LUNG CANCER WORKSHOP

prevent cancer FOUNDATION

Prevent Cancer Foundation
"Quantitative Imaging Workshop XIII: Lung Cancer, COPD and Cardiovascular Disease – Exploring the Intersections"
June 13-14, 2016, Bethesda Marriott, Bethesda, MD

The New Frontier in Integrating Quantitative Coronary Artery Calcification Analysis

Disclosure: Philips Medical Systems Consultant

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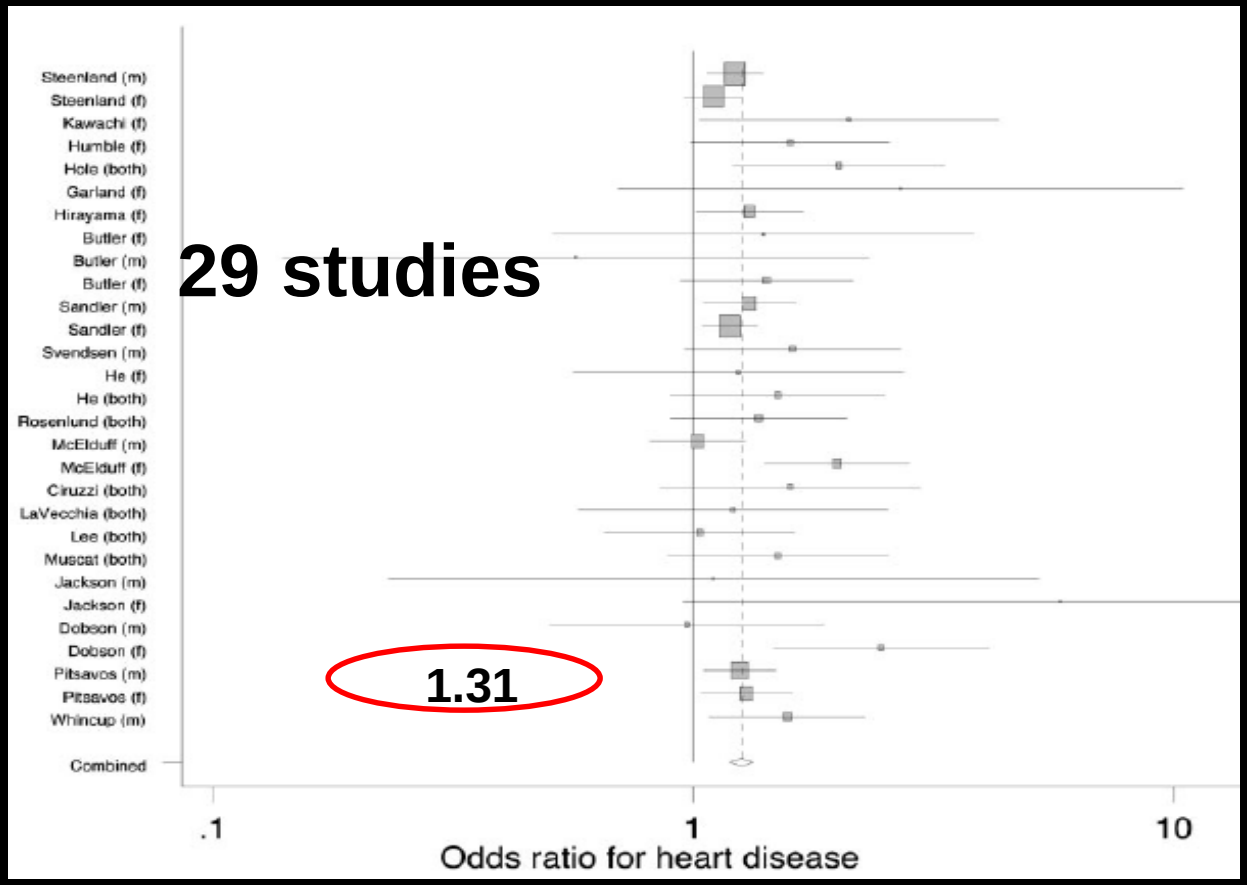
Comparative Effects of Passive and Active Smoking

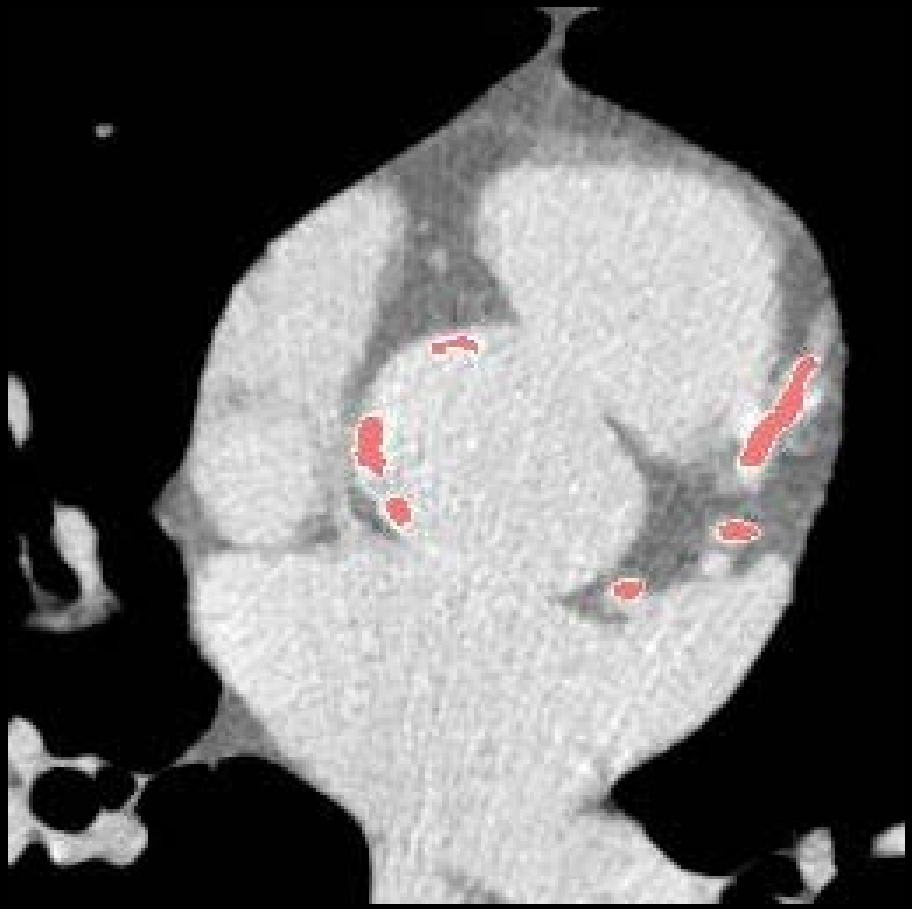


	SHS Exposure	Active	SHS/Active
Risk of heart disease			
29 study meta-analysis	1.31 Chronic	1.78	40%

Barnoya. Circulation. 2005;111:2684-2698

1. Risk Prediction

CAC is unequivocally the most powerful predictor of cardiac risk in the asymptomatic primary prevention population and should replace risk factor based analyses (FRS, Procam, ESC).



Prognostic Power of CAC in Asymptomatic Patients

	N	Mean Age (years)	Follow up (years)	Calcium Score Cutoff	Comparator Group for RR Calculat	Relative Risk Ratio
Arad (1)	1,173	53	3.6	CAC>160	CAC< 160	20.2
Park (2)	967	67	6.4	CAC >142.1	CAC <3.7	4.9
Raggi (3)	632	52	2.7	Top Quartile	Lowest	13
Wo						.8
Kor						0.5
Gre						.9
Sha						.4
Ara						0.7
Tay						1.8
Vliegenthart (10)	1795	71	3.3	CAC>1000	CAC<100	8.3
				CAC 400-1000	CAC<100	4.6
Budoff (11)	25,503	56	6.8	CAC>400	CAC 0	9.2
Lagoski (12)	3601	45-84	3.75	CAC>0	CAC 0	6.5
Becker (13)	1726	57.7	3.4	CAC>400	CAC 0	6.8 men 7.9 women
Detrano (14)	6814	62.2	3.8	CAC>300	CAC 0	14.1
Erbel (15)	4487	45-75	5	>75th%	<25th%	11.1 men 3.2 women

In every study, CAC has been superior to and significantly added to the area under the ROC curve for all risk factor based aalyses!

