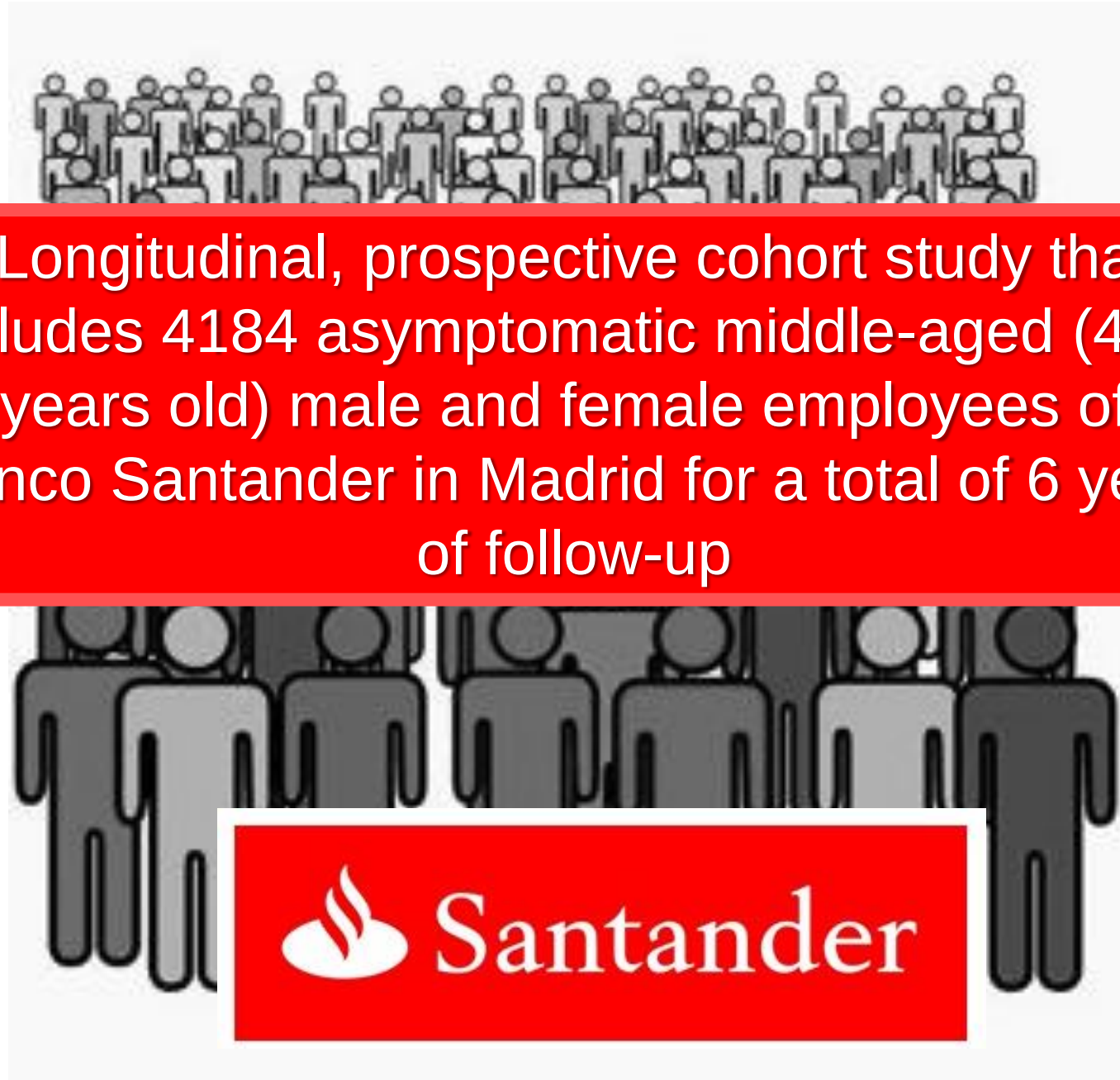
What is PESA-CNIC-Santander?



Longitudinal, prospective cohort study that includes 4184 asymptomatic middle-aged (40 to 54 years old) male and female employees of the Banco Santander in Madrid for a total of 6 years of follow-up

cnic

Objectives:

- To characterize the presence, location and progression of plaques in the early phases of subclinical atherosclerosis

- To study the association between the presence and progression of subclinical atherosclerosis with traditional and emerging cardiovascular risk factors (“omics”)

- To evaluate the influence of lifestyle behaviors (diet, physical activity and sleep patterns) and psychosocial factors on the prevalence and progression of subclinical atherosclerosis

- To characterize plaque composition and inflammation using PET/MRI in a subgroup of pts

PESA in context

Subclinical atherosclerosis cohorts

	Carotids		Coronaries		Femorals	
	Low-risk	High-risk	Low-risk	High-risk	Low-risk	High-risk
CARDIA Coronary Artery Risk Development in Young Adults			CACS 5.155 18-30 yo			
MESA	2D-US (IMT) 6814 45-84 yo		CACS 6834 45-84 yo			
ARIC Atherosclerosis Risk in Co	2D-US 15794 MRI 1670 45-64 yo					
HRP High-Risk Plaque		2D,3D-US 7687 55-80 yo		CACS 6814 55-80 yo		

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PESA in context

Subclinical atherosclerosis cohorts

	Carotids		Coronaries		Femorals	
	Low-risk	High-risk	Low-risk	High-risk	Low-risk	High-risk
CARDIA Coronary Artery Risk Development in Young Adults			CACS 5.155 18-30 yo			
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ARIC Atherosclerosis Risk in Co	2D-US 15794 MRI 1670 45-64 yo					
HRP High-Risk Plaque		2D,3D-US 7687 55-80 yo		CACS 6814 55-80 yo		
PESA	**2D,3D-US 4066 PET/MR 900 40-54 yo**		**CACS 4066 40-54 yo**		**2D,3D-US 4066 PET/MR 900 40-54 yo**	

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PESA in the context of CNIC

secondary

primary

primodial

CVD prevention

FOCUS Fixed Dose Combination Drug for Secondary cardiovascular Prevention

PESA

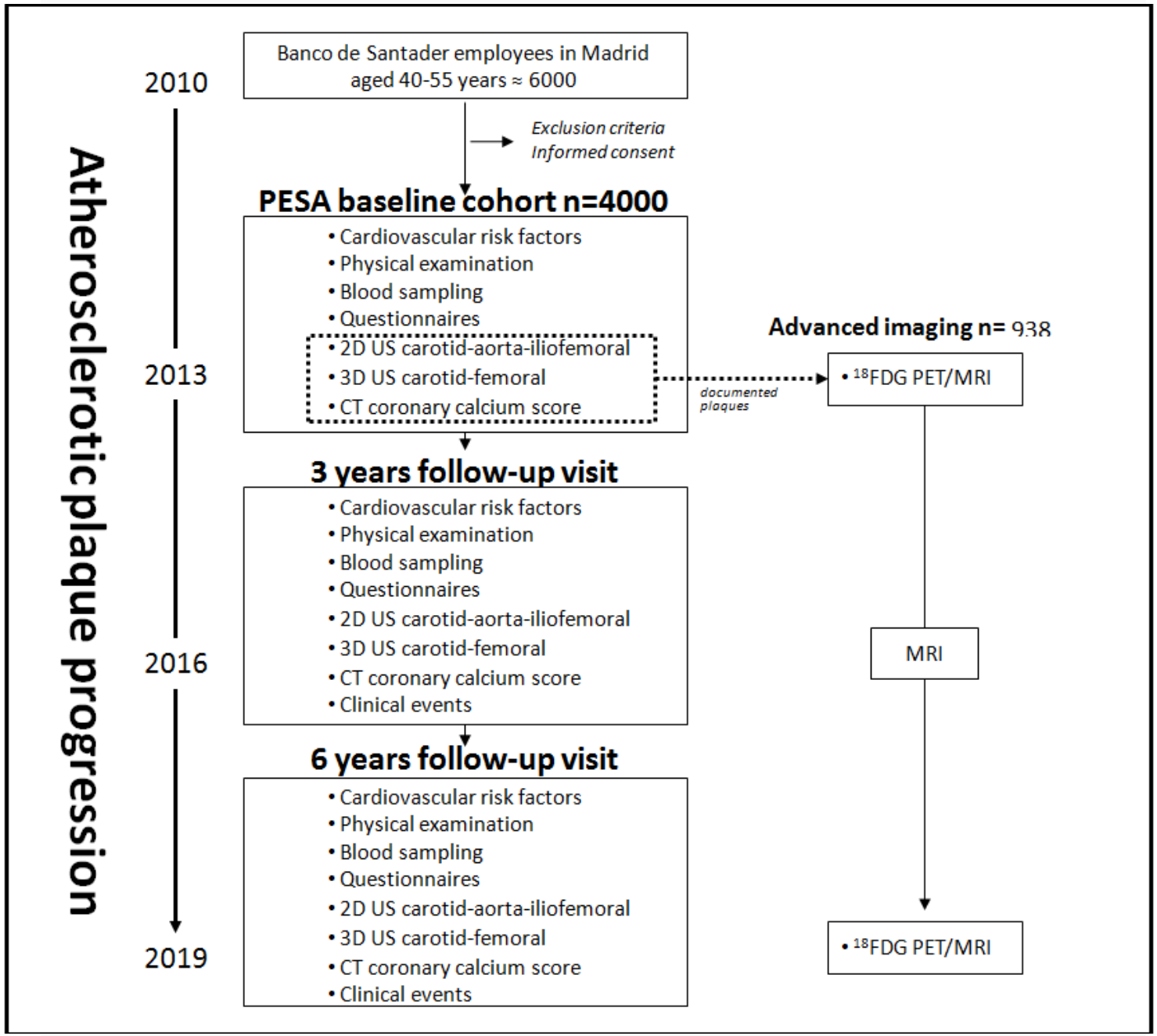
SECURE
SECONDARY PREVENTION OF CARDIOVASCULAR DISEASE IN THE ELDERLY

AWHS

Sí! Programa de Salud Integral

cnic

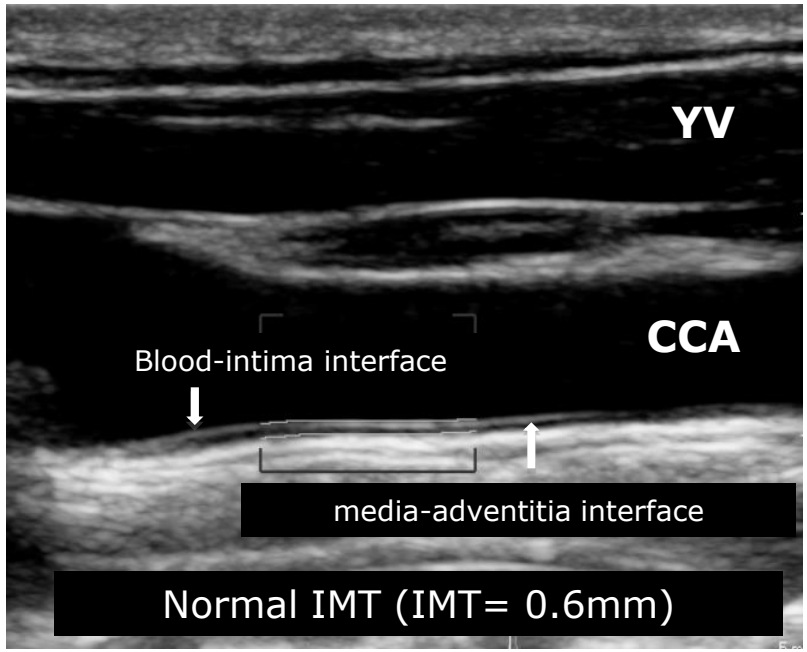
PESA-CNIC-Santander

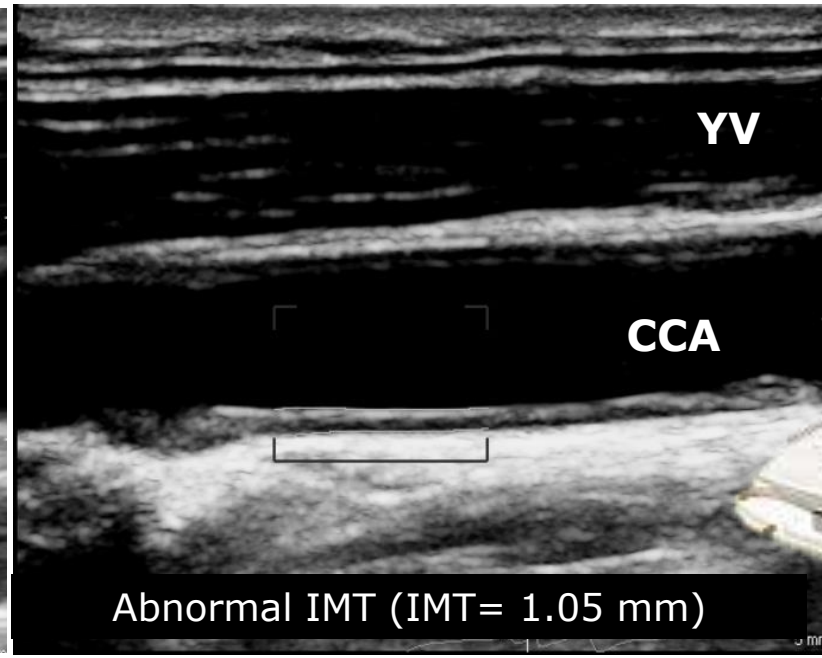


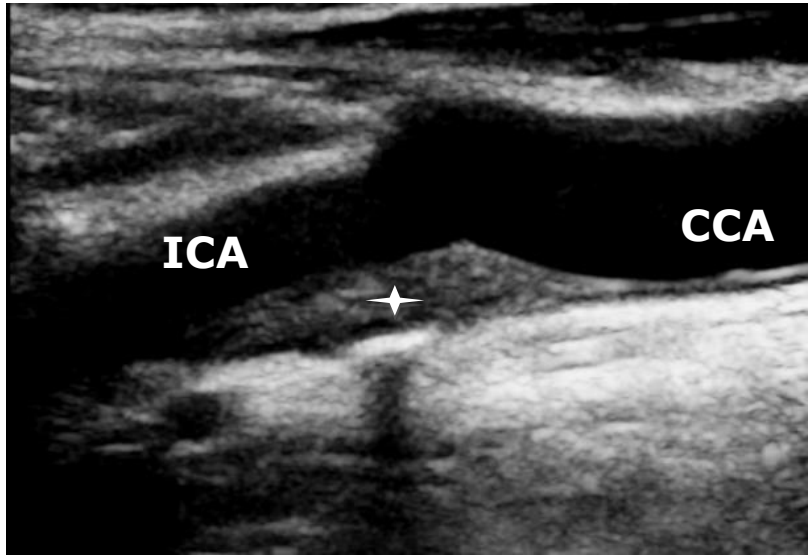
Carotid & Femoral 2D-Vascular ultrasound

