60% stenosis @ 5,300/surgery = $154,000.
- Total cost to screen and treat 1,000 patients = $219,000.
- Assuming stroke rate reduced by 7% = 2.1 strokes prevented.
- Assuming stroke cost of $190,000, savings of $392,000 (net $172K).
- Extrapolating data to the Medicare population, potential cost savings of **$4.2 billion**

Vilkomerson, AIUM 2010

Carotid screening

- ACAS data – 11% stroke incidence at 5 years in patients with >60% stenosis.
- AVA screening program of 18,446 senior found a 7.4% incidence of >60% stenosis.
- Assuming a stroke rate of <2% associated with CEA, estimated that 200,000 strokes may be prevented by screening.
- Stroke cost $145,000, compared to cost associated with evaluation and management of CAS of $82,000 (-$64,000).
- Overall cost saving potentially of $13 billion/year.

Levenson, JVS 2011

Asymptomatic carotid disease What do we do with the results?

The Natural History of Carotid Arterial Disease in Asymptomatic Patients With Cervical Bruits

G. O. ROEDERER, M.D., Y. E. LANGLOIS, M.D., F.R.C.S. (C), K. A. JAGER, M.D., J. F. PRIMOZICH, B.S., K. W. BEACH, PH.D., M.D., D. J. PHILLIPS, PH.D., AND D. E. STRANDNESS, JR., M.D.

- 2% normal
- 62% less than 50% stenosis
- 32 % were severe to critical/4% occluded.
- Mean annual rate of disease progression to moderate or greater was 8%.
- Risk factors associated with disease progression were active tobacco use, DM and age.

Stroke, 1984

Progression of asymptomatic mild carotid artery stenosis: Implications for frequency of surveillance.

Hamilton RD[1], Shield CE[1], Laughrun D[2].

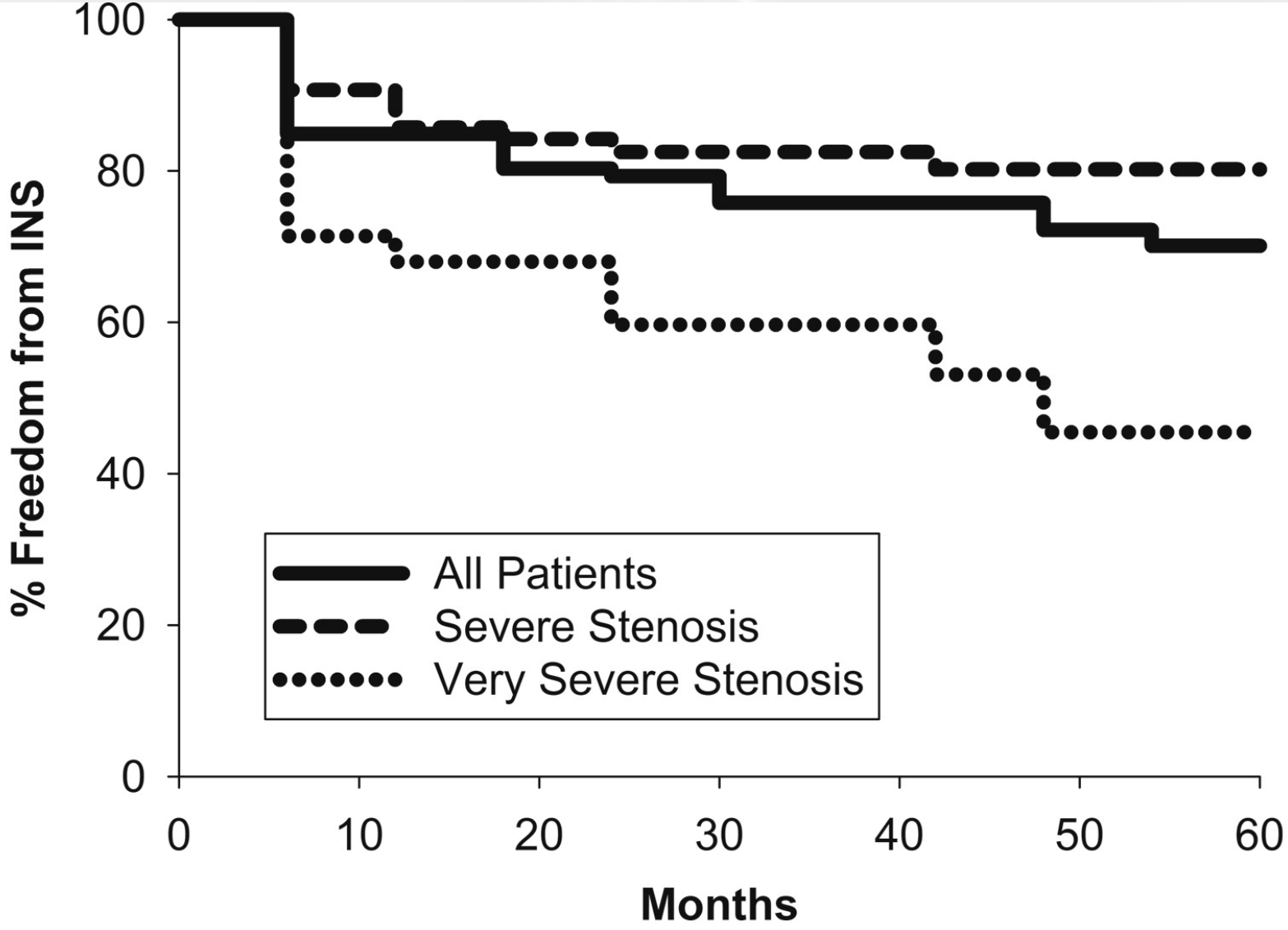
- Retrospective study over a 10 year period.
- Evaluated patients with 20 – 49% stenosis that were followed with serial DU at 3 and 5 year intervals.
- 440 vessels assessed; 5.45% progressed to moderate disease, 0.02% to severe.
- Decreased use of statin tx in group that progressed.