Summary of CAC Absolute Event Rates from 14,856 Pts in 5 Prospective Studies

CAC	FRS Risk	10 yr event rate
0	very low	1.1-1.7 %
1-100	low	2.3-5.9 %
100-400	intermediate	12.8-16.4 %
>400	high	22.5-28.6 %
>1000	very high	37 %

Reclassification of FRS Risk by CAC
Primary Prevention Outcome Studies

Study	% Reclassified	N	Age	Follow up (yrs)
MESA		5878	62.2	5.8
FRS 0-6%	11.6%			
FRS 6-20%	54.4%			
FRS				
NRI				
Heinz				
FRS <10%	13.0%			
FRS 10-20%	65.6%			
FRS >20%	34.2%			
NRI				
Rotte				
FRS<10%	12%			
FRS 10-20%	52%			
FRS>20%	34%			
NRI	19%			

RF based prediction in intermediate risk group is worse than a flip of the coin!

RF based prediction in high risk group is wrong in 1/3 of pts

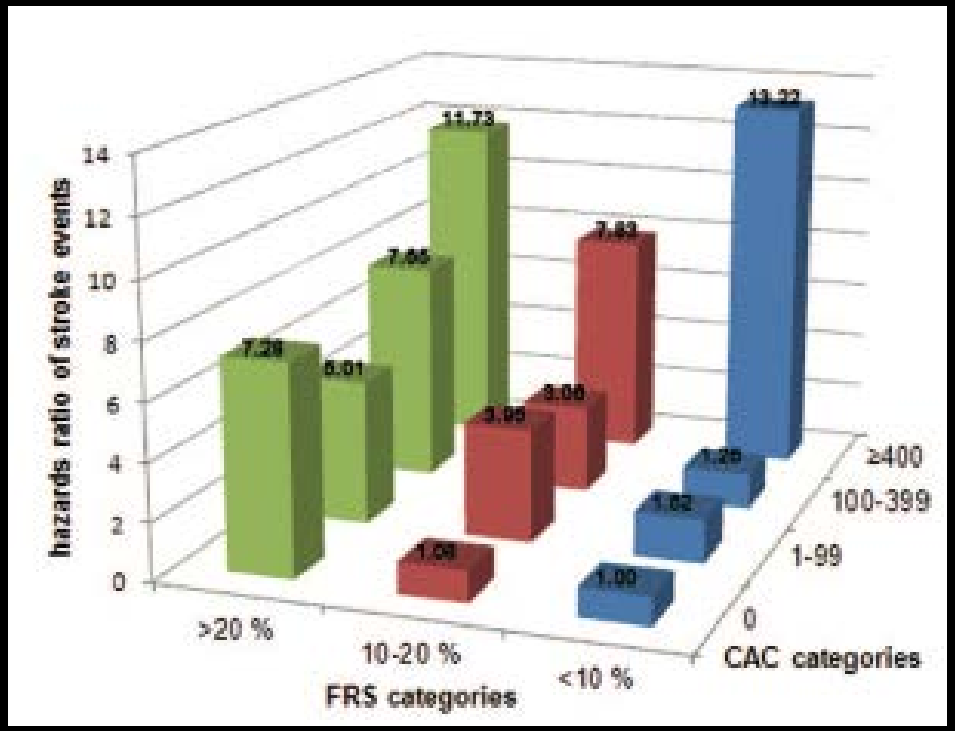
Hecht. J Diabetes. 2012

CAC is an independent Stroke Predictor in the General Population: Heinz Nixdorf Recall Study

4180 patients, 45–75 years; 47.1% men,
94.9±19month follow up

	CAC	
	CVA	no CVA
Median	104.8	11.2
Q1;Q3	14.0;482.2	0;106.2
P	<0.001	

	MV HR	p
log10(CAC+1)	1.52	0.001
Age/5y	1.35	<0.001
SBP/10mm	1.25	<0.001
Smoking	1.75	0.025



CAC predicted stroke:
men and women
esp<65 years of age
independent of AF
Low and intermediate FRS

Hermann. Stroke. 2013;44:1008-1013

Redefinition of Normal Lipids

There are no “normal cholesterol” values that apply to the individual patients in the population based studies from which they were derived

“normal” : cholesterol values at which level there is *no* subclinical atherosclerosis

“abnormal”: cholesterol values at which level there *is* subclinical atherosclerosis, with the severity of “abnormal” depending on the degree of subclinical atherosclerosis.

Major CAC Progression Studies

First Author (Ref. #)	N	Follow-Up, yrs	Progression	Progression HR
Raggi et al. (58)	813	2.1	Event: 47% No event: 26% $p < 0.01$	
Raggi et al. (59)	495	3.2	Event: 42% No event: 17% $p < 0.0001$	>15% vs. <15%: 17.2
Budoff et al. (60)	4,609	3.1		>15% vs. <15%: 2.98 $p < 0.0001$
Budoff et al. (61)	6,778	7.6	CAC 0 baseline CAC >0 baseline	>5 AU/yr vs. <5 AU/yr: 1.4 >100 AU/yr: 1.2 >300 AU/yr: 3.8 5%-14%/yr: 1.1 14%-29%/yr: 1.6 >30%/yr: 1.5
Wong et al. (62)	5,662	4.9	Third progression tertile Events/1,000 person-yrs DM + MetS: 30.7 MetS w/o DM: 26.4 Neither: 17.7	Third tertile vs. no progression 8.5 4.1
Kiramijyan et al. (63)	296 DM 300 non-DM	4.7	Event-free survival ΔCAC / DM / No DM <10% / 97.9% / 100% 10%-20% / 95.9% / 97.2% 21%-30% / 92.7% / 94% >30% / 79.6% / 90.6%	DM vs. no DM Δ10%-20% vs. <10%: 1.88 Δ21-30% vs. <10%: 2.29 Δ>30% vs. <10%: 6.95

Coronary Calcium Progression

- Significant progression indicates worse prognosis irrespective of baseline level
- Absence of progression indicates excellent prognosis irrespective of baseline level
- Increased progression associated with MI despite LDL lowering indicates failure of statin rx to halt plaque formation

Redefinition of Residual Risk

Old Definition: Occurrence of events despite treatment

New Definition: Disease progression measured by serial CAC evaluation of subclinical atherosclerosis

Guidelines and Appropriateness Criteria

Coronary Artery Calcium

	Population	Recommendation
2009 USPSTF	NA	C
2010 ACC/AHA Risk Guidelines	10-20% intermediate risk	IIA
	Diabetics >40 yo	IIA
	6-10% low to intermediate risk	IIB
2010 Appropriate Use Criteria	10-20% intermediate risk	Appropriate
	Low risk with family history of premature coronary disease	Appropriate
	High risk	Uncertain
	Low risk	Inappropriate
2012 ESC Risk Guideline	Intermediate risk	IIA
2013 ACC/AHA Cholesterol and Risk Guidelines	Uncertain risk after Pooled Cohort Equations	IIB
2016 SSCT CAC Guidelines	≥5.0% Risk by Pooled Cohort Equations	IIA

American College of Radiology Indications

A. Indications for Lung CT Scans

1. Evaluation of abnormalities discovered on chest images.
2. Evaluation of clinically suspected cardiothoracic pathology.
3. Staging and follow-up of lung cancer and other primary thoracic malignancies, and detection and evaluation of metastatic disease.
4. Evaluation of cardiothoracic manifestations of known extrathoracic diseases.
5. Evaluation of known or suspected thoracic cardiovascular abnormalities (congenital or acquired), including aortic stenosis, aortic aneurysms, and dissection.
6. Evaluation of suspected acute or chronic pulmonary emboli.
7. Evaluation of suspected pulmonary arterial hypertension.
8. Evaluation of known or suspected congenital cardiothoracic anomalies.
9. Evaluation and follow-up of pulmonary parenchymal and airway disease.
10. Evaluation of blunt and penetrating trauma.
11. Evaluation of postoperative patients and surgical complications.
12. Performance of CT-guided interventional procedures.
13. Evaluation of the chest wall.
14. Evaluation of pleural disease.
15. Treatment planning for radiation therapy.
16. Evaluation of medical complications in the intensive care unit or other settings.