PESA

Intima-media thickness and presence of plaques







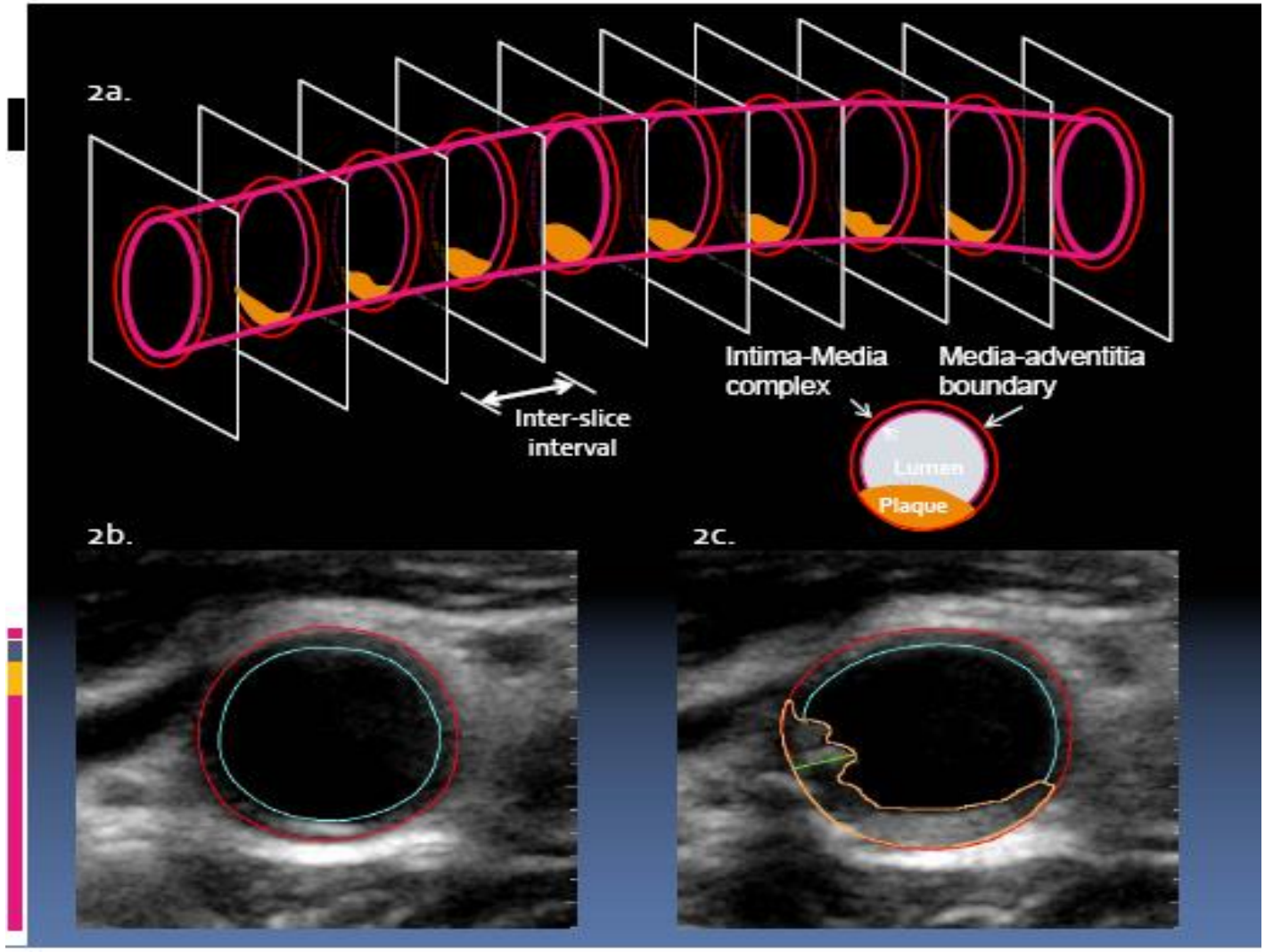
Presence of plaque

(yes/no, number, size)

<u>Plaque definition</u>: focal protrusion into the lumen >0.5 mm or >50% of the surrounding IMT or a diffuse thickness >1.5 mm.

3D-Ultrasound

3D-US of carotids and femorals



Plaque volume (mm^3)

H Sillesen, V Fuster, E Falk, P Muntendam 2009 (BioImage Study)

Advanced Imaging

PESA

Hybrid system: PET/MR

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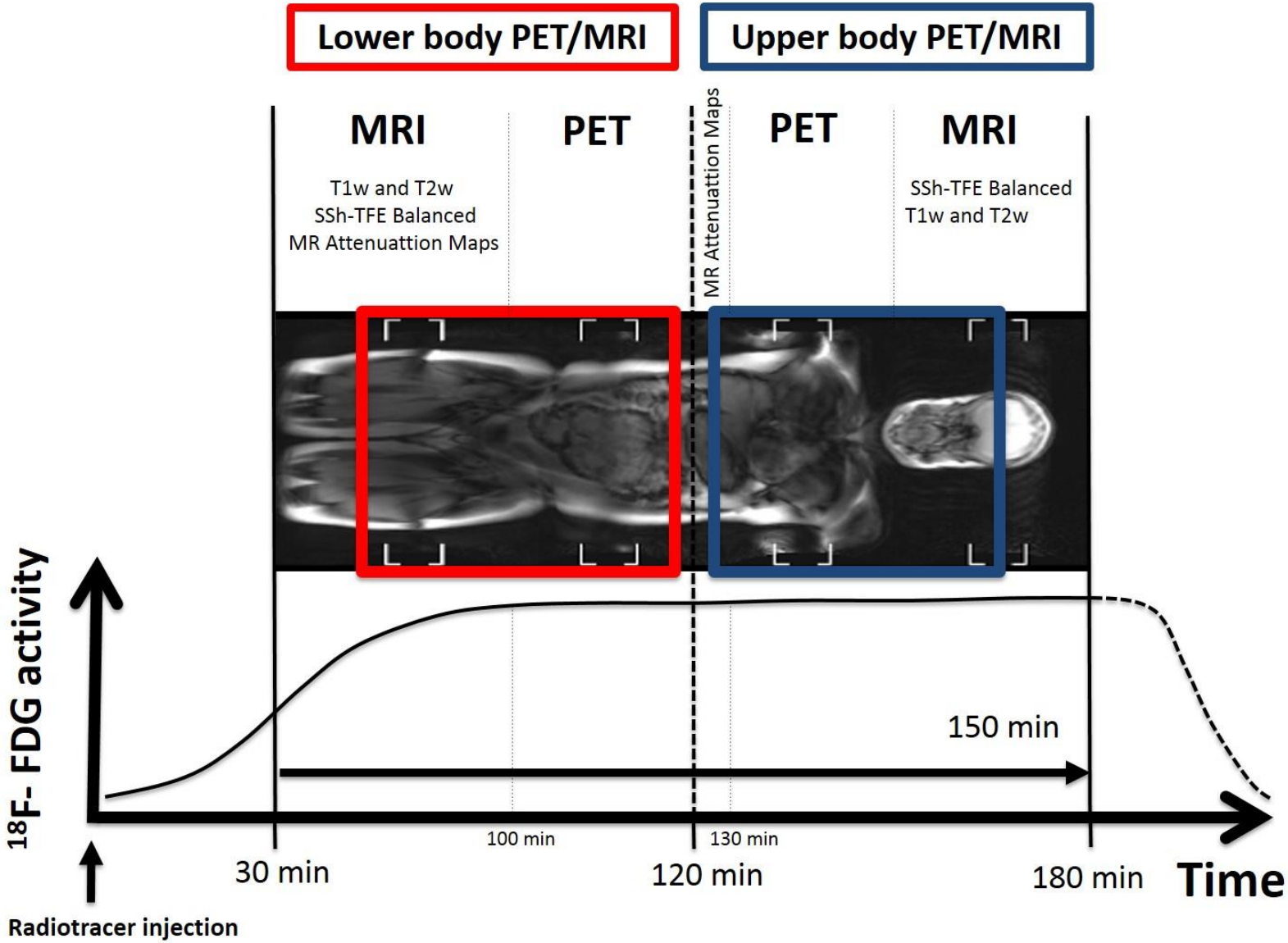
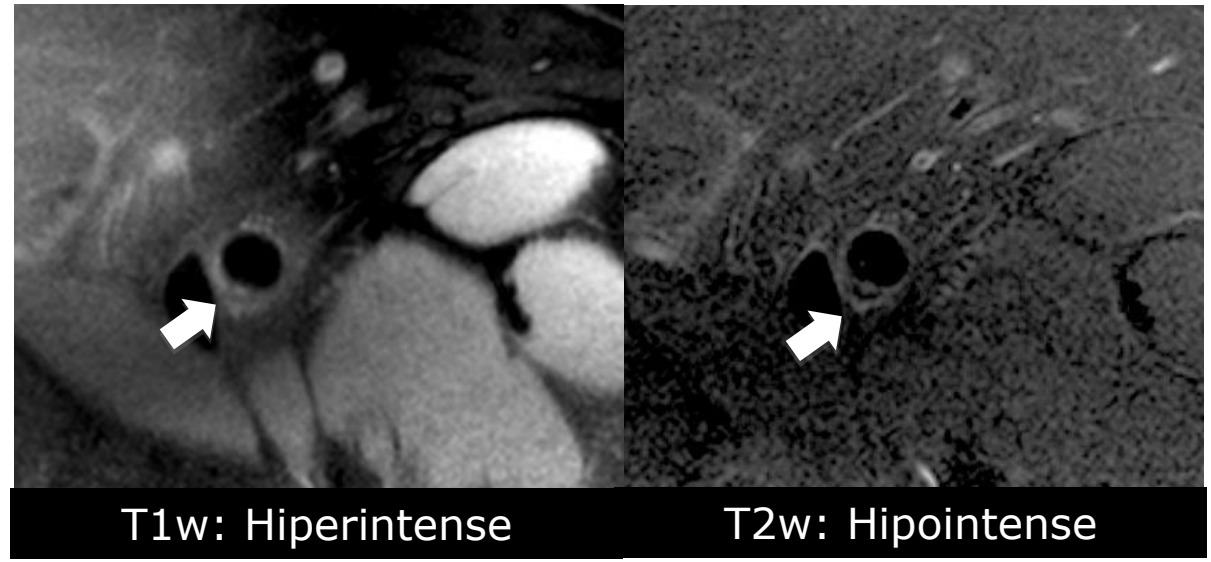


Protocol for the assessment of multiterritorial atherosclerosis by hybrid positron emission tomography/ magnetic resonance imaging (PET/MRI). ^{18}F-FDG: ^{18}F-fluordeoxyglucose; T1w: T1-weighted; T2w: T2-weighted; SSh-TFE: Single shot turbo field echo.

MR images: characterization

Lipid-rich plaque



Fibrous-rich plaque

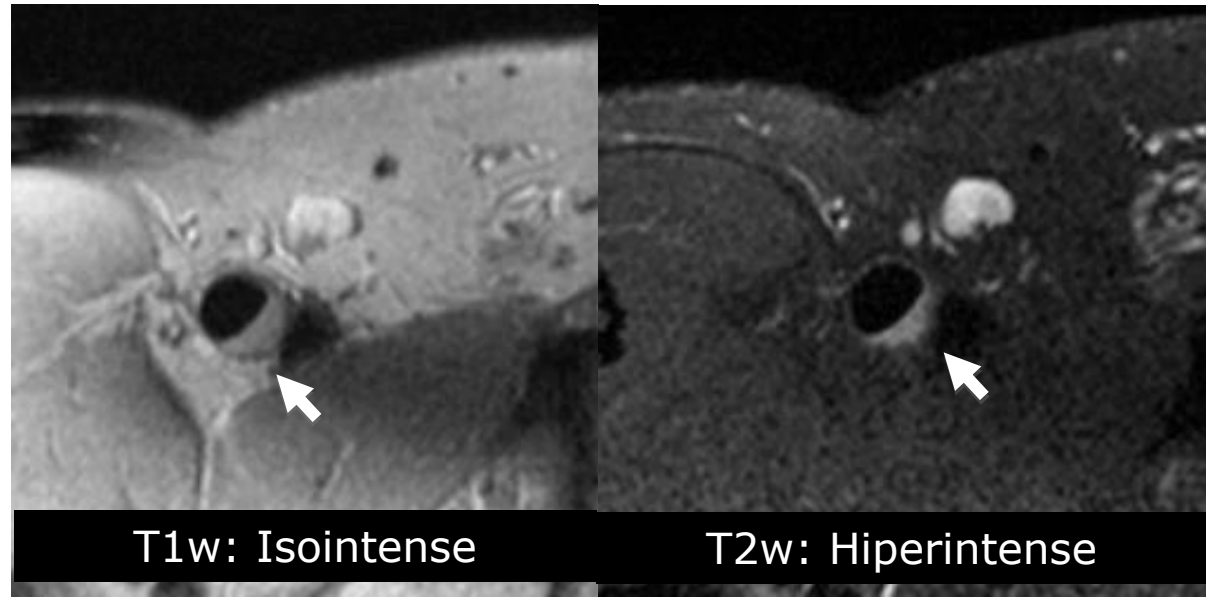
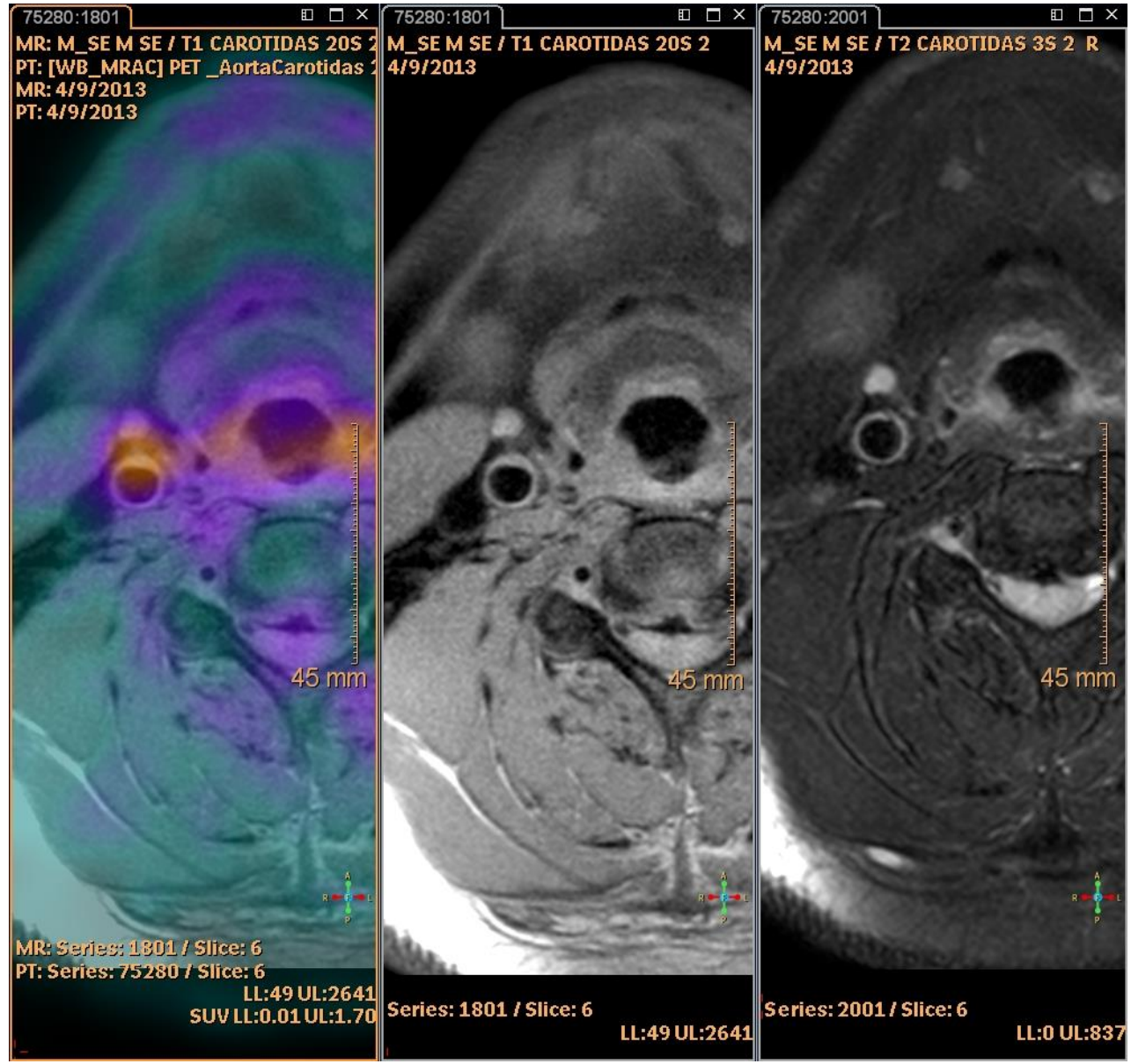


Image fusion: ^{18} FDGPET/RM

RIGHT CAROTID ARTERY UPTAKE



PESA-CNIC-Santander

Definition of Subclinical Atherosclerosis

Subclinical atherosclerosis was defined as the presence of atherosclerotic plaques in the carotid, aortic, or iliofemoral territories or CACS ≥1.