Ann Vasc Surg. 2011 Oct;25(7):887-94. doi: 10.1016/j.avsg.2011.05.021. Epub 2011 Aug 11.

The value of a carotid duplex surveillance program for stroke prevention.

Cull DL[1], Cole T, Miller B, Johnson B, Rawlinson D, Walker E, Taylor SM.

- Retrospective review of 3,003 patients following CEA over a 9 year period.
- 11,531 studies, or 3.84 per patient.
- 225 CEA (7.5%), preventing 13 CVA.
- Duplex cost: $332 per study.
- Total cost: $3,830,000, or $290,000 per CVA.
- "... eliminating routine surveillance in the absence of contralateral disease, and limiting number of studies in asymptomatic patients..."



Conrad, et al JVS 2013

Event rates in patients managed without revascularization

Table 2. Event Rates in Patients With Carotid Artery Stenosis Managed Without Revascularization

Study (Reference)	No. of Patients	Symptom Status	Stenosis, %	Follow-Up	Medication Therapy	Endpoint	Event Rate Over Study Period (%)
Observational studies							
Hertzer et al.[78]	290	Asymptomatic	≥50	33–38 mo	Aspirin or dipyridamole (n=104); or anticoagulation with warfarin (n=9); or no medical treatment (n=82)	Death TIA Stroke	22.0, or 7.33 annualized 8.21, or 2.74 annualized 9.23, or 3.1 annualized
Spence et al.[79]	168	Asymptomatic	≥60	≥12 mo	Multiple, including antiplatelet, statins, exercise, Mediterranean diet, ACE inhibitors	Stroke	3.8, or 1.3 annualized
Marquardt et al.[80]	1153	Asymptomatic	≥50	Mean 3 y	Multiple, including antiplatelet, anticoagulation, statin, antihypertensive drugs	Ipsilateral stroke	0.34 (95% CI 0.01 to 1.87) average annual event rate
Abbott et al.[81]	202	Asymptomatic	60–90	Mean 34 mo	Multiple, including antiplatelet, warfarin, antihypertensive drugs, cholesterol-lowering therapy	Ipsilateral stroke or TIA; ipsilateral carotid hemispheric stroke	Ipsilateral stroke or TIA or retinal event: 3.1 (95% CI 0.7 to 5.5) average annual rate; ipsilateral carotid hemispheric stroke: 1.0 (95% CI 0.4 to 2.4) average annual rate

Conclusions

- *Stroke is one of the leading causes of death and disability in industrialized nations.*
- *There are identifiable risk factors that predispose patients for carotid stenosis, which is responsible for up to 1/3 of all strokes.*
- *There is an accepted screening exam in place that is minimally invasive, and has a proven strong degree of sensitivity and specificity.*
- *Cost-effective alternatives to conventional carotid duplex already exist.*
- *Screening selected patients could result in potential health care savings costs in the billions.*

Conclusions

- *Mild, asymptomatic disease typically has a benign course with appropriate medical therapy.*
- *Moderate to severe disease should continue to be followed on at least a yearly basis.*
- *Current surveillance strategies are likely too conservative, though the frequency of follow-up care has yet to be determined.*

Thank you