American College of Radiology Performance Guidelines

B. Performance Guidelines for Lung CT Scans

1. Multirow detector acquisition.
2. Scan rotation time: ≤1 sec.
3. Acquired slice thickness: ≤2 mm.
4. Limiting spatial resolution: ≥8 lp/cm for ≥32-cm display field of view (DFOV) and ≥10 lp/cm for <24 cm DFOV.

Guidelines and Appropriateness Criteri

Low Dose Lung Scan

	Age	Pack Years	Within past
National Comprehensive Cancer Network	50-74	≥30	15 years
		≥20 with additional risk factor	15 years
American College of Chest Physicians and American Society for Clinical Oncology	55-74	≥30	15 years
American Cancer Society	55-74	≥30	15 years
American Association for Thoracic Surgery	55-79	≥30	15 years
	50-79	≥20 with 5% 5 year risk	15 years
American Lung Association	55-74	≥30	15 years
United States Preventive Services Task Force	55-79	≥30	15 years

Radiology imaging center eligibility criteria:

For purposes of Medicare coverage of lung cancer LDCT screening, an eligible LDCT screening facility is one that:

- Has participated in past lung cancer screening trials, such as the National Lung Screening Trial, or an accredited advanced diagnostic imaging center with training and experience in LDCT lung cancer screening;
- Must use LDCTs with an effective radiation dose less than 1.5 mSv; and
- Must collect and submit data to a CMS-approved national registry for each LDCT lung cancer screening performed. The data collected and submitted to a CMS-approved national registry must include, at minimum, all of the following elements:

Expand All | Collapse All

Decision Summary

The Centers for Medicare & Medicaid Services (CMS) proposes that the evidence is sufficient to add a lung cancer screening counseling and shared decision making visit, and for appropriate beneficiaries, screening for lung cancer with low dose computed tomography (LDCT), once per year, as an additional preventive service benefit under the Medicare program only if all of the following criteria are met:

Beneficiary eligibility criteria:

- Age 55-74 years;
- Asymptomatic (no signs or symptoms of lung disease);
- Tobacco smoking history of at least 30 pack-years (one pack-year = smoking one pack per day for one year; 1 pack = 20 cigarettes);
- Current smoker or one who has quit smoking within the last 15 years; and

A 45-yearold male underwent a noncontrast, nongated chest CT for further evaluation of pulmonary symptoms. Extensive CAC was present but not reported and statin therapy was not implemented. One year later he died suddenly from a massive myocardial infarction.

Choose the correct answer(s):

1. Catastrophic and potentially avoidable but within the standard of care because reporting CAC on noncontrast CT scans is not part of radiology guidelines.

2. Catastrophic and potentially avoidable but within the standard of care because there are no randomized controlled trials (RCTs) demonstrating that CAC guided treatment affects outcomes positively.

1. Catastrophic and potentially avoidable but within the standard of care because reporting CAC on noncontrast CT scans is not part of radiology guidelines.

2. Catastrophic and potentially avoidable but within

Are radiologists obligated to report all significant findings in the field of view?

Barriers to Reporting

Additional time and effort, not likely to exceed 5 min, are required of the interpreting radiologist. While this may not seem excessive, when multiplied by the number of scans to be read on a daily basis, additional stress will be added to an already overloaded schedule and will not be readily accepted or reimbursed

Reporting very abnormal results to referring physicians who did not request the information and who may not know how it should be utilized may be daunting and consume additional time.

Referring physicians will be forced to act on, and take responsibility for, results they did not request and may not understand, and they will often need to refer these patients to those physicians capable of implementing the findings into treatment plans.

Barriers to Reporting

The importance of CAC may not be fully appreciated by the radiology community

Absence of reporting guidelines

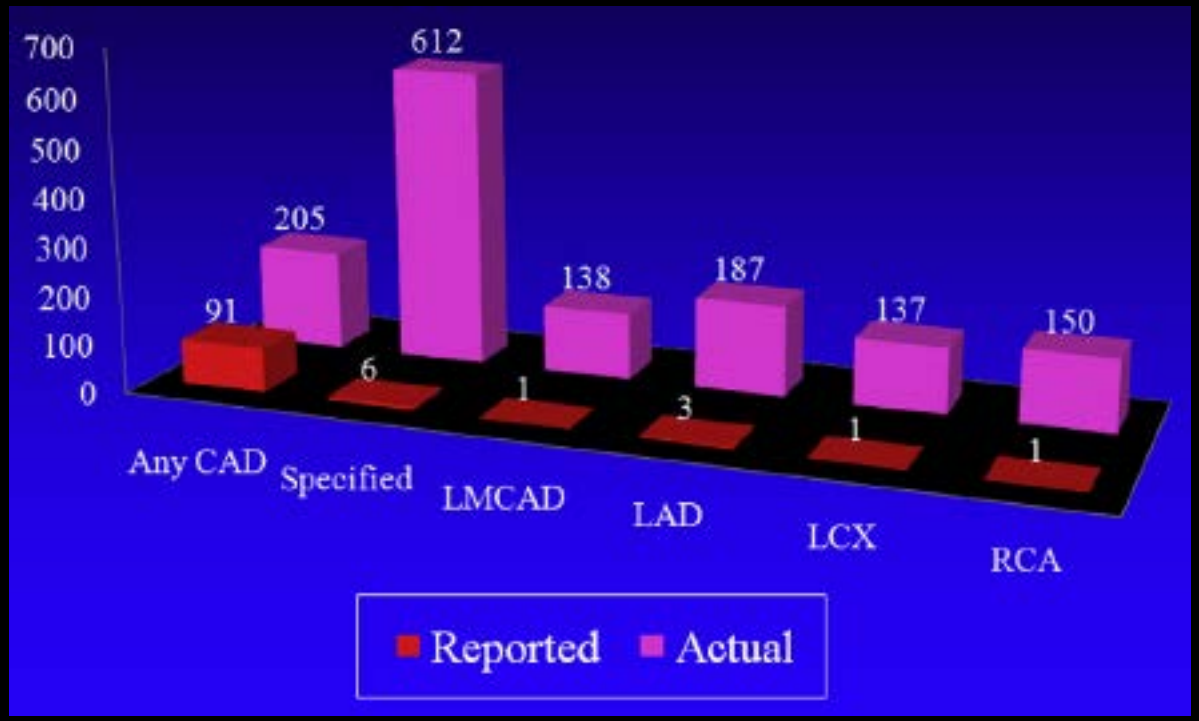
Expense of workstations capable of CAC analysis.

From the treatment perspective, the outstanding criticism of CAC has been the absence of RCTs demonstrating a positive effect on outcomes by CAC guided treatment, which has prevented its designation as a screening test by the U.S. Preventive Services Task Force and its reimbursement by insurance companies. In the absence of such trials can one be faulted for not reporting the CAC results or for not implementing them into patient care?