Extension of subclinical atherosclerosis was defined according to the number of vascular sites affected (right carotid, left carotid, abdominal aorta, right iliofemoral, left iliofemoral, and coronary arteries). Participants were classified as disease free (0 vascular sites affected) or as having focal (1 site), intermediate (2–3 sites), or generalized (4–6 sites) atherosclerosis.

Fernández-Friera L, et al. Circulation. 2015;131:2104-2113

PESA-CNIC-Santander study scientific milestones

Publication	Key Finding	Journal Citation	JCR Ranking
2015	64% of apparently healthy middle aged individuals have atherosclerosis	Circulation. 2015;131(24): 2104	2º
2016	Eating patterns impact atherosclerosis development	J Am Coll Cardiol. 2016;68(8):805	1º
2016	First study testing the role of telomere length in Atheros. development	J Am Coll Cardiol. 2016;67(21):2467	1º
2017	Oxidation of cholesterol is associated with the development of obesity	Diabetes. 2017 Feb;66(2):474-482	7º
2017	Novel 3D-US quantifies atherosclerosis burden in the body (mm^3)	J Am Coll Cardiol. 2017;70(3):301	1º
2017	Breakfast is the most important meal for protection against atheros.	J Am Coll Cardiol. 2017;70(15):1833	1º
2017	Question of what is considered “normal” cholesterol	J Am Coll Cardiol. 2017;70(24):2979	1º
2017	Fuster-BEWAT score for predicting the presence of atherosclerosis.	J Am Coll Cardiol. 2017;70(20):2463	1º
2019	Sleep duration and quality as a risk factor for atherosclerosis.	J Am Coll Cardiol. 2019;73(2):134	1º
2019	Findings of vascular inflammation in subclinical atherosclerosis.	J Am Coll Cardiol. 2019 (in press)	1º

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

Original Article

Prevalence, Vascular Distribution, and Multiterritorial Extent of Subclinical Atherosclerosis in a Middle-Aged Cohort

The PESA (Progression of Early Subclinical Atherosclerosis) Study

Leticia Fernández-Friera, MD, PhD; José L. Peñalvo, PhD; Antonio Fernández-Ortiz, MD, PhD; Borja Ibañez, MD, PhD; Beatriz López-Melgar, MD; Martín Laclaustra, MD, PhD; Belén Oliva, MSc; Agustín Mocoroa, MD; José Mendiguren, MD; Vicente Martínez de Vega, MD; Laura García, BSc; Jesús Molina, BSc; Javier Sanchez-Gonzalez, PhD; Gabriela Guzman, MD, PhD; Juan C. Alonso-Farto, MD, PhD; Eliseo Guallar, MD, PhD; Fernando Civeira, MD, PhD; Henrik Sillesen, MD, DMSc; Stuart Pocock, PhD; José M. Ordovás, PhD; Ginés Sanz, MD, PhD; Luis Jesús Jiménez-Borreguero, MD; Valentín Fuster, MD, PhD

Background—Data are limited on the presence, distribution, and extent of subclinical atherosclerosis in middle-aged populations.

Methods and Results—The PESA (Progression of Early Subclinical Atherosclerosis) study prospectively enrolled 4184 asymptomatic participants 40 to 54 years of age (mean age, 45.8 years; 63% male) to evaluate the systemic extent of atherosclerosis in the carotid, abdominal aortic, and iliofemoral territories by 2-/3-dimensional ultrasound and coronary artery calcification by computed tomography. The extent of subclinical atherosclerosis, defined as presence of plaque or coronary artery calcification ≥1, was classified as focal (1 site affected), intermediate (2–3 sites), or generalized (4–6 sites) after exploration of each vascular site (right/left carotids, aorta, right/left iliofemorals, and coronary arteries). Subclinical atherosclerosis was present in 63% of participants (71% of men, 48% of women). Intermediate and generalized atherosclerosis was identified in 41%. Plaques were most common in the iliofemorals (44%), followed by the carotids (31%) and aorta (25%), whereas coronary artery calcification was present in 18%. Among participants with low Framingham Heart Study (FHS) 10-year risk, subclinical disease was detected in 58%, with intermediate or generalized disease in 36%. When longer-term risk was assessed (30-year FHS), 83% of participants at high risk had atherosclerosis, with 66% classified as intermediate or generalized.

Conclusions—Subclinical atherosclerosis was highly prevalent in this middle-aged cohort, with nearly half of the participants classified as having intermediate or generalized disease. Most participants at high FHS risk had subclinical disease; however, extensive atherosclerosis was also present in a substantial number of low-risk individuals, suggesting added value of imaging for diagnosis and prevention.

Clinical Trial Registration—URL: http://www.clinicalTrials.gov. Unique identifier: NCT01410318.

(*Circulation*. 2015;131:00-00. DOI: 10.1161/CIRCULATIONAHA.114.014310.)

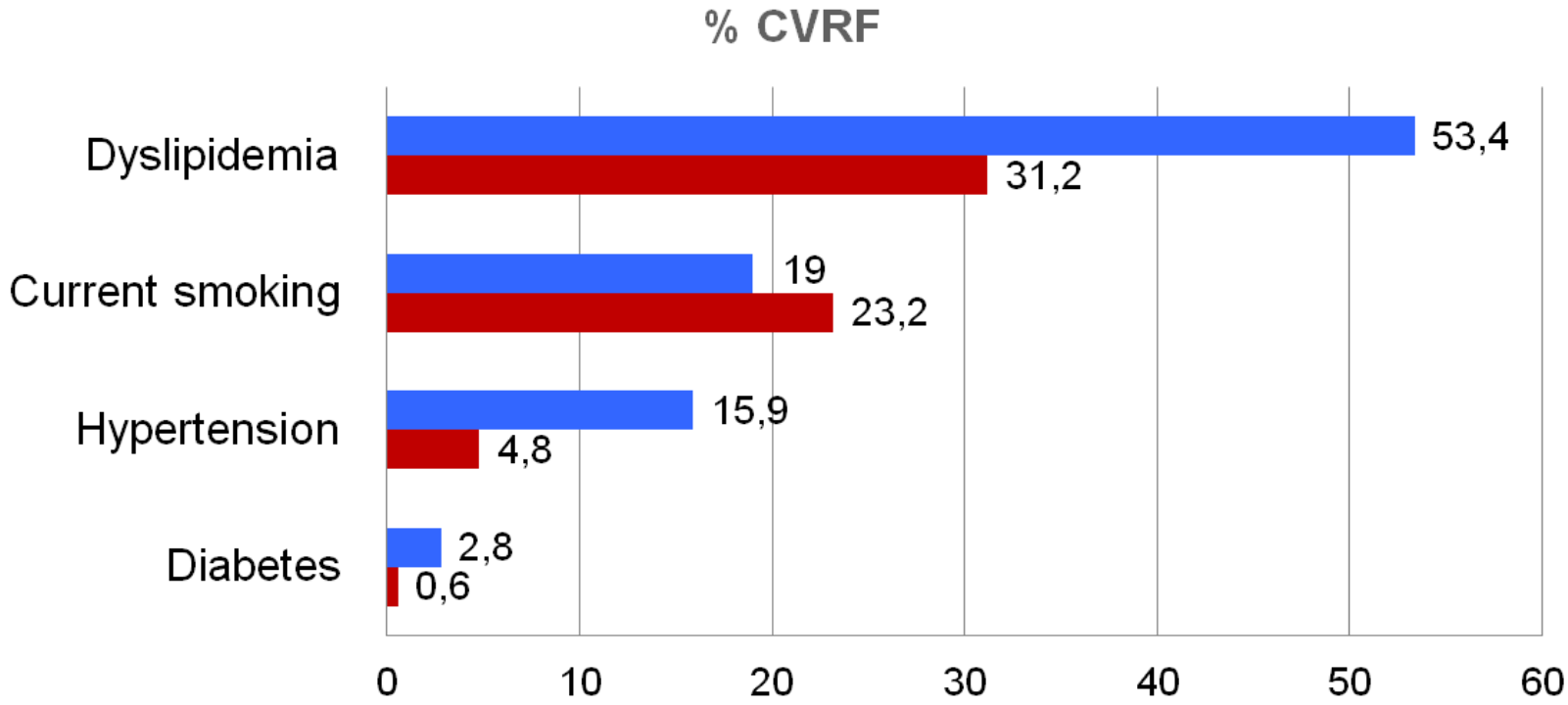
Key Words: atherosclerosis ■ cardiac imaging techniques ■ epidemiology ■ population ■ risk assessment

Demographics & Risk Factors

	Total (n=4066)	Men (n=2573)	Women (n=1493)	P value
Baseline characteristics				
Age,years	45.8±4.3	46.3±4.4	45±3.9	<0.001
BMI,kg/m^2	26.2±3.8	27.4±3.4	24.1±3.6	<0.001
Obese (BMI ≥ 30 Kg/m^2), n(%)	598(15)	493(19)	105(7)	<0.001
SBP,mmHg	116±12.5	121±11.1	109±11	<0.001
DBP,mmHg	72.5±9.4	74.7±9.1	68.7±8.7	<0.001
Total cholesterol,mg/dL	201±33.3	203±34.2	196±31.2	<0.001
LDLc,mg/dL	132±29.8	136±30.3	125±27.5	<0.001
HDLc,mg/dL	49±12.2	44.8±10.2	56.3±11.9	<0.001
Triglycerides,mg/dL	95±57.2	109±64	70.6±29.9	<0.001
Fasting glucose,mg/dL	90.6±13.8	93.4±15	85.7±9.7	<0.001
HbA1c,%	5.44±0.5	5.49±0.5	5.36±0.4	<0.001
Lipid-lowering therapy,n(%)	287(7)	242(9)	45(3)	<0.001
Antihypertensive therapy,n(%)	309(8)	266(10)	43(3)	<0.001
Antidiabetic therapy,n(%)	64(2)	56(2)	8(0.5)	<0.001

Fernández-Friera L, et al. Circulation. 2015;131:2104-2113

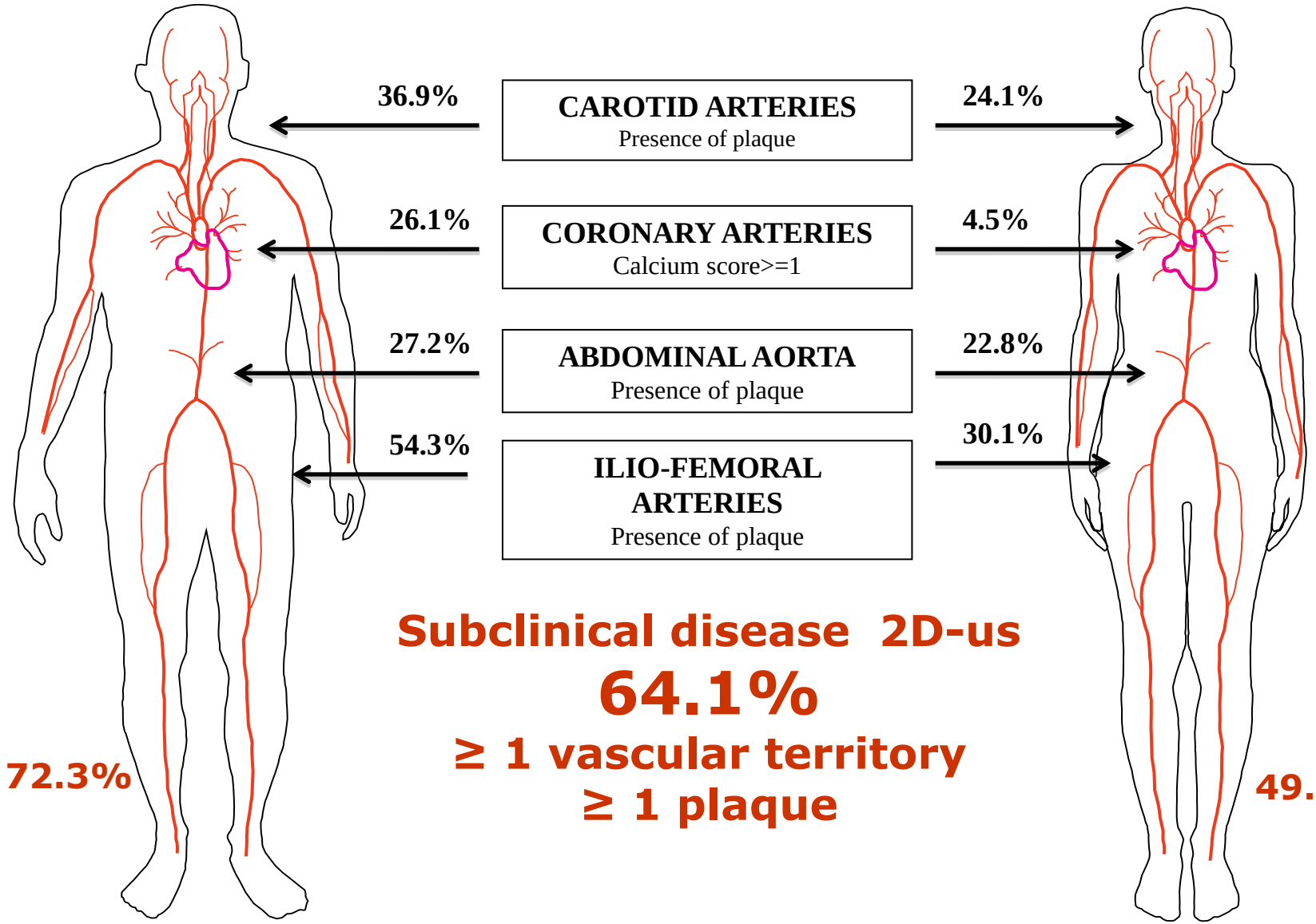
CV Risk Profile & Gender



# CVRF	Males N=2,586 (63.3%) Mean age 46.8 y	Females N=1,503 (36.7%) Mean age 45 y
0	34,6 %	59,9 %
1	43,3 %	31,1 %
2	18,6 %	8,2 %
>2	3,4 %	0,7 %

