Applying ACC/AHA guideline to Korean patients

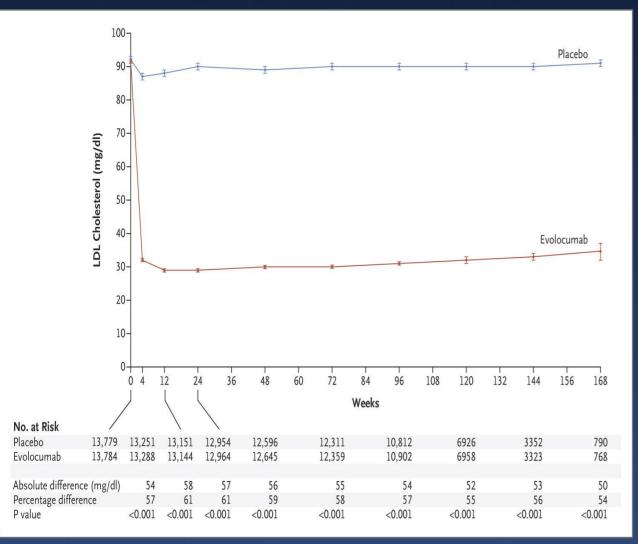
Kiyuk Chang MD

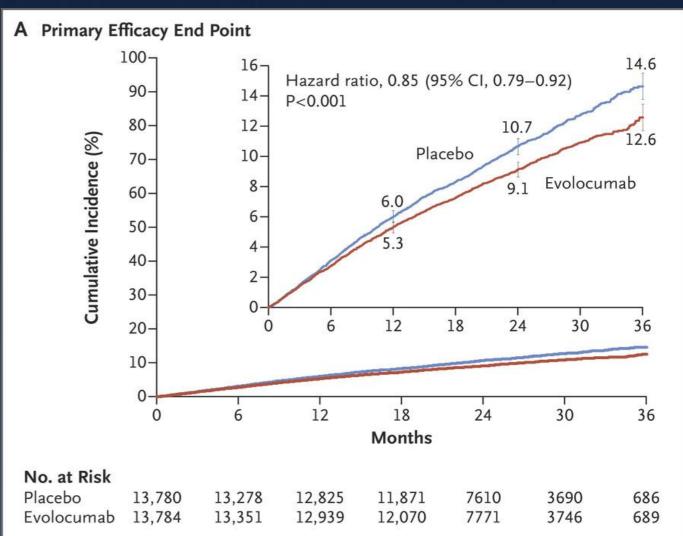
Cardiology
Seoul St. Mary's Hospital
The Catholic University of Korea

Evolocumab & Clinical outcome (FOURIER)

Inclusion criteria

- ASCVD: prior MI, stroke, PAD
- LDL > 70 mg/dL despite atorvastatin 20 mg higher±ezetimibe



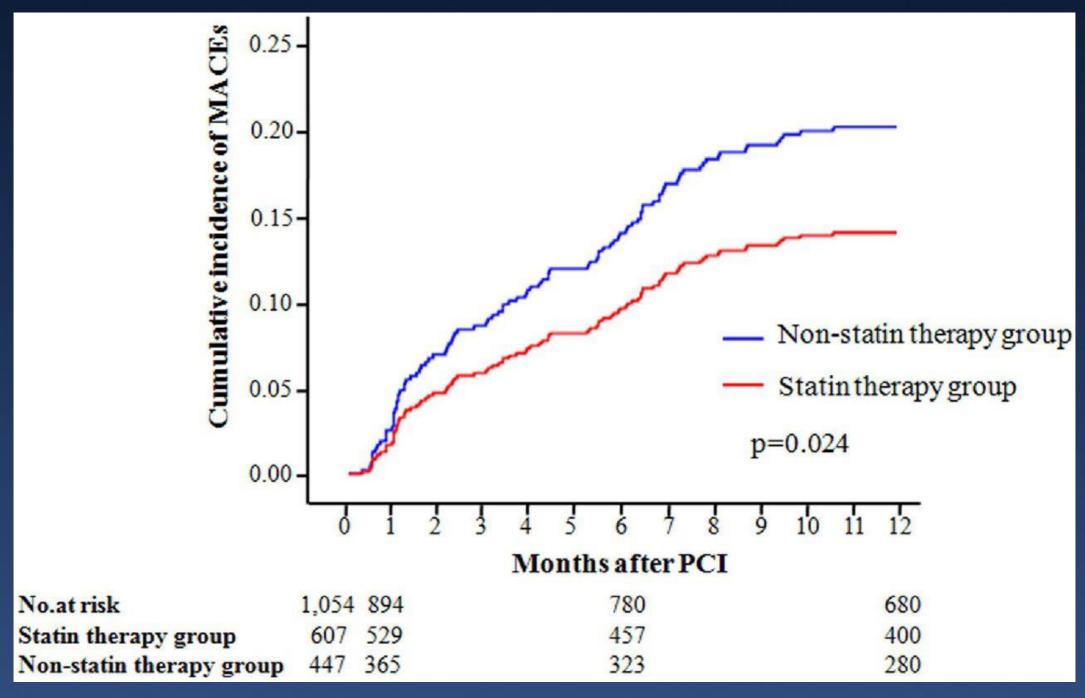


Sabatine MS et al, N Engl J Med 2017 Mar





Benefit of early statin therapy in patients wth AMI & LDL < 70 mg/dL



Lee KH et al, J Am Coll Cardiol 2011;58:1664-71





MUSTANG

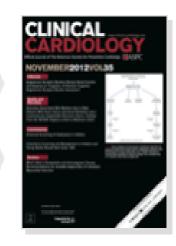
CLINICAL CARDIOLOGY

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Clinical Investigation

Current Statin Usage for Patients With Acute Coronary Syndrome Undergoing Percutaneous Coronary Intervention: Multicenter Survey in Korea