Frequency of unrecognized, unreported, or underreported CAC on noncardiac chest CT

355 pts: 136 known CAD, 219 suspected CAD
63 yo, 204 women

CAC + 58%; reported by radiologist in 58% of CAC+
LM CAC + 139; specified in 1 (0.7%)
LAD CAC+ 188; specified in 6 (3%)



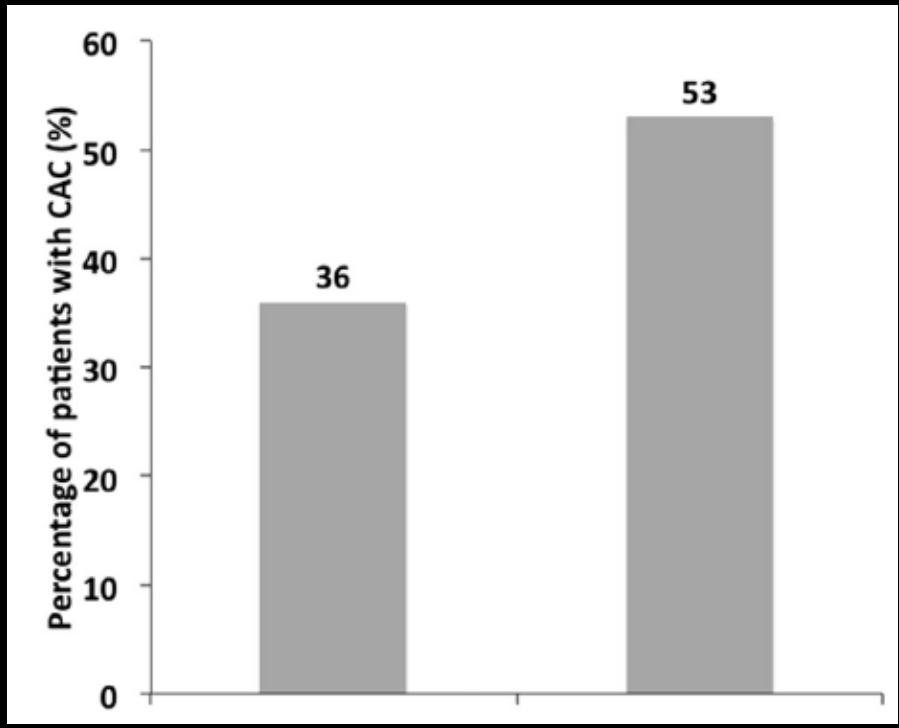
Williams, JCCT 2013;7:167-72. 2013;6:514-521

Interplay of Physician Awareness and Reporting of Incidentally Found CAC on Noncontrast CT on Clinical Management

201 consecutive pts
CAC evaluated by radiologist and expert reader

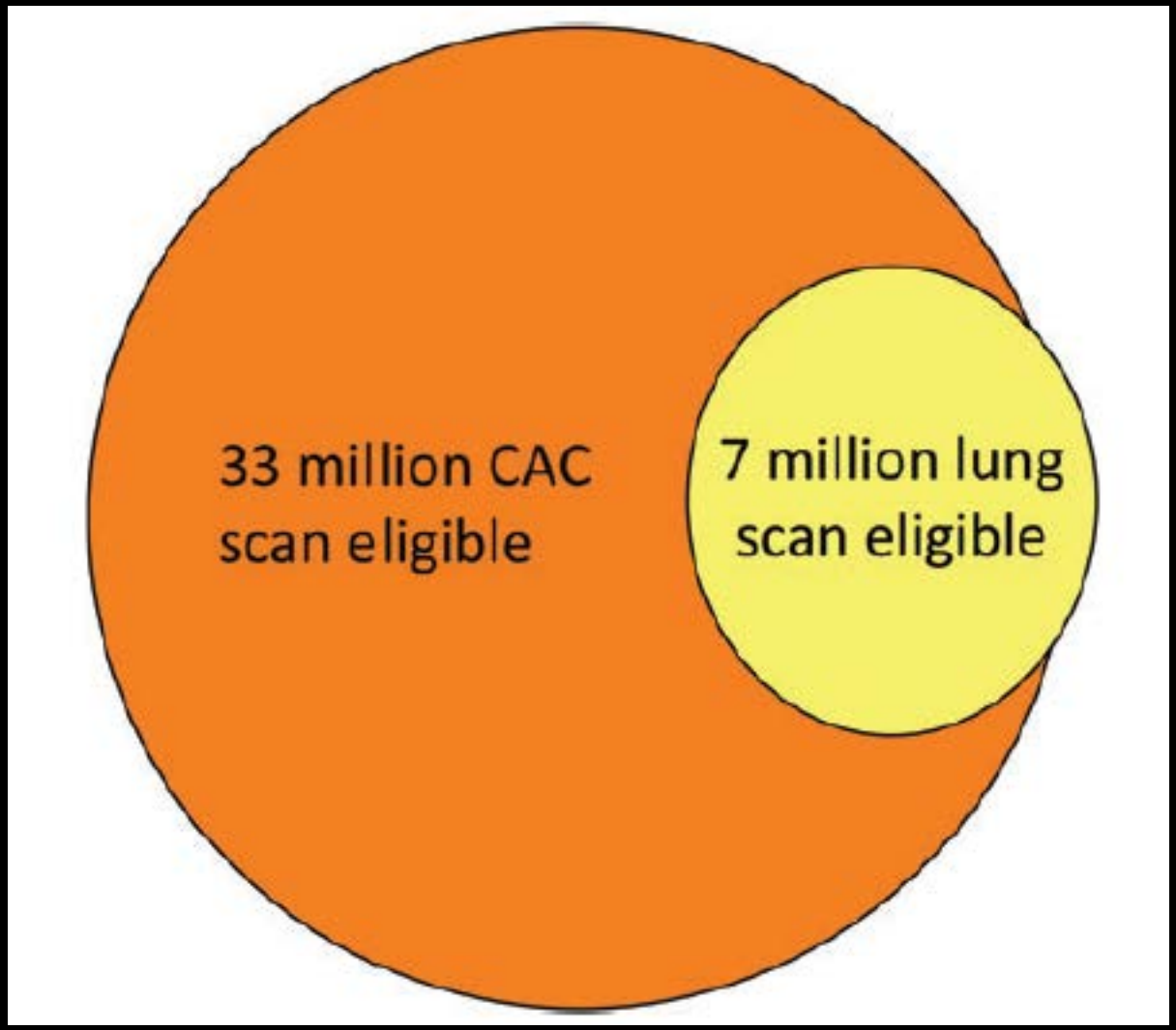
72 (36%) CAC>0 by radiologist
108 (53%) CAC>0 by expert reader
74/108 were CAC>0 by radiologist
increase in stain 4% and aspirin 5%

132 physicians
54% - CAD equivalent
23% were aware that incidental CAC was reported
4% would make CAC based decisions



Rozanski. Am J Cardiol 2015;115:1513-7

~95% of lung scan candidates are CAC candidates as well



European Heart Journal
doi:10.1093/eurheartj/ehu296

CURRENT OPINION

Combined detection of coronary artery disease and lung cancer

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At the present time, it is logical and reasonable that gated CAC scanning be performed on lung scans and that the entire thorax be imaged during CAC scans in those who meet recommendations for both evaluations.

American College of Radiology National Radiology Data Registry- Lung Cancer Screening Registry (ACR NRDR-LCSR)

7A15. *Other clinically significant or potentially significant abnormalities – CT exam result modifier S:

O No O Yes

If yes, what were the other findings? (Select all that apply.)