Fernández-Friera L, et al. Circulation. 2015;131:2104-2113

Prevalence of subclinical atherosclerosis by vascular territory



Fernández-Friera L, et al. Circulation. 2015;131:2104-2113

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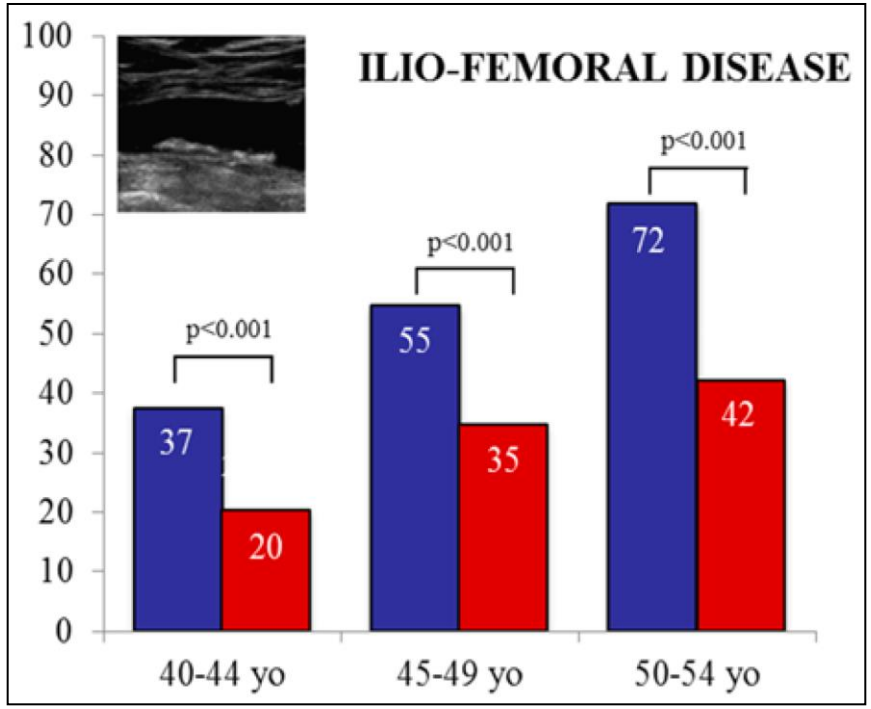
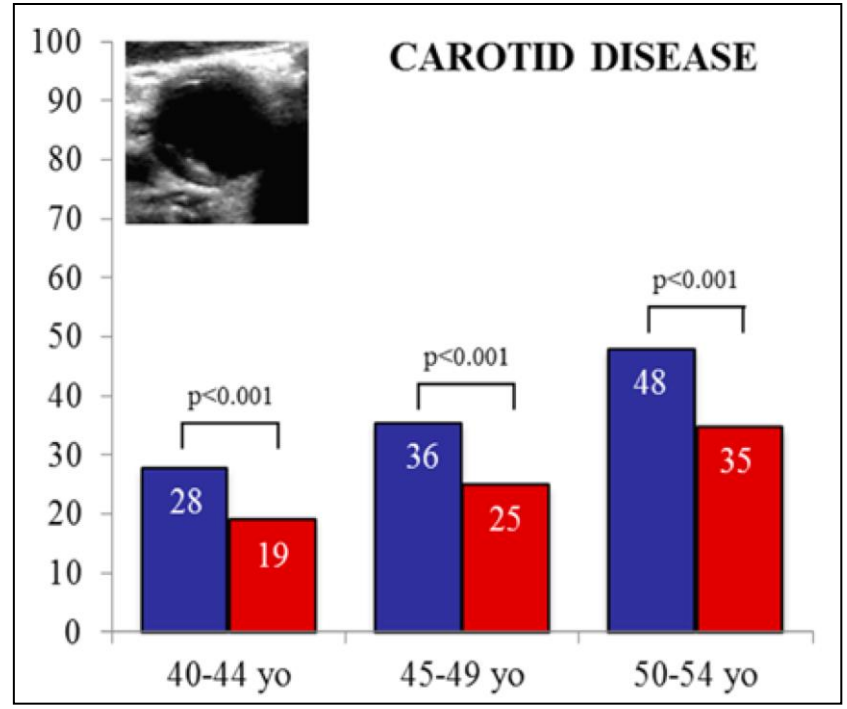
Incidence of subclinical atherosclerosis in femorals and carotids

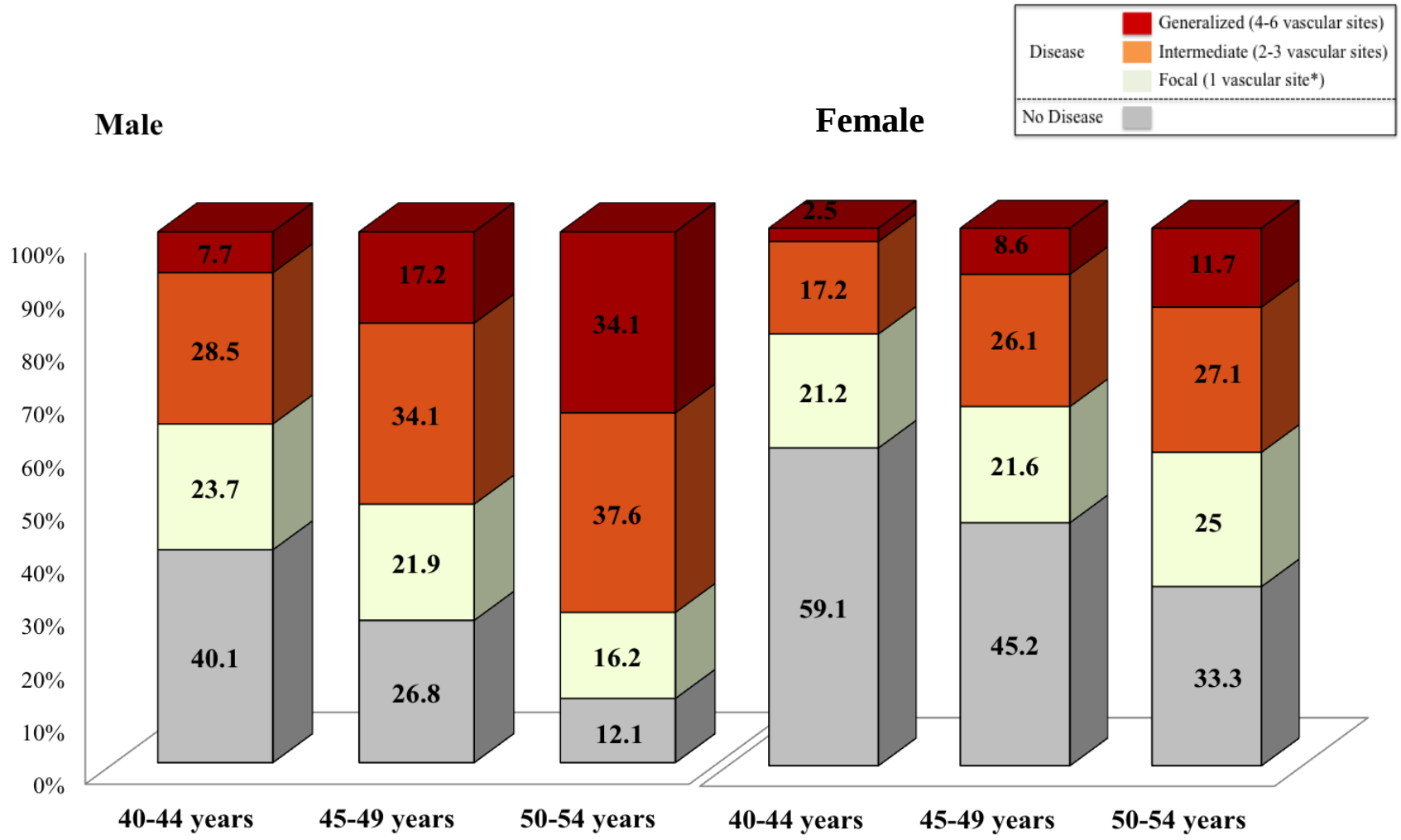


Men Women



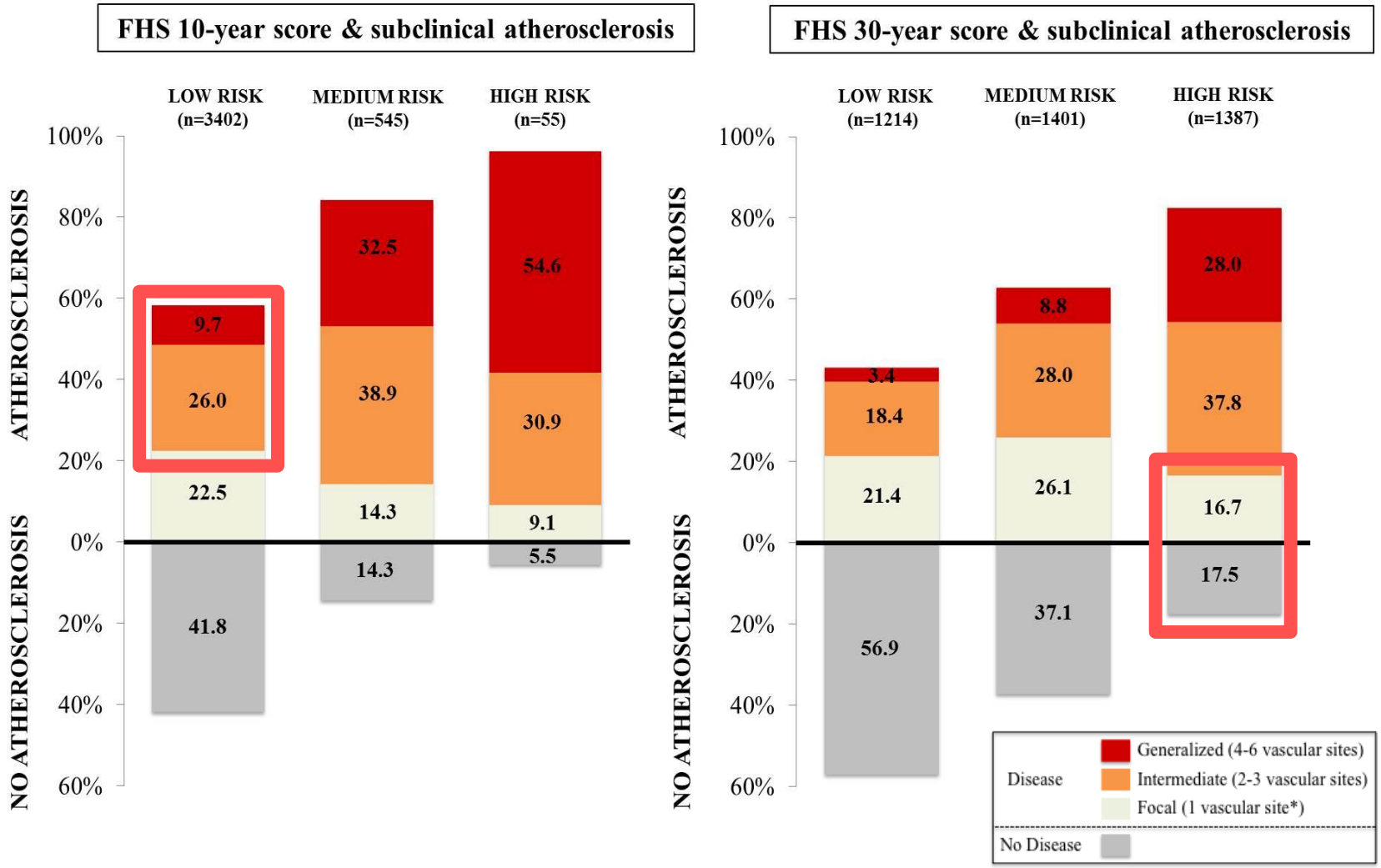
Men Women

Systemic extent of subclinical atherosclerosis by age and gender



*Vascular sites: right carotid, left carotid, abdominal aorta, right ilio-femoral, left ilio-femoral, coronary arteries (CACS ≥1)

Distribution of subclinical atherosclerosis according to FHS risk categories



Fernández-Friera L, et al. Circulation. 2015;131:2104-2113

Subclinical atherosclerosis & dietary patterns

PESA

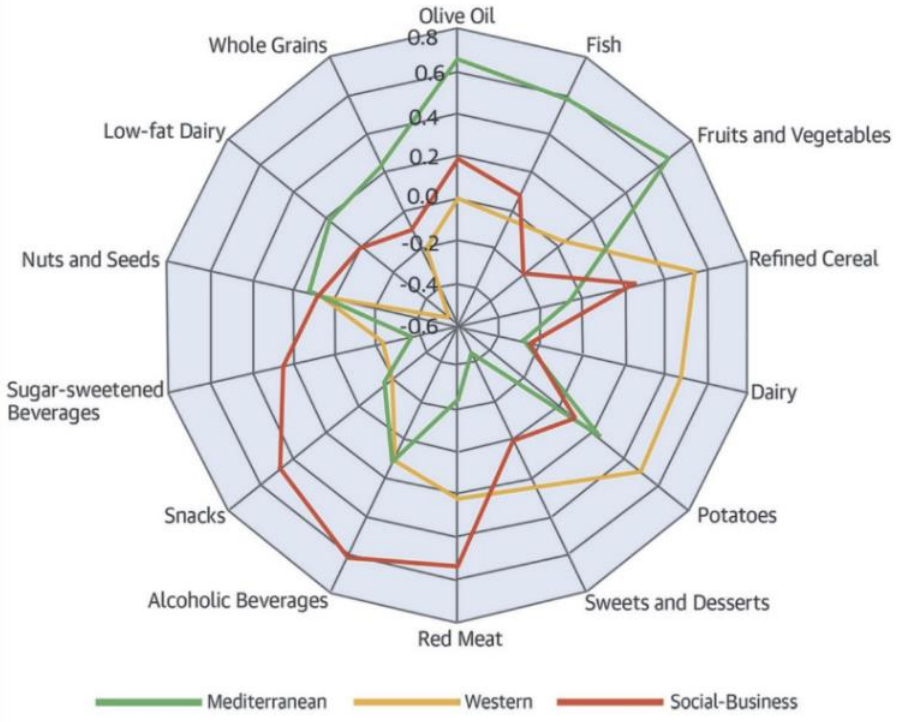
	Total (n=4052)	Cluster 1 (n=1615)	Cluster 2 (n=1668)	Cluster 3 (n=769)
Coronary calcium (Agatston score)	14.8 ± 84.5	12.8 ± 82.8	11.7 ± 69.9	**25.4 ± 111.6***
CAC ≥ 1	734 (18.1)	225 (13.9)	294 (17.6)*	**215 (28)***
CAC > 400	29.0 (0.71)	13 (0.80)	7 (0.42)	**9 (1.17)**
Intima media thickness carotid (mm)	0.59 ± 0.1	0.58 ± 0.09	0.59 ± 0.10*	**0.61 ± 0.11***
IMT carotid > 0.9, n (%)	33.0 (0.81)	8 (0.495)	15 (0.9)	**10 (1.3)***
Intima media thickness femoral (mm)	0.61 ± 0.2	0.58 ± 0.2	0.61 ± 0.2*	**0.66 ± 0.3***
IMT femoral > 0.9, n (%)	344 (8.51)	100 (6.22)	135 (8.11)*	**109 (14.2)***
Presence of any plaque, n (%)	2407 (60.3)	880 (55.1)	1011 (61.4)*	**516 (69)***
Aorta	992 (24.6)	384 (23.8)	388 (23.4)	**220 (28.9)***
Carotids	1276 (31.5)	448 (27.7)	538 (32.3)*	**290 (37.8)***
Femoral	1437 (35.5)	471 (29.3)	592 (35.5)*	**374 (48.7)***
Iliacs	840 (21)	316 (19.7)	334 (20.2)	**190 (25.3)***
Ilio-femorals	1782 (44.2)	613 (38.2)	742 (44.6)*	**427 (56)***
Presence of any plaque & CAC≥1, n (%)	2496 (62.5)	906 (56.7)	1047 (63.6)*	**543 (72.6)***