Mi-Jeong Kim MD, Doo Soo Jeon MD, Hyeon-Cheol Gwon MD, Soo-Joong Kim MD, Kiyuk Chang MD, Hyo-Soo Kim MD, Seung-Jea Tahk MD ⊠, for Korean MUSTANG Investigators



View issue TOC Volume 35, Issue 11 November 2012 Pages 700-706

Kim MJ et al, Clin Cardiol 2012;35:700-6



MUSTANG

OBJECTIVES

 Examination of statin treatment patterns in acute coronary syndrome(ACS) undergoing percutaneous coronary intervention(PCI)

POPULATION and DATA COLLECTION

- √ 3362 patients registered and followed for 30 days after enrollment from 48 hospitals
- diagnosed with unstable angina,(UA) non-STelevated MI(NSTEMI), or ST-elevated MI(STEMI)
- ✓ High dose: atorvastatin ≥40 mg or rosuvastatin ≥20 mg per day

Kim MJ et al, Clin Cardiol 2012;35:700-6



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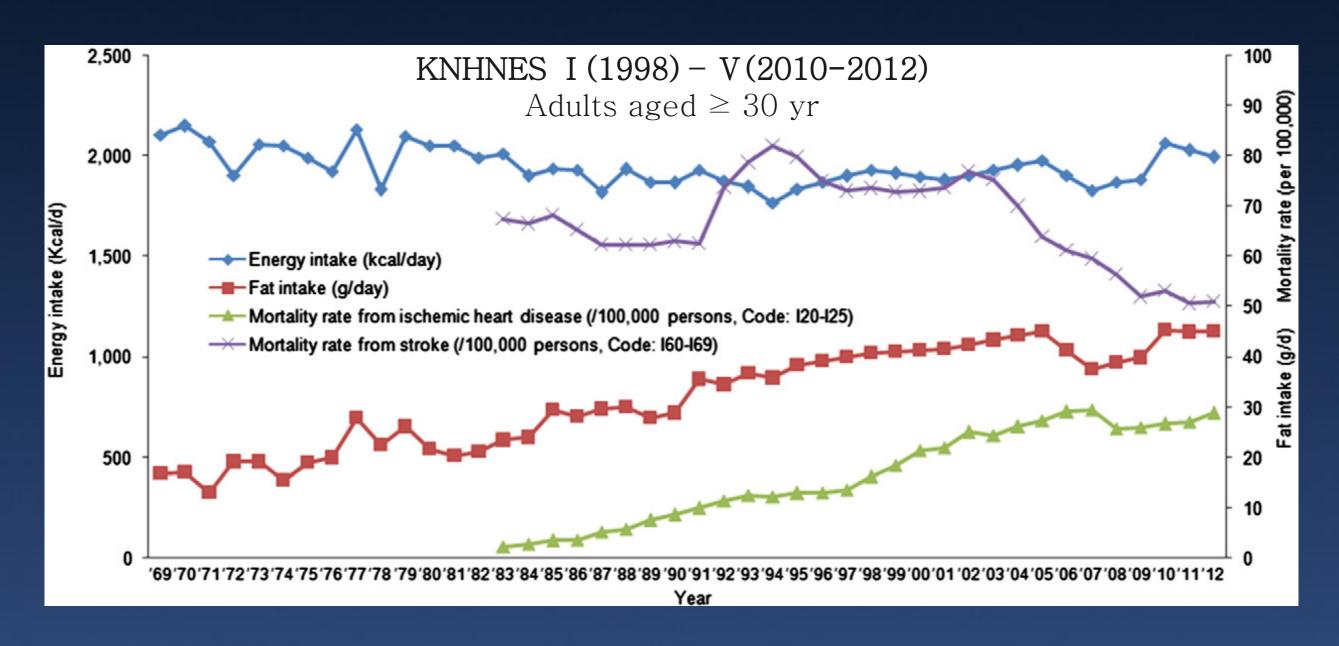


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Trends in mortality rate from CHD and stroke in Korea



KNHNES, Korea National Health and Nutrition Examination Survey

Kim HJ, et al. Intern J Cardiol 2014;174:64-72.