☐ Aortic aneurysm ☐ Coronary arterial calcification, moderate or severe ☐ Pulmonary fibrosis

☐ Mass, please specify, e.g., neck, mediastinum, liver, kidneys: _____

☐ Other interstitial lung disease, select type if known:

O UIP/IPF
O ILD, other, please specify: _____
O ILD, unknown

2016 SCCT/STR Guidelines for Coronary Artery Calcium Scoring of Noncontrast Noncardiac CT Scans

A Report of the Society of Cardiovascular Computed Tomography/Society of Thoracic Radiology

Expert Work Group Members

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Site Requirements

ALARA

≥300 CT/year

≥10 detector rows

state and federal requirements and ACR or equivalent technical standards and practice guidelines

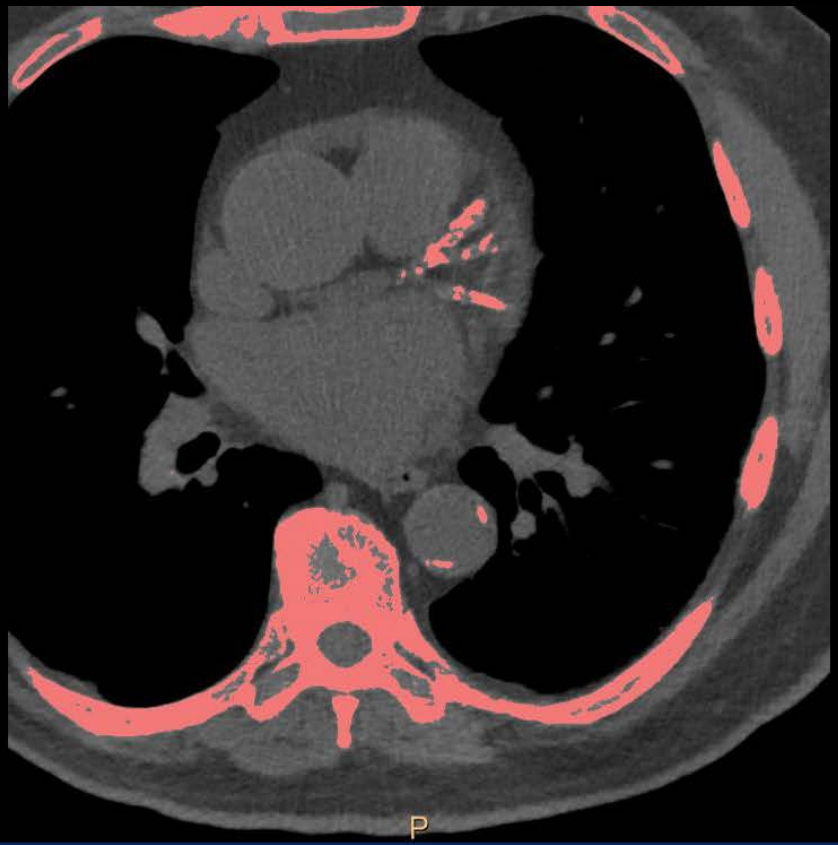
Technical Issues

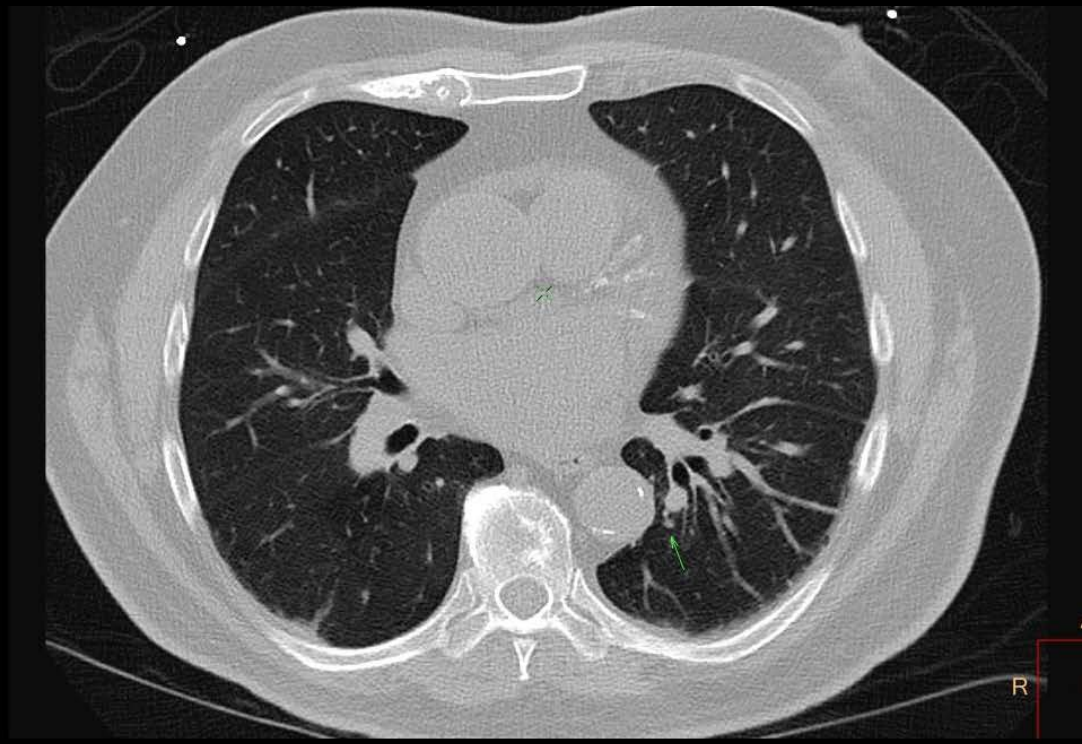
Always 120kVp: database driven

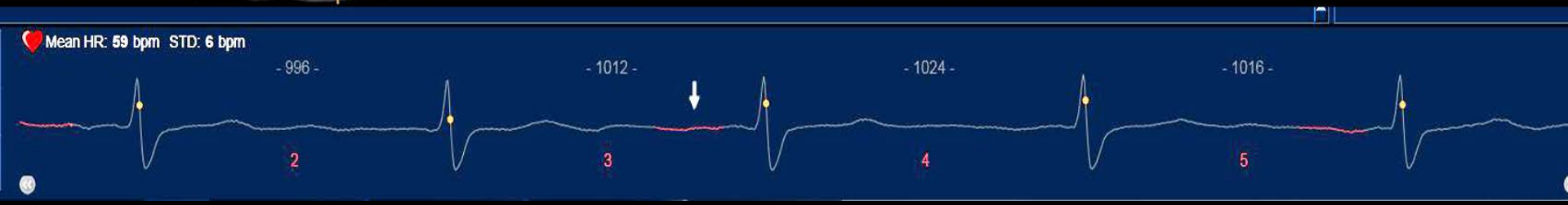
Reconstruction to 2.5-3 mm slices

Iterative reconstruction and lower mAs to reduce radiation

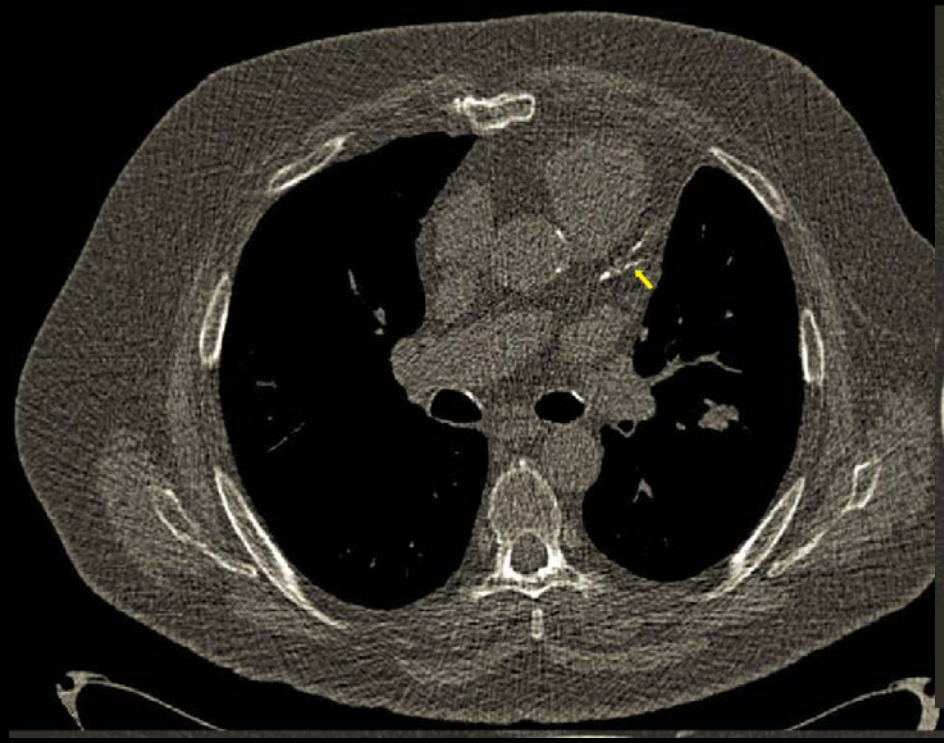
Gated

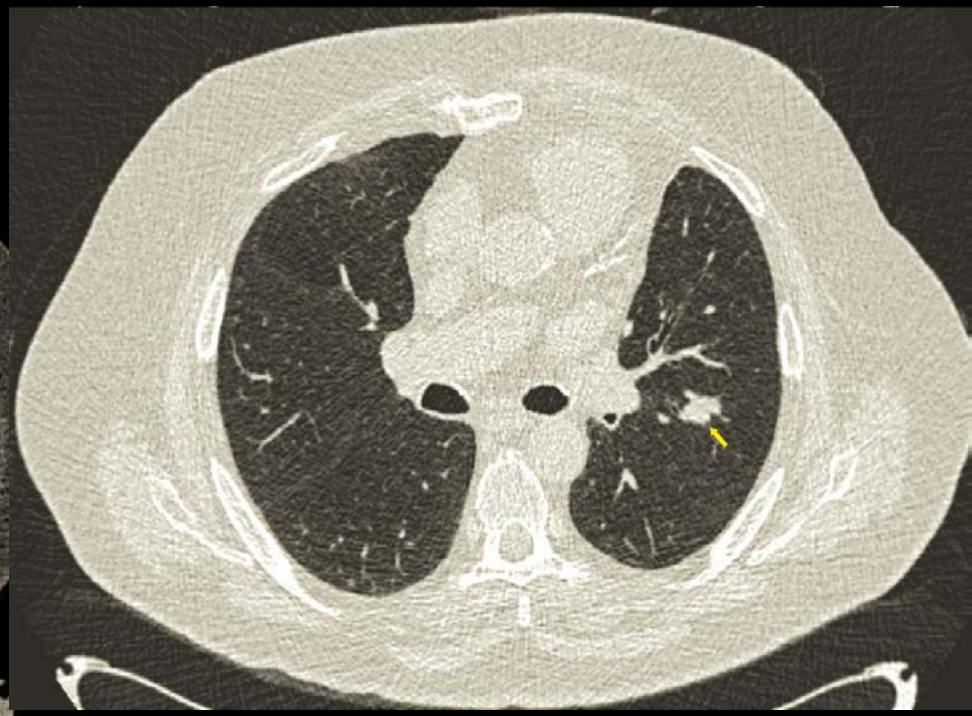






Nongated





Coronary Calcium Scores as Function of Patient Age and Gender – Results of National Database

MEN (n=28,250)	**EBCT Coronary Calcium Scores in Asymptomatic Patients as a Function of Patient Age at the Time of the Examination**						
Percentiles /Age (yrs)	40-45	46-50	51-55	56-60	61-65	66-70	70+
10	0	0	0	1	1	3	3
25	0	1	2	5	12	30	***69***
50	2	3	15	54	117	166	350
75	11	36	110	229	386	538	844