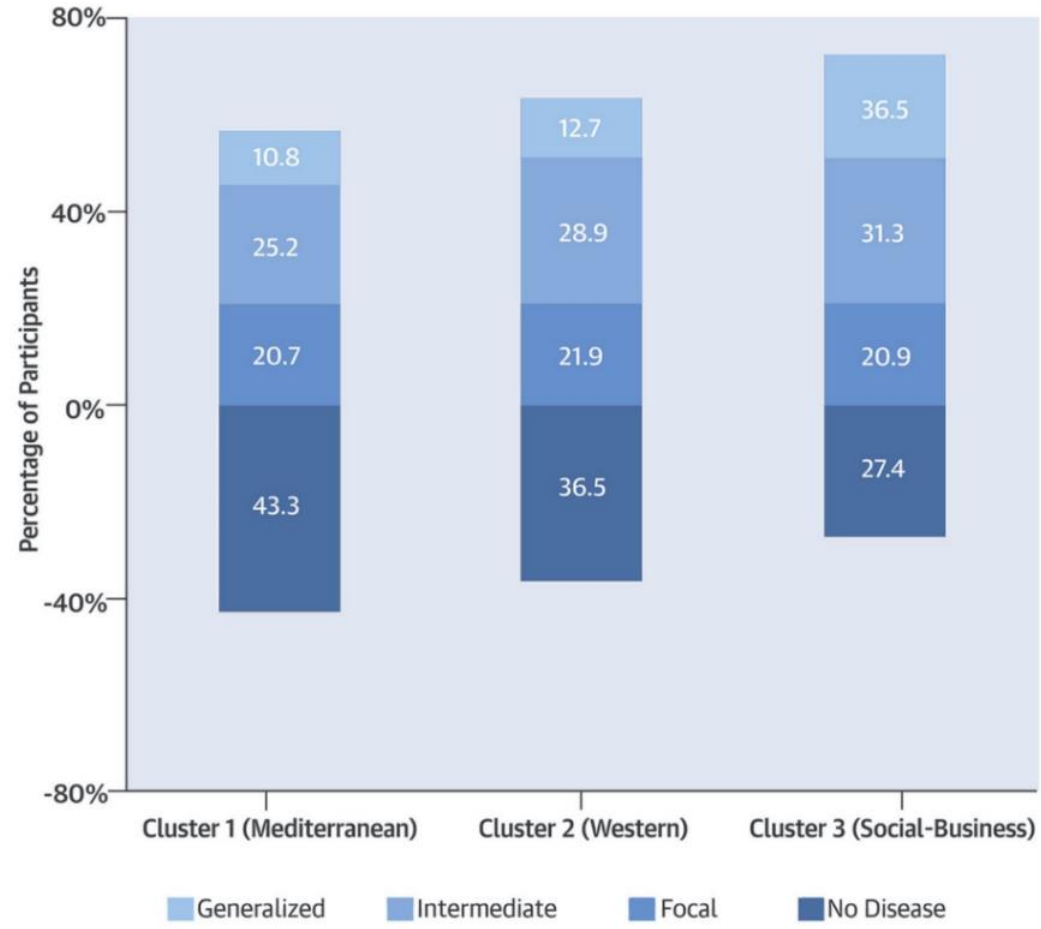
** Differences using cluster 1 as reference (p-value<0.05)*

Peñalvo JL, et al .J Am Coll Cardiol. 2016;68(8):805-14

Subclinical atherosclerosis & dietary patterns

CENTRAL ILLUSTRATION: Social Eating and Atherosclerosis: Comparison of Mediterranean Pattern, Western Pattern, and Social-Business Pattern

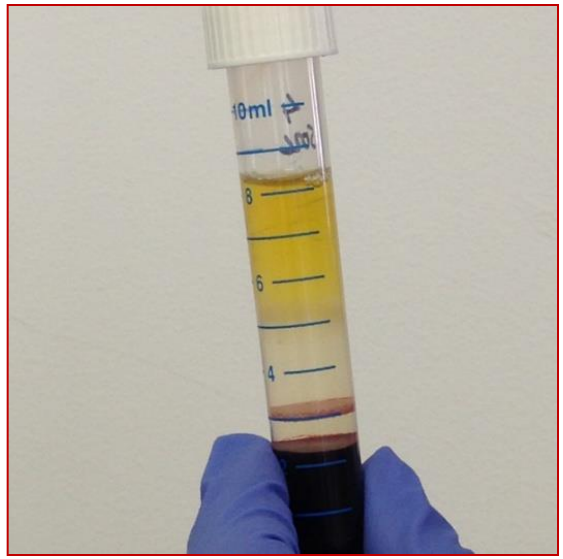




Peñalvo, J.L. et al. J Am Coll Cardiol. 2016;68(8):805–14.

Telomeres & Subclinical Atherosclerosis

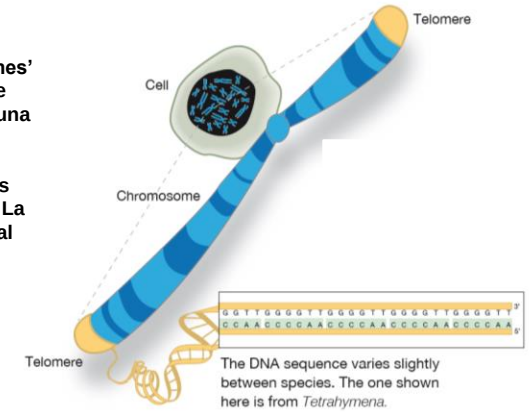
Objective: Investigate how leukocyte telomere length (LTL) and the rate of telomere ablation relate to atherosclerosis initiation and progression.



TELÓMERO

telos: **parte** ***meros:*** **final**

Los telómeros son 'capuchones' que protegen los extremos de los cromosomas. Contienen una secuencia de ADN repetida muchas veces y proteínas asociadas que son necesarias para mantener su integridad. La enzima telomerasa es esencial para el mantenimiento de la longitud de los telómeros.



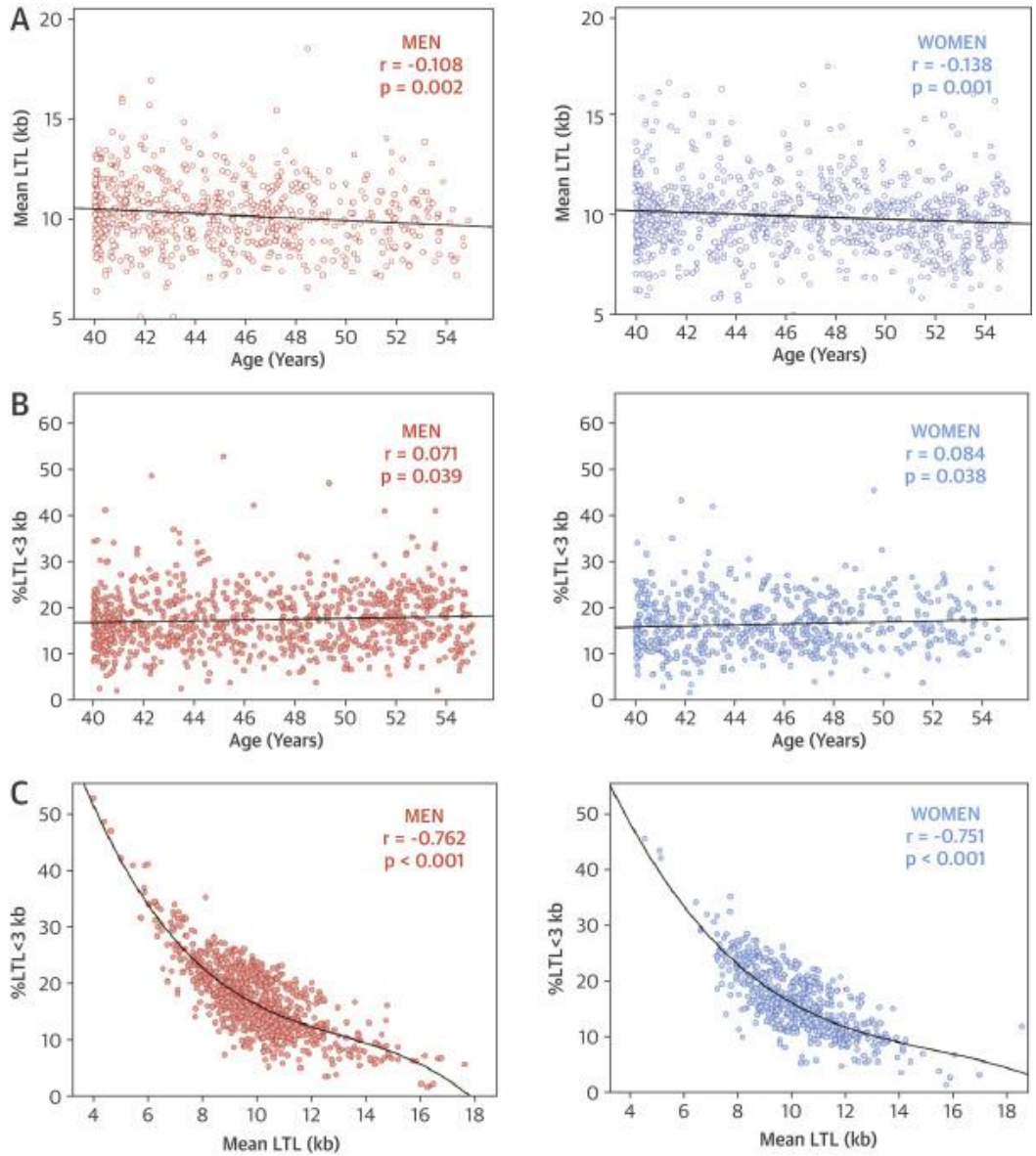
- *1500 PESA participants*
- *6 ml of additional blood sample for PBMC isolation using Hystopaque followed by freezing in 80% FBS 20% DMSO*

Valentín Fuster, Vicente Andrés, María Blasco et al.

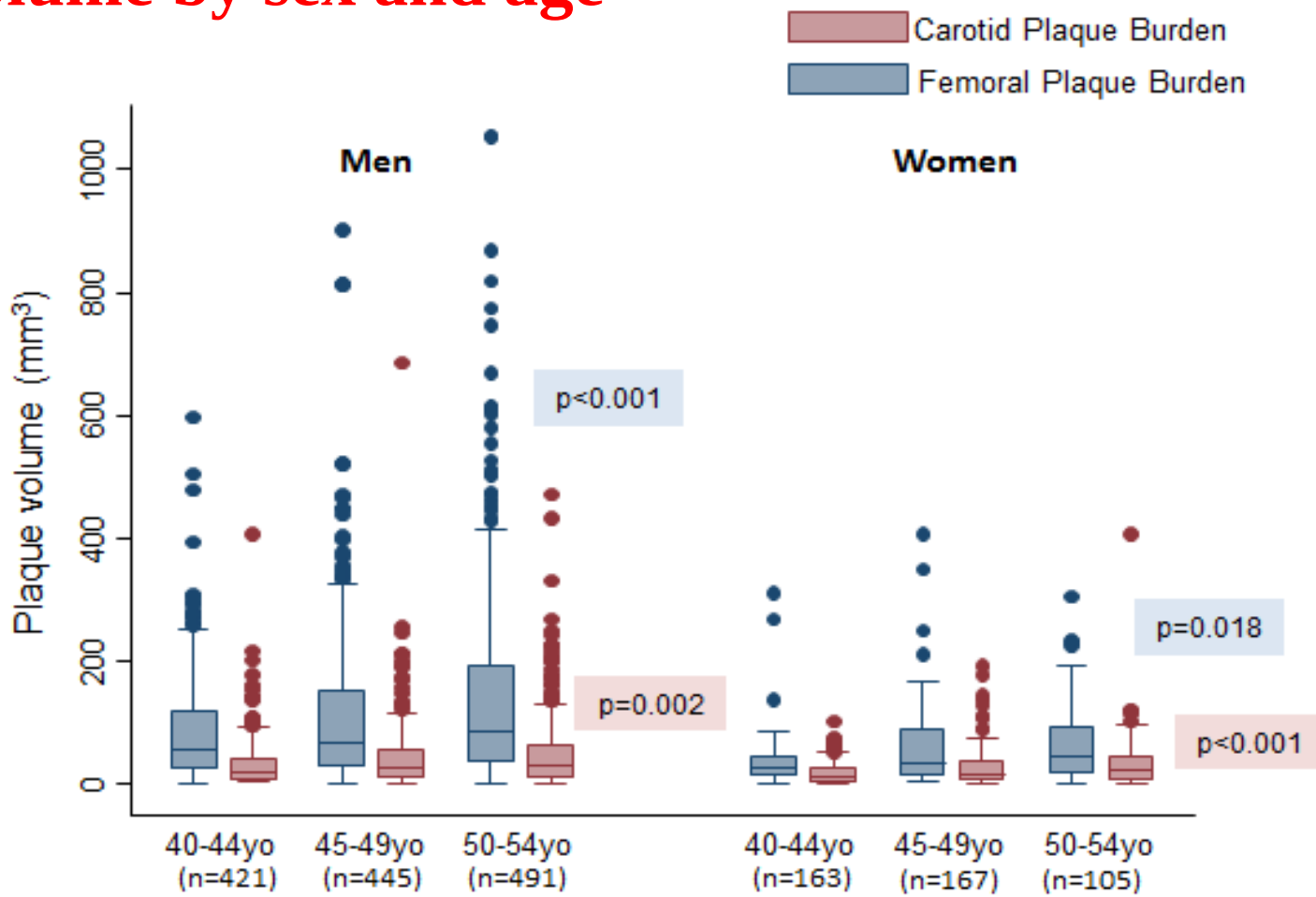
Centro Nacional de Investigaciones Oncológicas