Lipid profile of general Korean population

	KNHANES			P for trend ^a
	III	IV	V	
	(2005)	(2007–09)	(2010–12)	
Men (no. of \geq 30 yr)	1976	5878	6273	
Total cholesterol (mg/dL, mean \pm SE)	186.6 ± 0.9	189.3 ± 0.5	191.2 ± 0.6	<0.0001
Total cholesterol (mg/dL, age-standardized mean \pm SE)	186.4 ± 0.9	189.2 ± 0.5	191.0 ± 0.6	< 0.0001
Hypercholesterolemia (%, SE) ^b				
Total (≥30 yr)	7.3 (0.6)	10.1 (0.5)	12.9 (0.5)	< 0.0001
Total (≥30 yr, age-standardized)	7.2 (0.6)	10.0 (0.5)	12.6 (0.5)	< 0.0001
30–39 yr	5.9 (1.1)	7.9 (0.8)	10.2 (1.0)	0.0063
40–49 yr	8.7 (1.3)	10.8 (0.9)	10.9 (0.9)	0.1851
50–59 yr	7.9 (1.5)	12.2 (1.1)	16.9 (1.2)	< 0.0001
60–69 yr	8.8 (1.7)	11.3 (1.2)	15.6 (1.3)	0.0027
≥70 yr	3.6 (1.3)	8.1 (1.1)	13.0 (1.3)	< 0.0001
<i>P</i> -value ^c	0.0934	0.0046	< 0.0001	
Women (no. of \geq 30 yr)	2651	7992	8384	
Total cholesterol (mg/dL, mean \pm SE)	187.6 ± 0.8	190.6 ± 0.5	192.9 ± 0.5	< 0.0001
Total cholesterol (mg/dL, age-standardized mean \pm SE)	187.1 ± 0.7	189.4 ± 0.5	191.4 ± 0.5	< 0.0001
Hypercholesterolemia (%, SE)				
Total (≥30 yr)	8.7 (0.7)	12.6 (0.4)	16.4 (0.5)	< 0.0001
Total (≥30 yr, age-standardized)	8.4 (0.6)	11.8 (0.4)	14.9 (0.5)	< 0.0001
30–39 yr	1.8 (0.5)	4.1 (0.5)	4.6 (0.6)	0.0017
40–49 yr	5.5 (1.0)	6.8 (0.6)	8.8 (0.9)	0.0226
50–59 yr	15.2 (1.9)	20.0 (1.2)	24.5 (1.2)	0.0001
60–69 yr	17.4 (2.1)	24.2 (1.3)	32.2 (1.5)	< 0.0001
≥70 yr	13.2 (2.4)	19.2 (1.4)	24.5 (1.4)	0.0002
P-value ^c	< 0.0001	< 0.0001	< 0.0001	



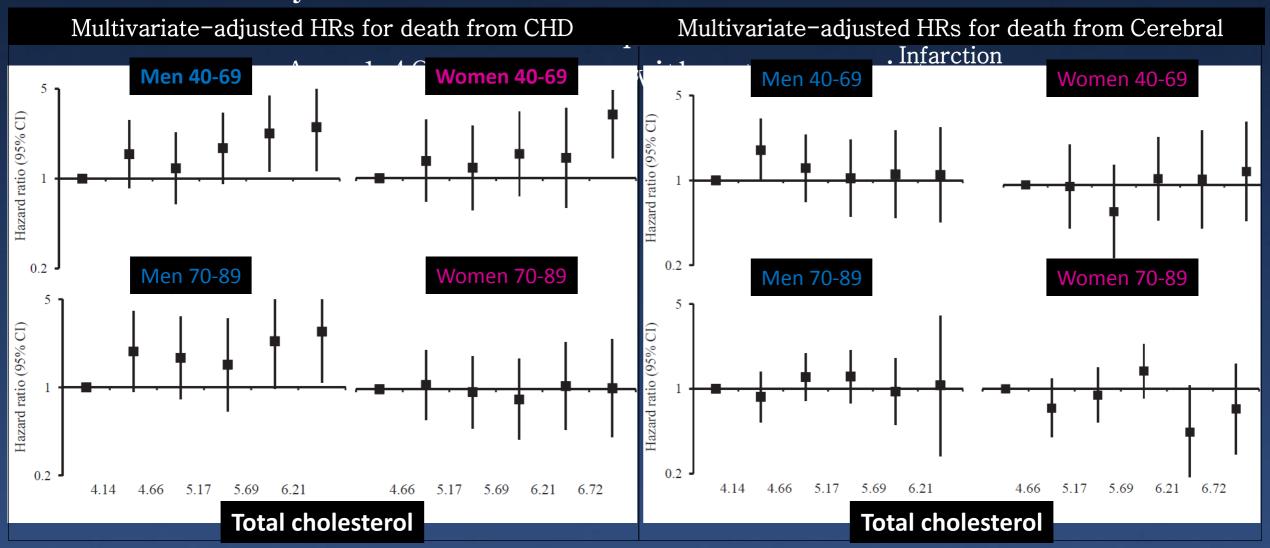


Relation Between Serum TC Level and CVD in Japan

EPOCH-JAPAN study

(Evidence for Cardiovascular Prevention from Observational Cohorts in Japan)

A Pooled Analysis of 65 594 Individuals From 10 Cohort Studies in



HRs, Hazard ratio was adjusted for cohort, age, systolic blood pressure, body mass index, and smoking and drinking categories.