90	***69***	151	346	588	933	1151	1650
WOMEN (n=14,540)							
10	0	0	0	0	0	0	0
25	0	0	0	0	0	1	***4***
50	0	0	1	1	3	25	51
75	1	2	6	22	68	148	231
90	***4***	21	61	127	208	327	698

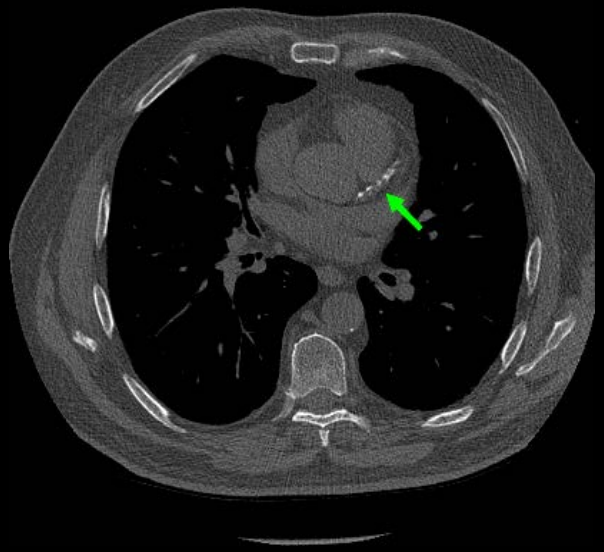
CAC on Low-Dose Ungated MDCT for Lung Cancer Screening: Concordance Study with Dedicated Cardiac CT

483 pts: 2 scans: gated and low dose ungated
16 slice, 3 mm thickness, 120 kVp

Variability	Nongated	Gated
Interobserver	9.6%	3.6%
Intertechnique	40-43%	
Concordance risk group	K=0.89	
NPV	98-99%	
Median	57	54

Wu. AJR 2008; 190:923–928

Nongated Ordinal CAC Scoring

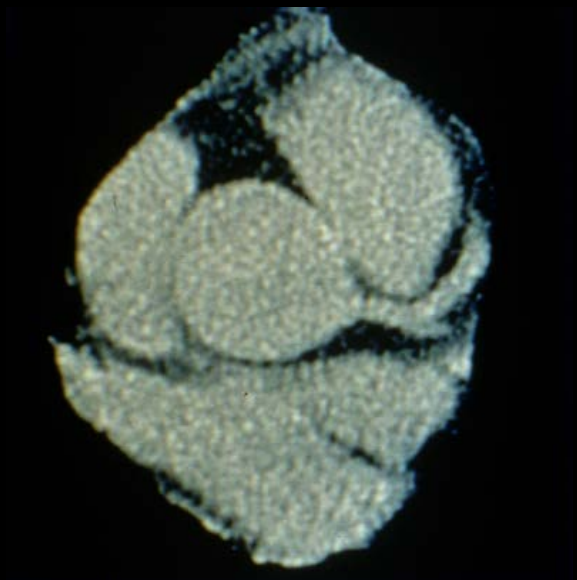


LM, LAD, LCx, RCA

CAC/artery: none (0), mild (1), moderate (2), marked (3)

CAC score: 0 -12/scan

Nongated Visual Analysis



Normal

Moderate Calcification

Severe Calcification

Nongated Agatston Score Prognostic Studies

Study	Duration	Pts/events	Adjusted	HR vs 0	95% CI
Jacobs	20.5 months	958/127 CHD events	1-100	1.38	0.39, 4.90
			101-1000	3.04	0.95, 9.73
			>1000	7.77	2.44, 24.75
Mets	3 years	1834/145 CVD events	100mm^3	1.08	1.05, 1.11
			500mm^3	1.48	1.27, 1.72
			>1500mm^3	3.22	2.05, 5.07
Chiles	7 years	1442/210 CHD death	1-100	1.27	0.69, 3.57
			101-1000	3.57	2.14, 7.48
			>1000	6.63	3.57, 14.97
Hughes-Austin	>6 years	651/157 All cause death	Nongated 6 mm		
			1-100	1.9	1.1, 3.1
			101-300	2.3	1.2, 4.3
			>300	2.6	1.4, 4.9
			Gated 3mm		
			1-100	2.1	1.1, 3.8
			101-300	2.9	1.5, 5.7
			>300	3.2	1.7, 6.0