GOBIERNO DE ESPAÑA · MINISTERIO DE ECONOMÍA Y COMPETITIVIDAD · Instituto de Salud Carlos III

Short Telomere Load, Telomere Length, and Subclinical Atherosclerosis: The PESA Study

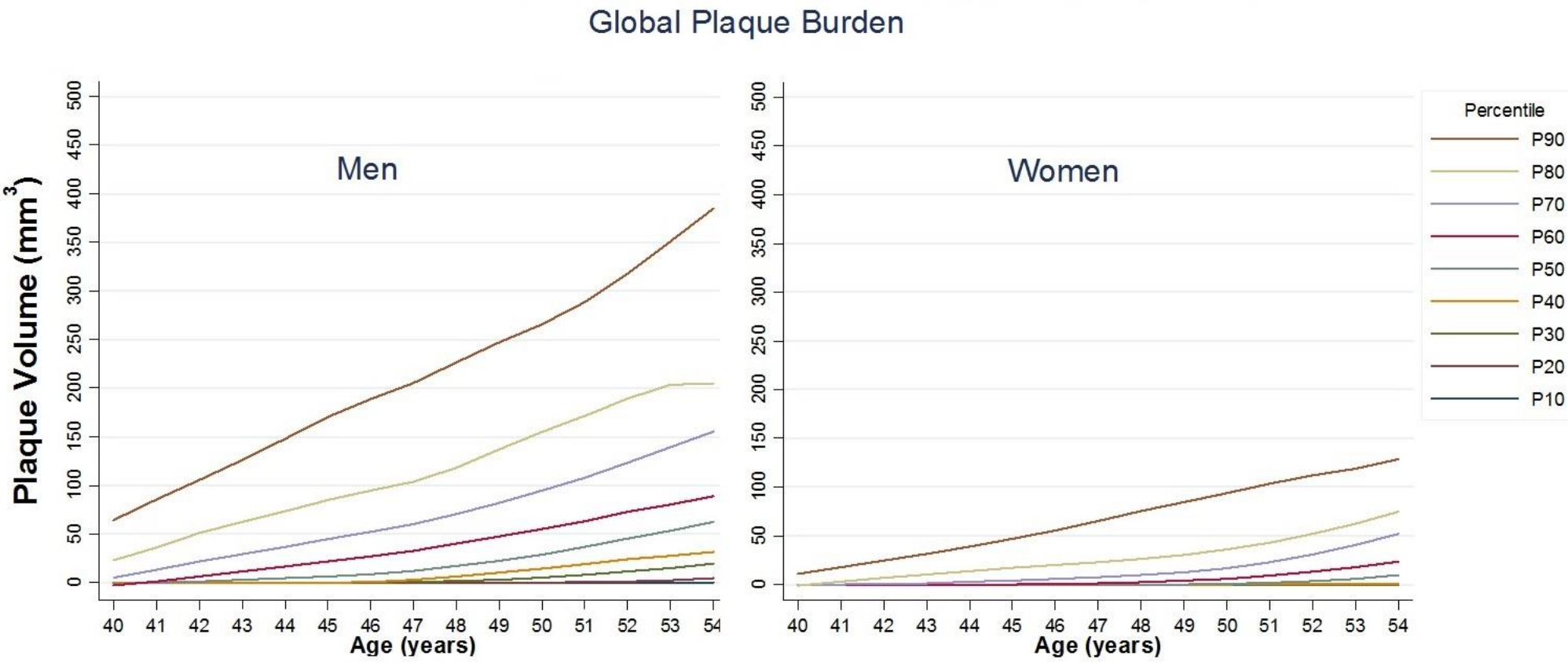


Distribution of femoral and carotid atherosclerotic plaque volume by sex and age



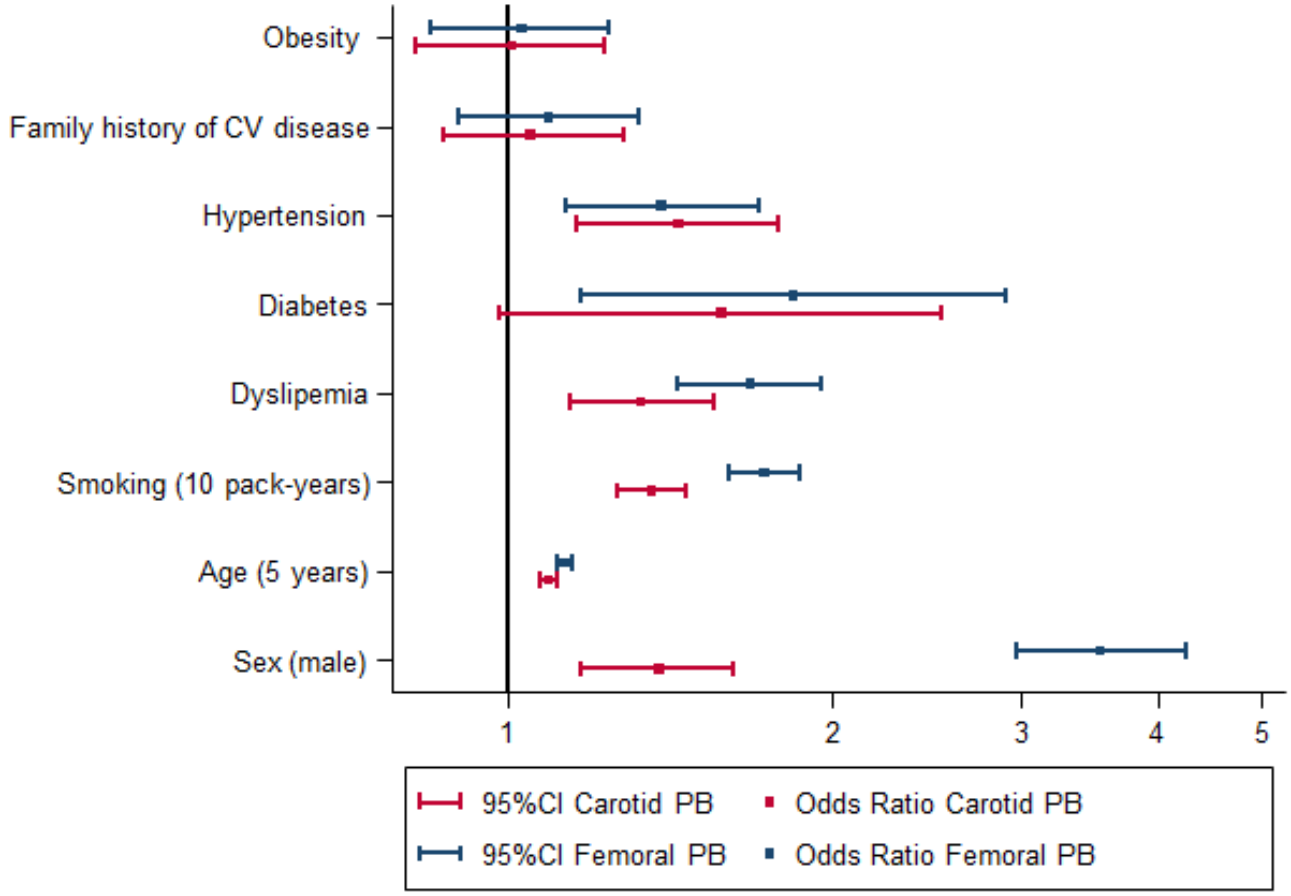
Box-plots represent median and interquartile range, and dots represent the outlier values of femoral and carotid plaque burden in mm^3 across age categories in those participants with evidence of atherosclerotic disease (i.e. excluding participants with a plaque burden of 0 mm^3). The p values for trend of the age-related increases in carotid and femoral plaque burden are shown.

Percentiles of global plaque burden stratified by age and sex



Each plot shows the curves for the percentiles of global plaque burden in mm^3 across age in the study cohort, including healthy participants (plaque burden of 0 mm^3) and diseased participants. Disease appears later in women than in men, and plaque burden in men is strikingly higher than in women of the same age.

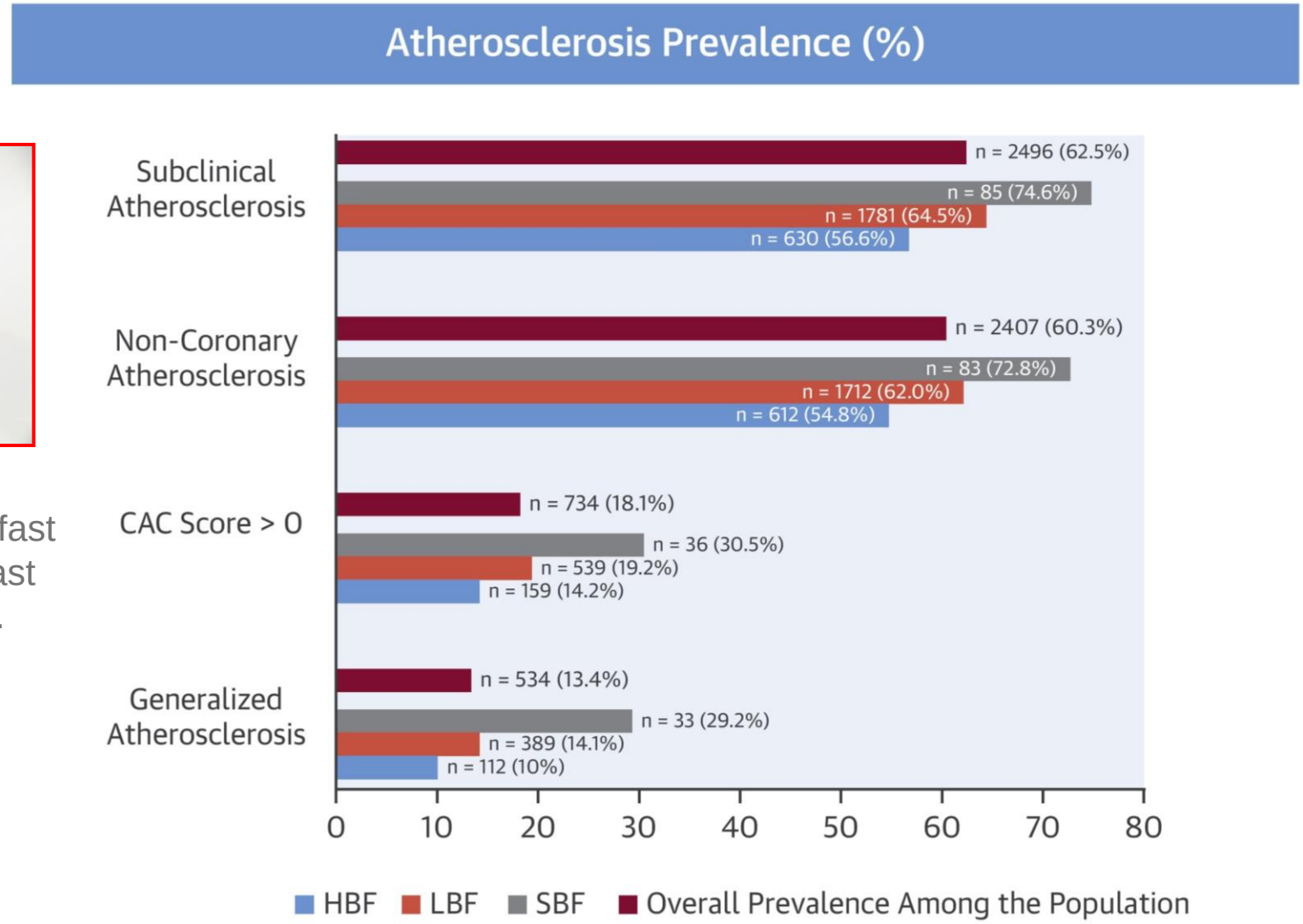
Multivariable analysis for the prediction of carotid and femoral atherosclerotic plaque burden



Smoking, dyslipidemia, diabetes and hypertension were predictors of atherosclerotic plaque burden after adjustment for sex, age, and all evaluated CVRFs. The strength of the relationship between sex, age, and CVRFs tends to be higher in the femoral territory, except for hypertension.

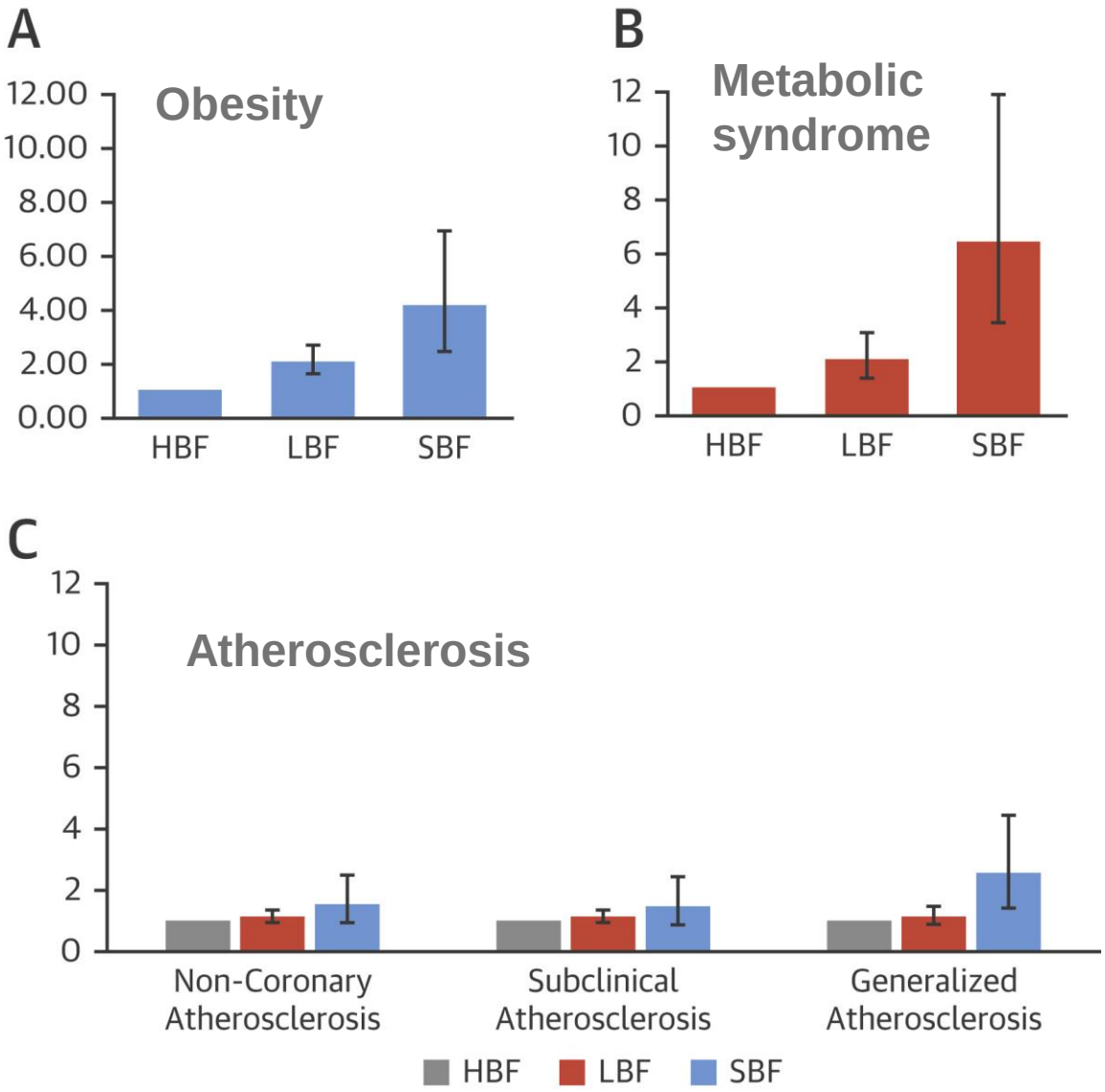
The Importance of Breakfast in Atherosclerosis Disease: Insights From the PESA Study

HBF = high-energy breakfast
LBF = low-energy breakfast
SBF = skipping breakfast.