Difference in lipid among Asians and non-Asians

An Analysis From the INTERHEART Study

4,247 cases of a first AMI and 5,452 control subjects in Asia 4,455 cases of a first AMI and 5,867 control subjects in non-Asian

Mean LDL-C, HDL-C in Subjects From Asia and Other Regions

	LDL-C* (mg/dl) Cases Controls		HDL-C* (mg/dl)		
			Cases	Controls	
Asia (n = 9,699)	126.8 (40)	118.6 (37)	39.2 (12.3)	41.2 (14.3)	
Non-Asian regions (n = $10,322$)	136.2 (42.4)	127.1 (39.1)	40.8 (13.2)	42.6 (15)	
South Asia (n = $2,674$)	125.2 (39.8)	115.4 (37.1)	32.5 (10)	33.5 (11.6)	
China/Hong Kong (n = $5,232$)	121.6 (36)	113.8 (33.8)	41.9 (12)	44.0 (13.3)	
Southeast Asia (n = 1,546)	150.4 (47.6)	135.6 (41)	41.0 (12.5)	42.6 (15.5)	
Japan (n = 247)	133.6 (34.6)	133.1 (30.9)	44.2 (12.8)	56.4 (13.2)	

^{*}p<0.0001. †p=0.01, for both between-case and between-control comparisons between Asian and non-Asian regions.

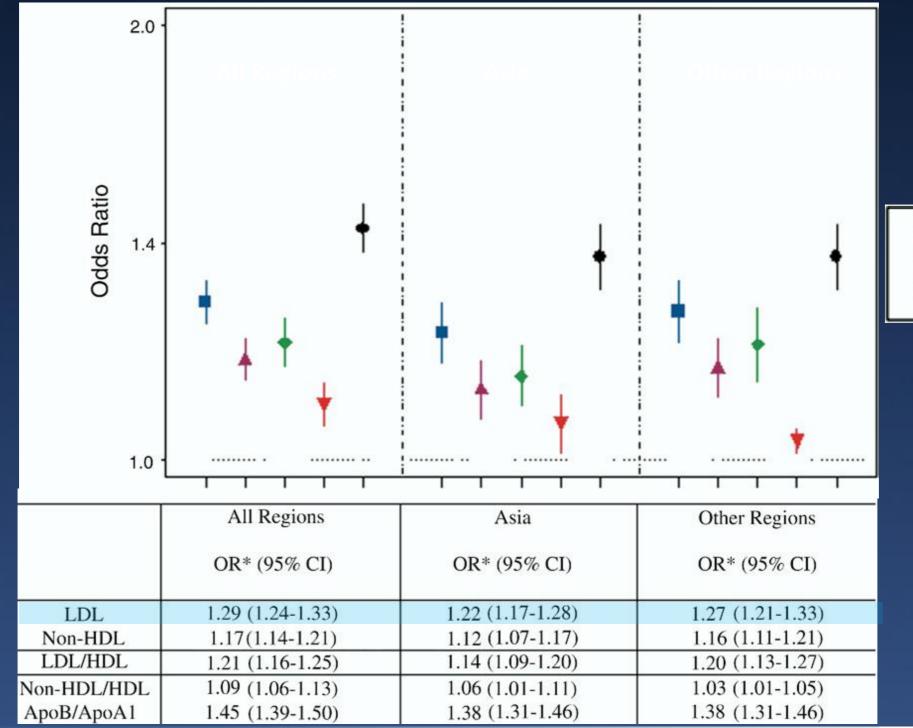
A greater proportion of Asian cases and controls had LDL-C≤ 100 mg/dl (25.5% and 32.3% in Asians vs. 19.4% and 25.3% in non-Asians, respectively).





Impact of lipid abnormality on CVD risk In an Asian population

Risk of First AMI for 1-SD Change in the Various Lipid





LDL

Non-HDL





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More than 40% of major CHD events annually occur in persons with established CHD

The average annual age-standardized prevalence of CHD in the Perth metropolitan region (population 1.6 million) was 28 373 (8.8%) in men and 14 966 (4.0%) in women

Characteristics of Men and Women Ages 35 to 84 Years With and Without Coronary Heart Disease in Perth, Western Australia, Between 1995 and 2005

	Established CHD		CHD) Free	
	Men	Women	Men	Women	
Average annual population, n	28 373	14 966	313 999	324 409	
Average annual prevalence,*† %	8.8	4.0	91.2	96.0	
Total nonfatal MI, CHD deaths, n (%)	8335 (43)	4117 (43)	11 121 (57)	5368 (57)	
Total CHD deaths, n (%)	4192 (55)	2276 (51)	3470 (45)	2165 (49)	
Total nonfatal MI, n (%)	4143 (35)	1841 (36)	7651 (65)	3203 (64)	
Average annual crude rates per 100 000 person-years					
Total nonfatal MI+CHD deaths	2686	2513	325	144	
CHD deaths	1361	1397	111	63	
Nonfatal MI	1325	1116	244	93	