Nongated Ordinal Score Prognostic Studies

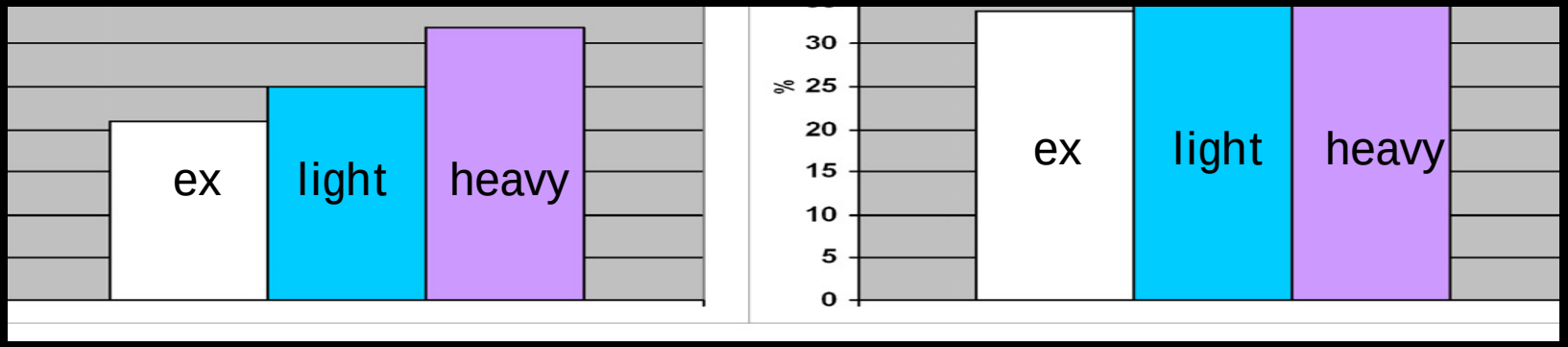
Study	Duration	Pts/events	Adjusted HR vs 0		95% CI
Shemesh	6 years	8782/193 CHD death	CAC 1-3	1.0	0.7, 1.5
			CAC 4-12	2.1	1.4, 3.1
Chiles	7 years	1442/210 CHD death	CAC 1-5	1.72	1.05, 3.34
			CAC 6-11	5.11	2.92, 10.94
			CAC 12-30	6.11	3.19, 14.05

Nongated Visual Score Prognostic Studies

Study	Duration	Pts/events	Adjusted HR vs 0		95% CI
Chiles	7 years	1447/210 CHD death	mild	2.09	1.3, 4.16
			moderate	3.86	2.02, 8.20
			heavy	6.9	3.73, 15.67

Development and progression of Coronary Artery Calcification in Long-term Smokers – Adverse Effects of Continued Smoking

1265 smokers, 50-70y, median 57; 45% women, >20 pack years, median 34
No CAD, 4 y volumetric nongated MDCT f/u
3 groups: ex, light (1-17/d), heavy (>17/d



0 CAC to >0CAC

CAC progression

Rasmussen. JACC 2013

Coronary Artery Calcium Scoring Techniques

Technique	Advantages	Disadvantages
EKG gated Agatston scoring	Huge database Standard of care 1000's of articles Guidelines	Software required EKG gating required
	with gated	No database
Nongated Ordinal scoring	No software required	No database Few articles Manual analysis Less reproducible
Visual assessment	No software required Quickest analysis	No database 1 article Eyeball analysis Less reproducible

The decision to report CAC, rather than the analysis method, is the most critical issue!

Coronary Artery Calcium Score Reports for Noncontrast CT Scans

Coronary Artery Calcium Gated and Nongated Agatston score

Total: Percentile: LM: LAD: LCx: RCA:

Score	Risk	Recommendations
0	very low	healthy lifestyle
1-99	mildly increased	healthy lifestyle consider moderate statin, especially if >75th%
100-399	moderately increased	healthy lifestyle moderate to very intensive statin + ASA
400-1000 or ≥75th percentile for age, gender and ethnicity (MESA database)	moderate to severely increased	healthy lifestyle very intensive statin + second drug as needed ASA consider functional testing to r/o obstruction aggressive BP lowering referral to internist or preventive cardiologist
>1000	severely increased	healthy lifestyle very intensive statin + second drug as needed ASA functional testing to r/o obstruction aggressive BP lowering referral to internist or preventive cardiologist

Coronary Artery Calcium Score Reports for Noncontrast CT Scans

Coronary Artery Calcium Ordinal Score (0-12)

Total: LM: LAD: LCx: RCA:

Score	Risk	Recommendations
0	very low	healthy lifestyle
1-3	mild to moderately increased	healthy lifestyle moderate statin + ASA
4-12	moderate to severely increased	healthy lifestyle very intensive statin + second drug as needed ASA consider functional testing to r/o obstruction aggressive BP lowering referral to internist or preventive cardiologist

Coronary Artery Calcium Score Reports for Noncontrast CT Scans

Coronary Artery Calcium Ordinal Score (0-30)

Total: LM: LAD: LCx: RCA:

Score	Risk	Recommendations
0	very low	healthy lifestyle
1-5	mildly increased	healthy lifestyle consider moderate statin especially if >75th%
6-11	moderately increased	healthy lifestyle moderate to very intensive statin +ASA
12-30	moderate to severeley increased	healthy lifestyle very intensive statin + second drug as needed cSA Consider functional testing to r/o obstruction aggressive BP lowering referral to internist or preventive cardiologist

Coronary Artery Calcium Score Reports for Noncontrast CT Scans

Coronary Artery Calcium Visual Score

Total: LM: LAD: LCx: RCA:

Score	Risk	
None	very low	healthy lifestyle
Mild	mildly increased	healthy lifestyle consider moderate statin especially if >75th%
Moderate	moderately increased	healthy lifestyle moderate to very intensive statin + statin
Severe	moderate to severely increased	healthy lifestyle very intensive statin + second drug as needed ASA functional testing to rule out obstruction aggressive BP lowering referral to internist or preventive cardiologist

Shared Decision Making

The new SCCT CAC guidelines have recommended the inclusion of CAC in the statin SDM to ensure patients awareness of the potential effect it may have on the initiation of statin treatment.

Should CAC be included in the lung cancer screening shared decision making session, with a discussion of its benefits and harms, and should the patient be offered the option of declining CAC analysis and reporting?

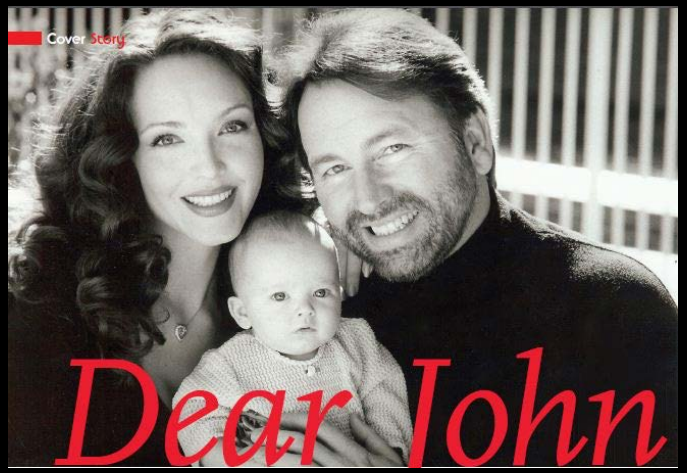
Since CAC is not the primary indication for the scan, has not been specifically mandated for SDM inclusion and may further complicate an already complicated discussion, it appears reasonable to treat it like any “other clinically significant or potentially significant abnormalities” to be recorded in the ACR NRDR-LCSR, rather than to include it in the SDM.