Uzhova, I. et al. J Am Coll Cardiol. 2017;70(15):1833-42.

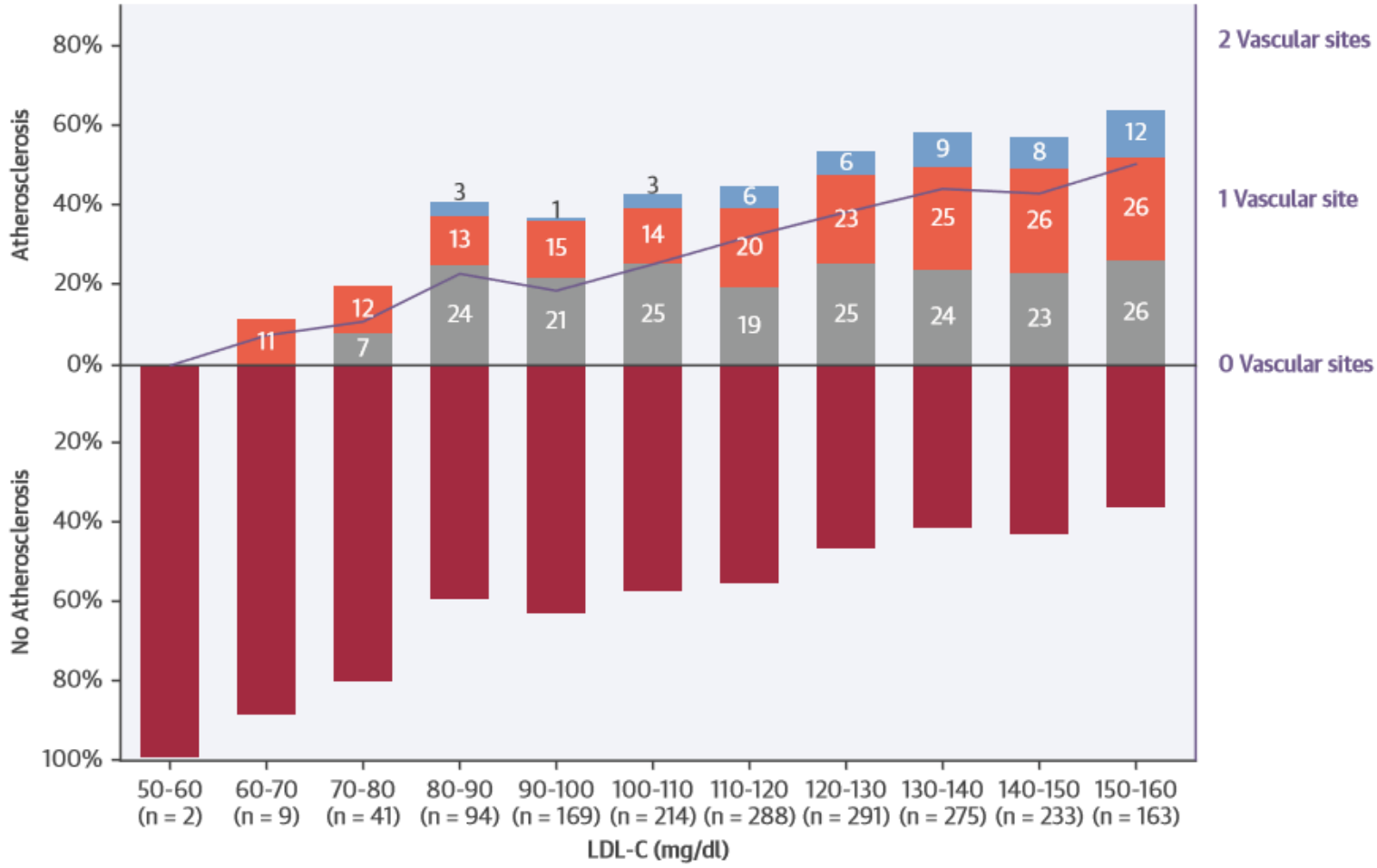
The Importance of Breakfast in Atherosclerosis Disease: Insights From the PESA Study



(A) Adjusted odds ratios for obesity by breakfast pattern (odds ratio [OR] and 95% confidence interval [CI]). Model adjusted for age (years), sex (male/female), energy intake (kcal/day), smoking (yes/no), daily alcohol consumption (g/day), hypertension (yes/no), diabetes (yes/no), dyslipidemia (yes/no), and dieting (yes/no). Obesity defined as body mass index ≥30 kg/m^2. **(B)** Adjusted ORs for metabolic syndrome (MetS) by breakfast pattern (OR and 95% CI). Model adjusted for age (years), sex (male/female), energy intake (kcal/day), smoking (yes/no), daily alcohol consumption (g/day), and family history of cardiovascular disease (yes/no). **(C)** Adjusted odds ratios for atherosclerosis by breakfast pattern (OR and 95% CI). Model adjusted for age (years), sex (male/female), smoking (yes/no), hypertension (yes/no), diabetes (yes/no), dyslipidemia (yes/no), waist circumference (cm), and daily intakes of red meat, alcohol, and salt (g). HBF = high-energy breakfast; LBF = low-energy breakfast; SBF = skipping breakfast.

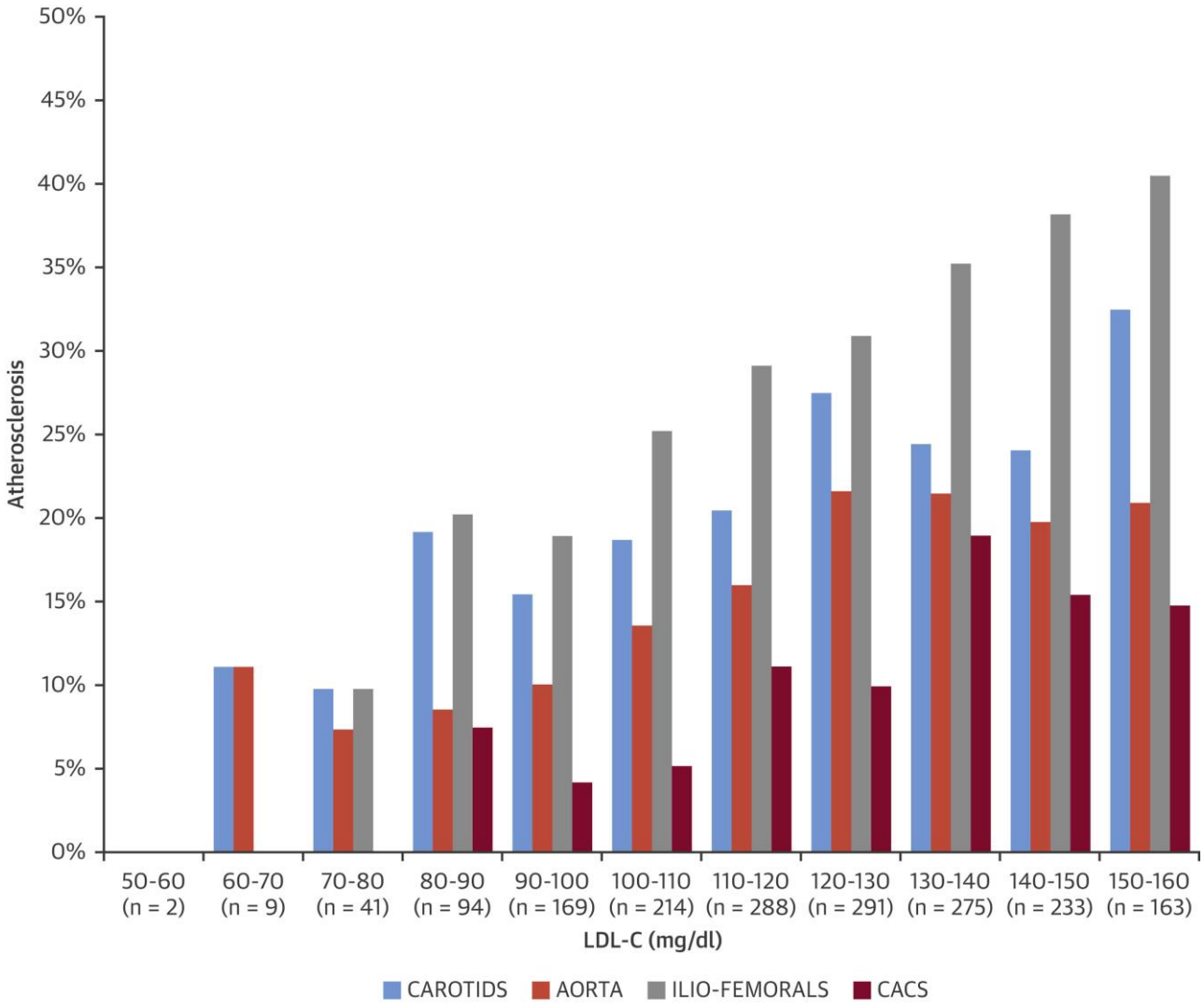
PESA-CNIC-SANTANDER

Relation Between LDL-Cholesterol Levels and Atherosclerosis



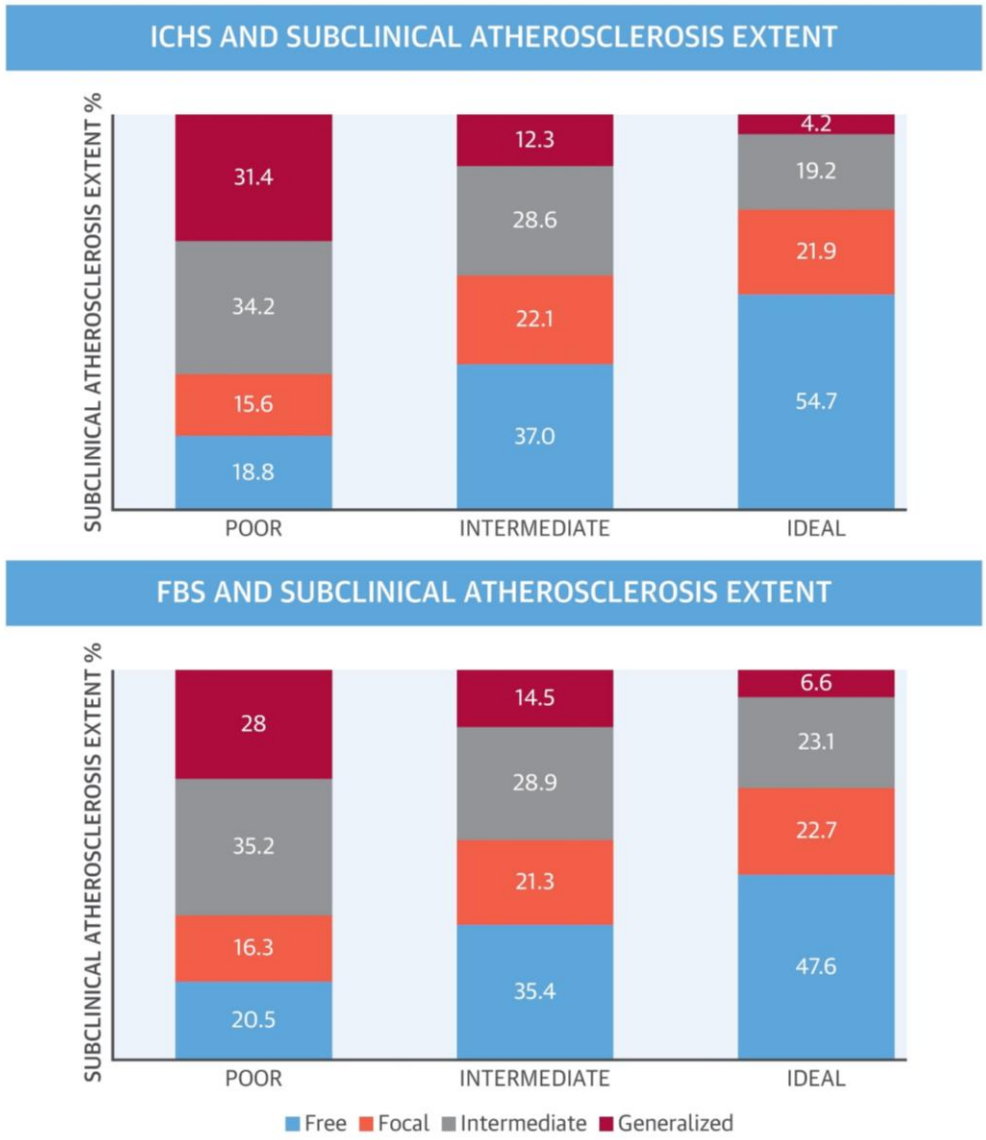
Fernández-Friera, L. et al. J Am Coll Cardiol. 2017;70(24):2979–91.

Normal LDL-Cholesterol Levels Are Associated With Subclinical Atherosclerosis in the Absence of Risk Factors



Relation Between LDL-Cholesterol Levels and Atherosclerosis by Vascular Territory. As LDL-C levels rises, there is a significant increase in the prevalence of disease in each evaluated territory: carotid, aortic, iliofemoral and coronary. CACS = coronary artery calcium score; LDL-C = low-density lipoprotein cholesterol.