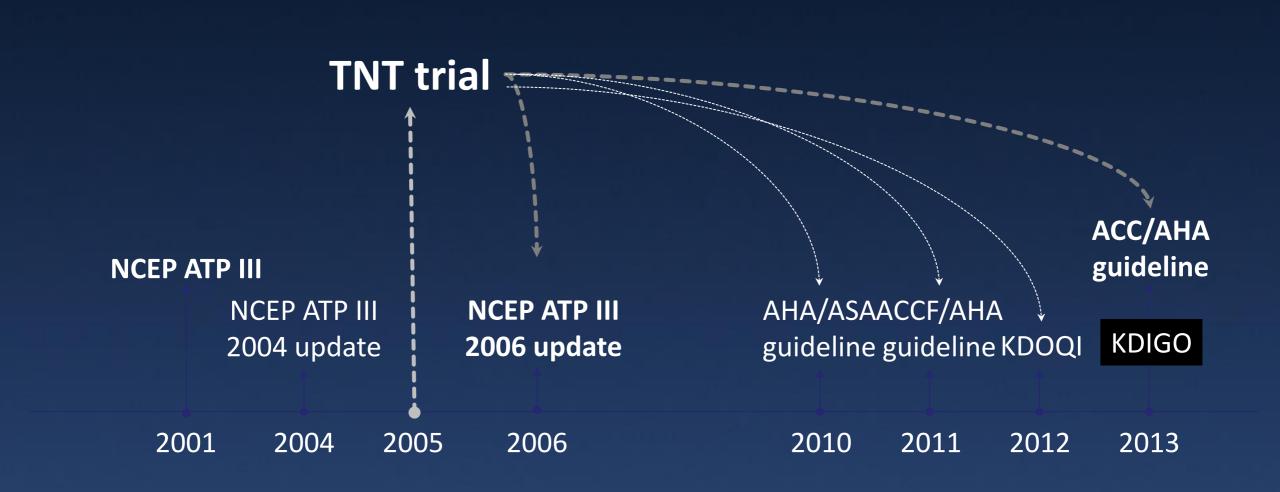
^{*}Average prevalence of previous admission for CHD in the past 15 years at June 30 in each calendar year 1995 to 2005.

†Age-standardized.





Role of TNT Trial in Lipid Guideline Evolution

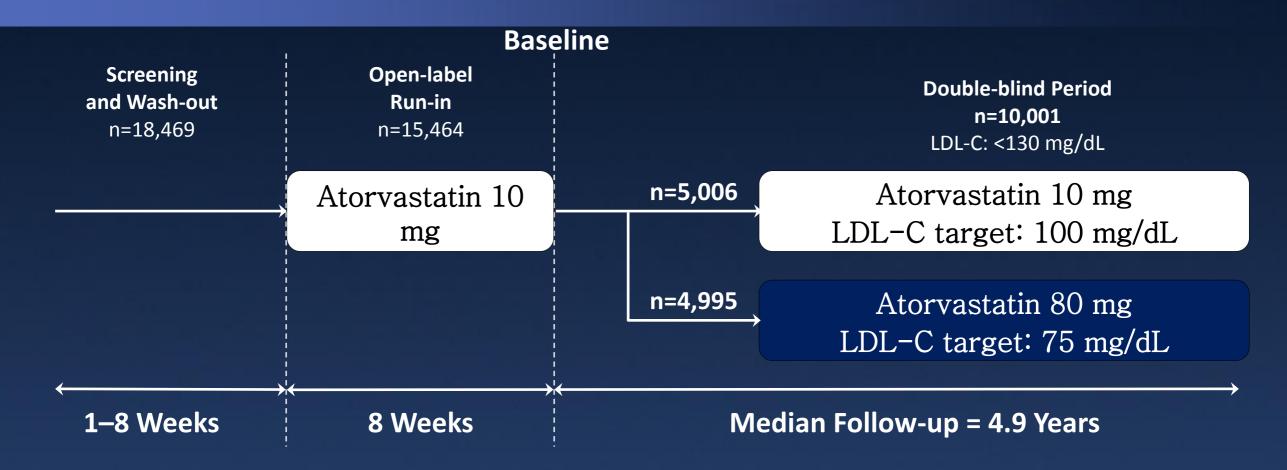


TNT was the First Randomized Clinical Trial to Prospectively Assess the Efficacy and Safety of Treating Patients with Stable CHD to LDL-C Levels Well Below 100 mg/dL





TNT: Study Design



Patient Population

35-75 yrs with stable CHD

LDL-C: 130-250 mg/dL

Triglycerides ≤600 mg/dL

Primary Efficacy Outcome

Time to occurrence of a major CV event:

CHD death

Nonfatal, non-procedure-related MI Resuscitated cardiac arrest Fatal or nonfatal stroke