Thoracic Aortic Aneurysm

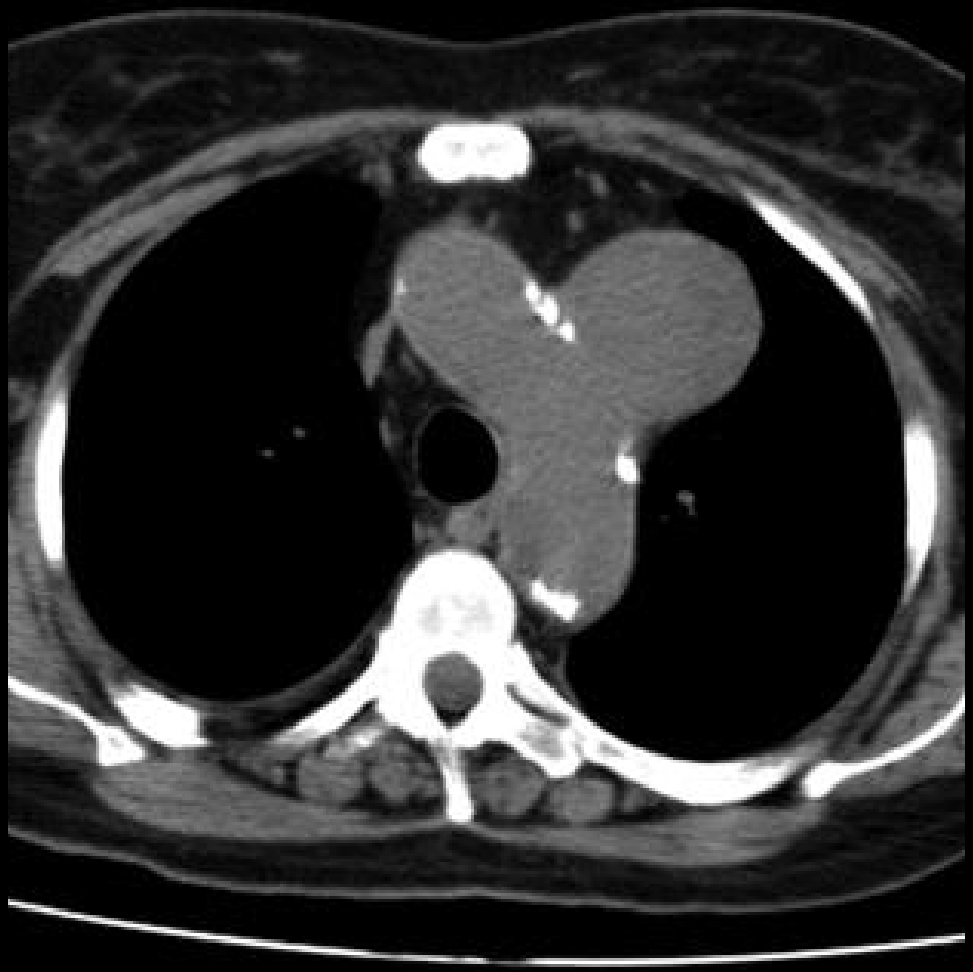
By SAMMY SALTZMAN CBS NEWS *December 14, 2010*

Richard Holbrooke Dies of Aortic Tear: What's That?

If John had been screened for the aneurysm prior to the aortic tear, he might be alive today



Thoracic Aortic Aneurysm



Thoracic Aortic Aneurysm

Aortic aneurysms were the primary cause of 10,597 deaths and a contributing cause in more than 17,215 deaths in the United States in 2009: 25% are thoracic

About two-thirds of people who have an aortic dissection are male.

The USPSTF recommends that men 65–75 years who have ever smoked should get an ultrasound screening for AAA, even if they have no symptoms.

There is no screening for thoracic aortic aneurysm!

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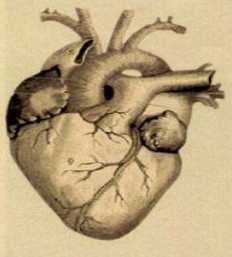
EDITORIAL COMMENT

"See No Evil"*

Harvey S. Hecht, MD

Screening for lung cancer, which always contains the CAC data without extra radiation or cost of acquisition, should be positioned as not just a scan for lung cancer but as an opportunity to detect the early stages of CAD. Moreover, because the aorta is always in the field of view, it would be reasonable to include the detection of thoracic aneurysms as well: a "triple rule out" of a different kind.

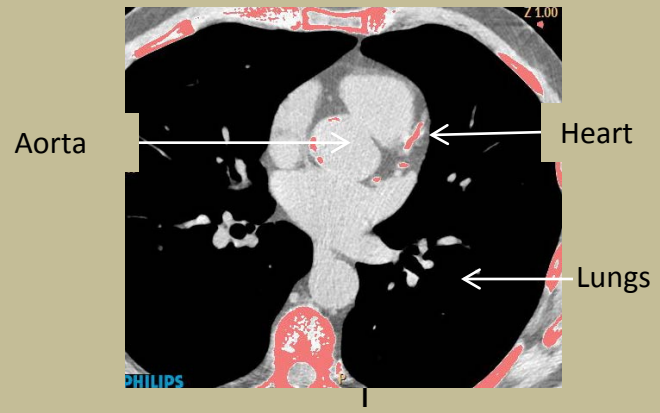
WE  NY

Even though we are one of the best in the country at lung cancer surgery and putting in stents and performing coronary artery bypass surgery and, we are working hard to make sure you never need them.

A PICTURE

IS WORTH

A THOUSAND LIVES



If you have risk factors for lung cancer, heart disease, aortic aneurysm or COPD, for $150 and 3 seconds of your time our noninvasive combined lung and coronary calcium heart scans (with the minimal radiation of a mammogram), can determine your risk of lung cancer, heart attack, aneurysm, and COPD and help you take the steps needed to avoid visiting our surgical suites and cath labs.

Call 212 241-3000 to schedule your appointment from 7 AM to 8 PM

Mount Sinai

New York's foremost center for lung and heart care. Staffed with world- reknowned lung and heart specialists, we're the first to bring world class combined lung and heart scanning to the world's greatest city.

Screening Randomized Controlled Trials

Disease	RCT
Lung cancer	yes
CAC for CAD	no
Thoracic aneurysm	no

Irrelevant: the information has already been acquired

Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials

What is already known about this topic

Parachutes are widely used to prevent death and major injury after gravitational challenge

Parachute use is associated with adverse effects due to failure of the intervention and iatrogenic injury

Studies of free fall do not show 100% mortality

What this study adds

No randomised controlled trials of parachute use have been undertaken

The basis for parachute use is purely observational, and its apparent efficacy could potentially be explained by a "healthy cohort" effect

Individuals who insist that all interventions need to be validated by a randomised controlled trial need to come down to earth with a bump

Conclusions: As with many interventions intended to prevent ill health, the effectiveness of parachutes has not been subjected to rigorous evaluation by using randomised controlled trials. Advocates of evidence based medicine have criticised the adoption of interventions evaluated by using only observational data. We think that everyone might benefit if the most radical protagonists of evidence based medicine organised and participated in a double blind, randomised, placebo controlled, crossover trial of the parachute.

Smith. BMJ 2003;327:1459–61

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"This approach transforms the problems of dealing with everything in the field of view into an unparalleled opportunity to save lives. As a responsible medical community, we cannot "see no evil" (ignore the CAC), "speak no evil" (not report the results), and "hear no evil" (not listen to and act on the results)."