Predicting Subclinical Atherosclerosis in Low-Risk Individuals:
Ideal Cardiovascular Health Score and Fuster-BEWAT Score



ICH Score:

- Lifestyle factors (smoking, body weight, physical activity, and diet)
- Established risk factors (blood cholesterol, blood glucose, and blood pressure)

Fuster-BEWAT Score:

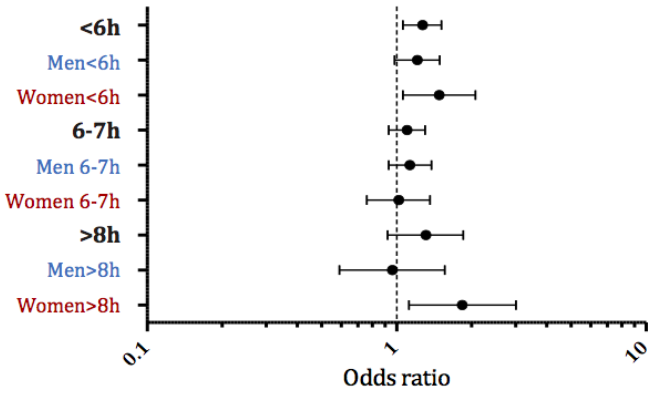
- **B**lood pressure
- **E**xercise
- **W**eight
- **A**limentation
- **T**obacco

Fernández-Alvira JM, et al. J Am Coll Cardiol 2017;70(20):2463-2473

SLEEP DURATION AND QUALITY AND SUBCLINICAL ATHEROSCLEROSIS

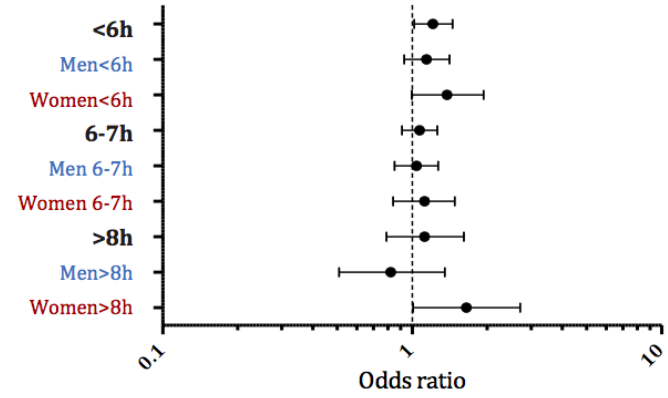
SLEEP DURATION*

NONCORONARY PLAQUE BURDEN (mm^3)



	OR (CI 95%)	p value
<6h	1.27 (1.06-1.52)	**0.008**
Men<6h	1.21 (0.98-1.49)	0.08
Women<6h	1.48 (1.06-2.07)	0.02
6-7h	1.10 (0.94-1.30)	0.25
Men 6-7h	1.13 (0.93-1.38)	0.23
Women 6-7h	1.01 (0.76-1.36)	0.90
>8h	1.31 (0.92-1.85)	0.13
Men>8h	0.96 (0.59-1.56)	0.87
Women>8h	1.83 (1.12-3.01)	0.02

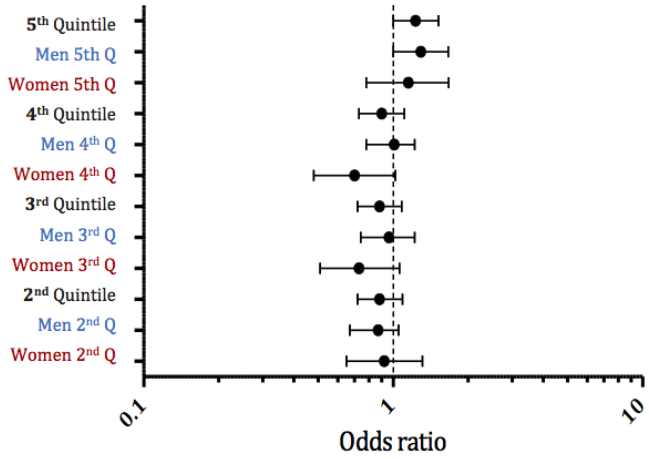
NUMBER OF TERRITORIES AFFECTED (1-4)



	OR (CI 95%)	p value
<6h	1.21 (1.02-1.45)	0.03
Men<6h	1.14 (0.93-1.41)	0.21
Women<6h	1.38 (1.00-1.93)	0.053
6-7h	1.07 (0.9-1.26)	0.40
Men 6-7h	1.04 (0.85-1.27)	0.71
Women 6-7h	1.12 (0.84-1.48)	0.44
>8h	1.13 (0.79-1.13)	0.50
Men>8h	0.85 (0.50-1.35)	0.44
Women>8h	1.65 (1.01-2.72)	0.05

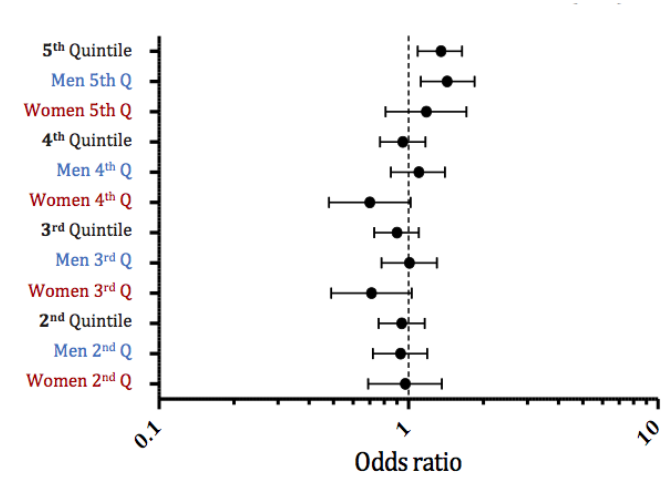
SLEEP FRAGMENTATION*

NONCORONARY PLAQUE BURDEN (mm^3)



	OR (CI 95%)	p value
5th Quintile	1.23 (1.00-1.52)	0.048
Men 5th Q	1.29 (1.00-1.66)	0.048
Women 5th Q	1.15 (0.79-1.67)	0.47
4th Quintile	0.90(0.73-1.11)	0.33
Men 4th Q	1.01 (0.78-1.30)	0.95
Women 4th Q	0.70 (0.48-1.02)	0.07
3rd Quintile	0.88 (0.71-1.08)	0.23
Men 3rd Q	0.96 (0.74-1.24)	0.76
Women 3rd Q	0.73 (0.59-1.06)	0.10
2nd Quintile	0.88 (0.72-1.09)	0.25
Men 2nd Q	0.87 (0.67-113.)	0.29
Women 2nd Q	0.92 (0.65-1.31)	0.64

NUMBER OF TERRITORIES AFFECTED (1-4)

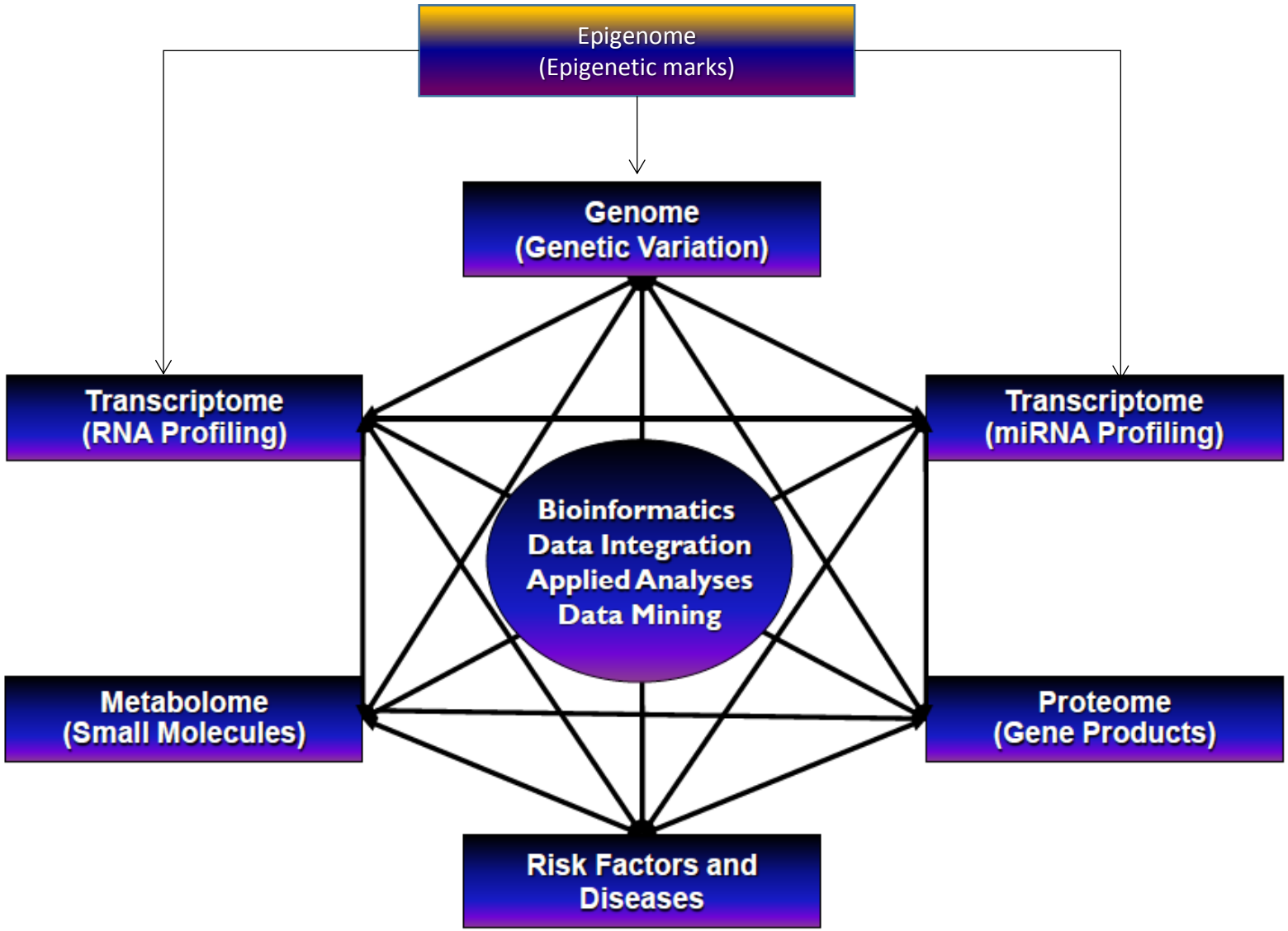


	OR (CI 95%)	p value
5th Quintile	1.34 (1.09-1.64)	**0.006**
Men 5th Q	1.43 (1.12-1.85)	**0.005**
Women 5th Q	1.18 (0.81-1.71)	0.38
4th Quintile	0.95(0.77-1.74)	0.65
Men 4th Q	1.10 (0.84-1.42)	0.48
Women 4th Q	0.70 (0.48-1.02)	0.07
3rd Quintile	0.90 (0.73-1.10)	0.31
Men 3rd Q	1.01 (0.78-1.30)	0.96
Women 3rd Q	0.71 (0.49-1.03)	0.07
2nd Quintile	0.94 (0.76-1.16)	0.54
Men 2nd Q	0.93 (0.72-1.21)	0.60
Women 2nd Q	0.97 (0.68-1.36)	0.84

*Reference: 7-8 hours
*Reference: Quintile 1, less fragmented sleep

PESA CNIC-Santander

PESA Phenomics



PESA Phenomics

1,000 participants

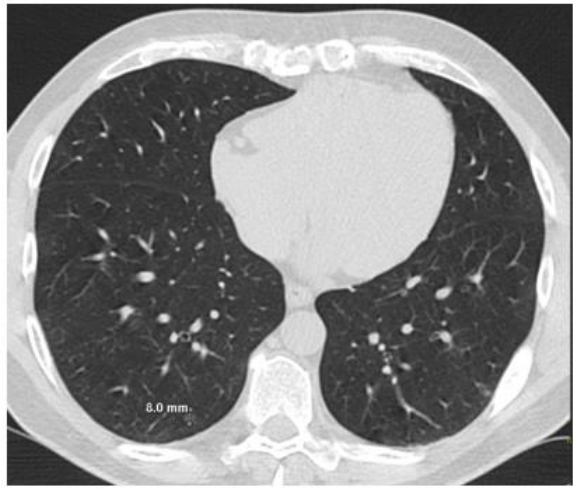
4,000 phenotypes
2,000,000 SNP
850,000 methylation sites
15,000 mRNA
1,000 miRNA
5,000 peptides
1,000 metabolites

≈3x10^9 data points

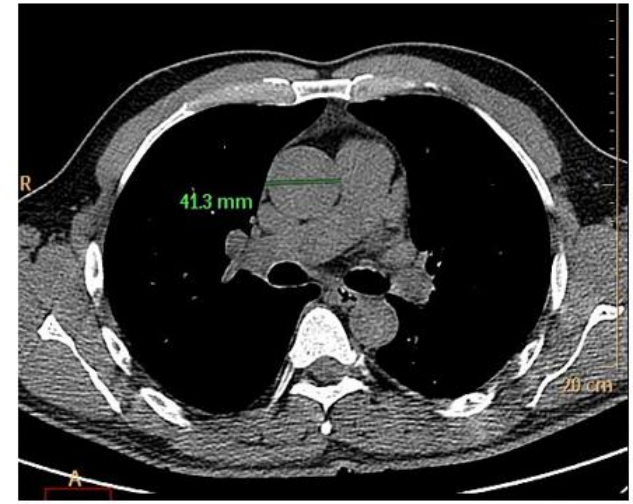
PESA

Hallazgos incidentales más prevalentes

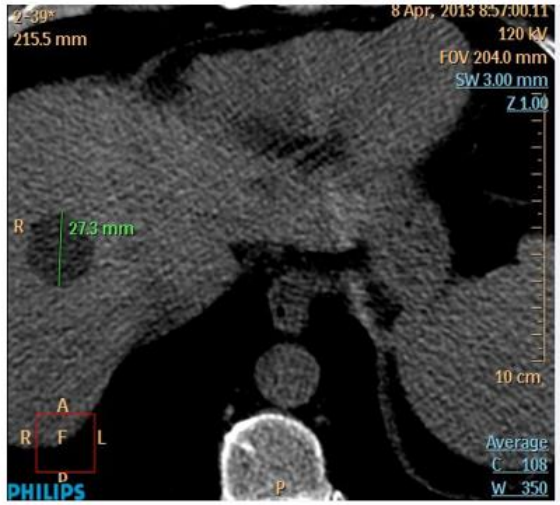
PESA



373 nódulos pulmonares
(2 casos neoplasia pulmonar)



430 dilataciones de aorta
(12 casos por encima de 45 mm)



302 granulomas/quistes hepáticos

340 nódulos tiroideos
(11 casos cirugía de tiroides)

HITOS PESA-CNIC-Santander

Jun' 10	Primer participante en el estudio
Diciem' 12	Primer participante PET-RM (total 946)
Junio' 13	Inicio de la segunda visita (3 años)
Febrero' 14	Cohorte basal completa (4.184 participantes)
Mayo' 15	Inicio subestudio TANSNIP (intervención)
Junio' 15	Primeros resultados imagen vascular (Circulation)
Mayo' 16	Primeros resultados telómeros (J Am Coll Cardiol)
Junio'16	Inicio de la tercera visita (6 años)
Agosto' 16	Primeros resultados dieta (J Am Coll Cardiol)
Julio' 17	Resultados carga aterosclerótica con eco 3D (J Am Coll Cardiol)
Octubre' 17	Resultados desayuno y aterosclerosis (J Am Coll Cardiol)
Noviem' 17	Puntuación Fuster-Bewat y aterosclerosis (J Am Coll Cardiol)
Diciem' 17	LDL-colesterol "normal" y aterosclerosis (J Am Coll Cardiol)

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Thank you !!