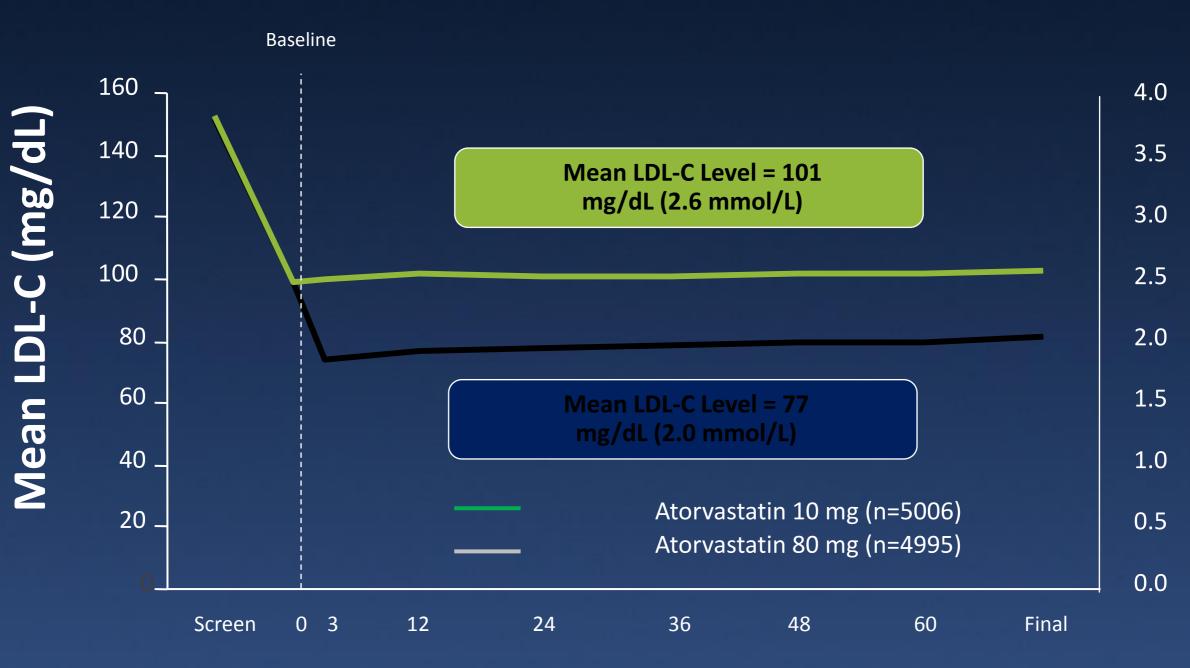
TNT: Baseline Patient Characteristics

	Atorvastatin 10 mg (n=5,006)	Atorvastatin 80 mg (n=4,995)
Age (mean ± SD) Men White	61 ± 8.8 yrs 81% 94%	61 ± 8.8 yrs 81% 94%
Cardiovascular Risk Factors (%) • Current Smoker • Hypertension • Diabetes Mellitus	13% 54% 15%	13% 54% 15%
Cardiovascular History (%)	81% 58% 54% 47% 5%	82% 59% 54% 47% 5%





TNT: Changes in Lipid Levels



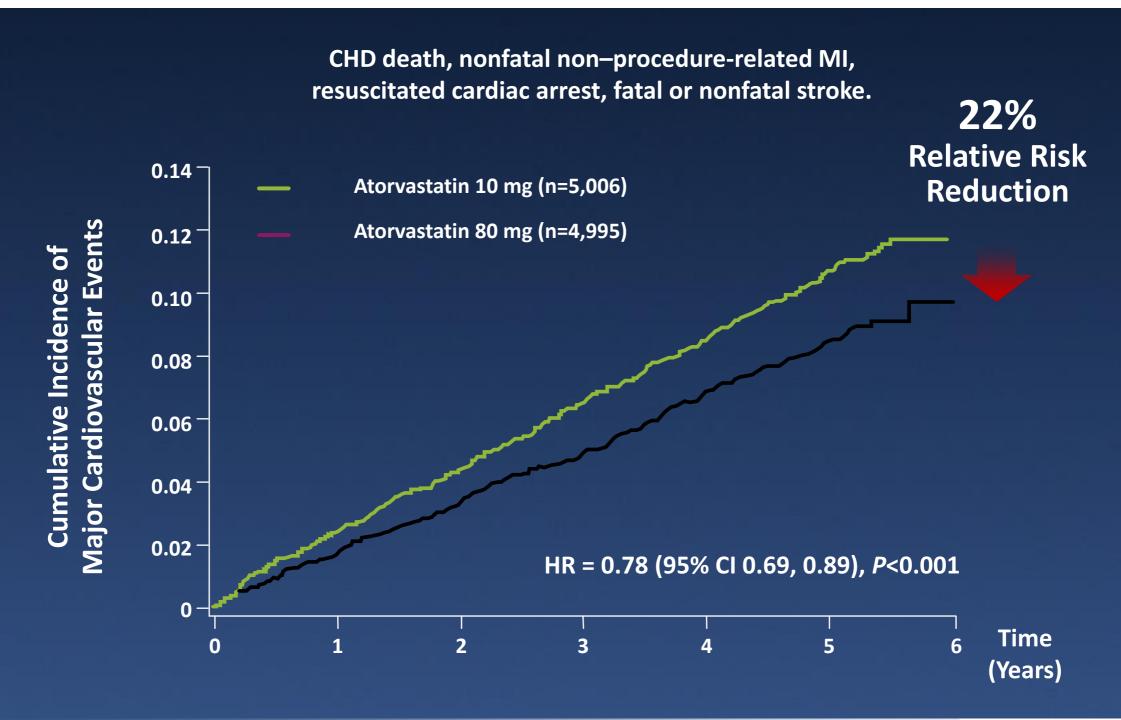




Mean LDL-C (mmol/L)

TNT: Primary Efficacy Outcome

Kaplan-Meier Estimates of the Incidence of the Primary End Point







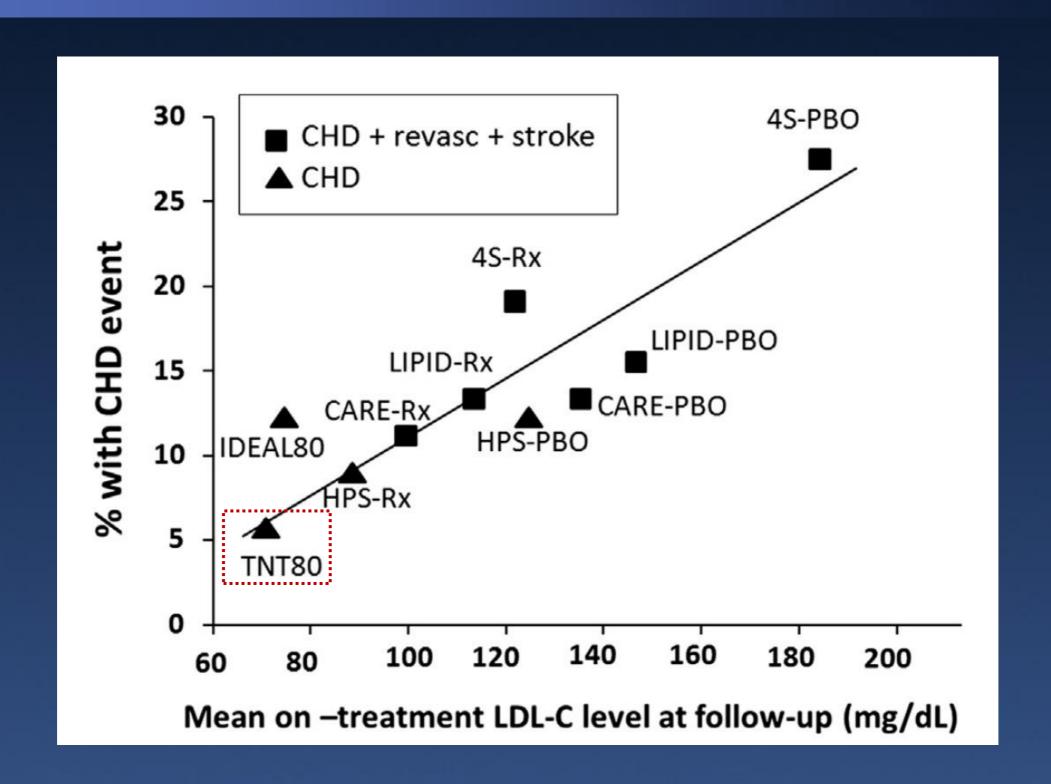
TNT: Safety Profile

	No. of Patients (%)			
	Atorvastatin 10 mg (n=5,006)	Atorvastatin 80 mg (n=4,995)		
Treatment discontinuation due to treatment-related AEs	264 (5.3)	359 (7.2)		
Myalgia (treatment-related)	234 (4.7)	241 (4.8)		
Rhabdomyolysis*	3 (0.06)	2 (0.04)		
AST/ALT elevation >3 x ULN [†]	9 (0.2)	60 (1.2)		





TNT: LDL < 100 mg/dL



ATP III Guideline vs ACC/AHA Guideline

	ATP III Guideline	ACC/AHA Guideline		
Year	2001 (updated in 2005)	2013		
Focus	Reducing CHD risk	Reducing risk of ASCVD*		
Risk Framingham 10 yr risk sco assessmen e (CHD death + non fatal Mi		Pooled cohort equations [†] (fatal & nonfatal CHD + fatal & nonfatal stroke)		

*ASCVD: ACS, a history of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, or PAD presumed to be of atherosclerotic origin

†Developed by the Risk Assessment Work Group to estimate the 10-year ASCVD risk for the identification of candidates for statin therapy





ATP III Guideline vs ACC/AHA Guideline

	ATP III Guideline	ACC/AHA Guideline
Risk Categories	 3 main risk categories: • CHD / CHD risk equivalent* • 2+ risk factors & 10-yr risk ≤ 20% • 0-1 risk factors & 10-yr risk <10% 	 4 statin benefit groups: Clinical ASCVD Primary LDL-C ≥190 mg/dl DM without clinical ASCVD No DM/CVD with 10-yr ASCV D risk ≥7.5%
Rx targets	LDL-C primary target • <70mg/dl • <130mg/dl (<100 if risk 10-20 %) • <160mg/dl	Intensity of statin therapy High or moderate intensity
Rx recomm endations	Statin (or bile acid sequestrants or nicotinic acid) to achieve LDL -C goal	Maximally tolerated statin first-l ine to reduce risk of ASCVD events



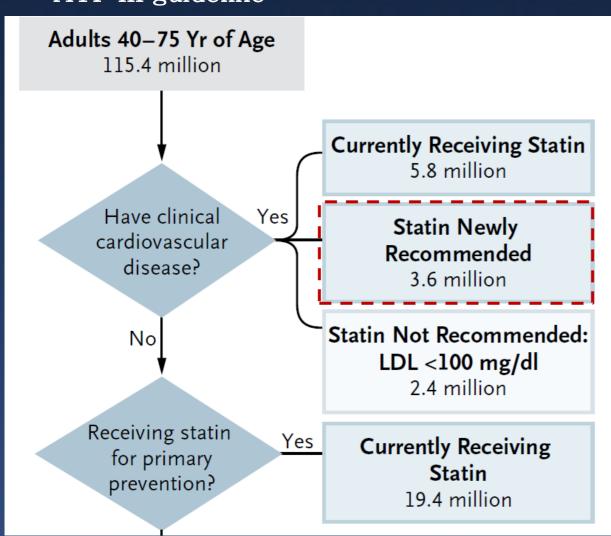
Estimated numbers of adults eligible for statin therapy by ATP III and ACC/AHA guideline in US

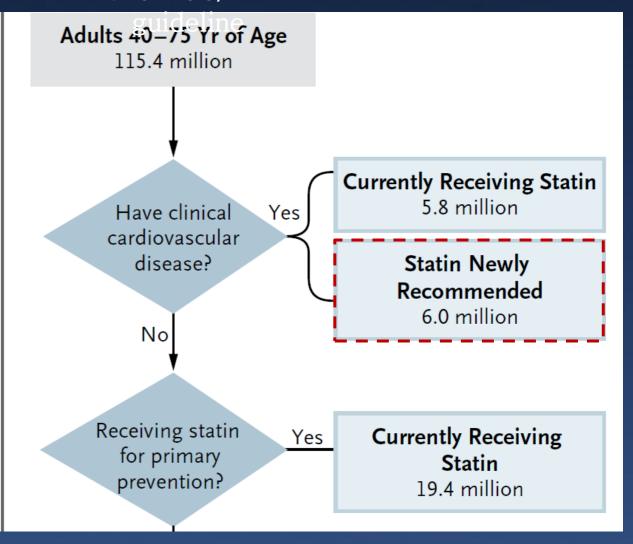
Ages of 40 and 75 Years in National Health and Nutrition Examination Surveys

Secondary prevention for adults with CVD

ATP III guideline

2013 ACC/AHA

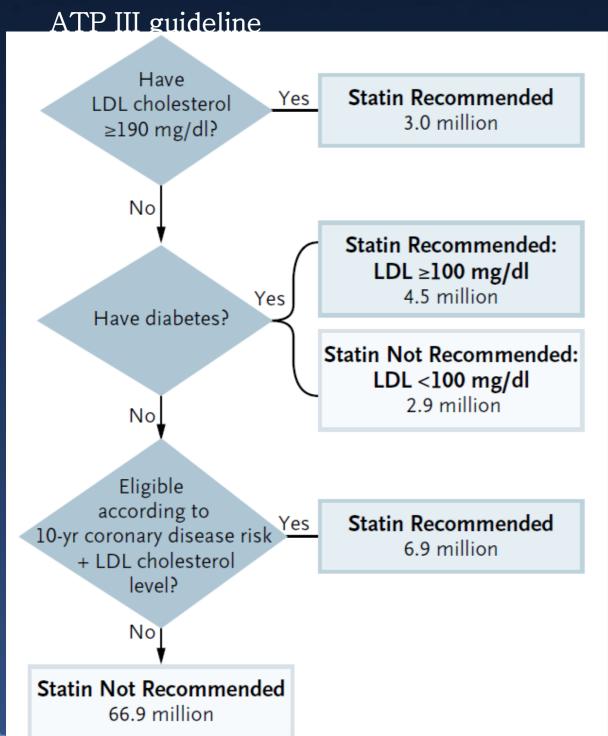


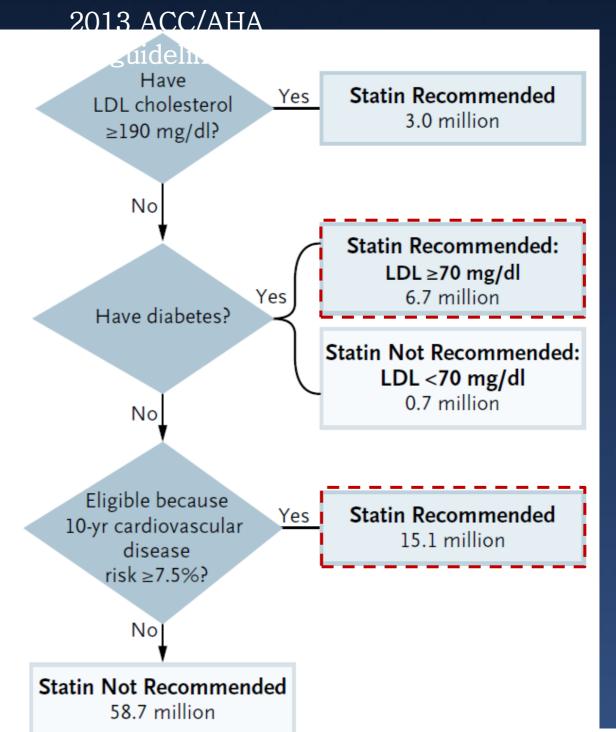




Estimated numbers of adults eligible for statin therapy by ATP III and ACC/AHA guideline in US

Primary prevention for adults receiving no statin





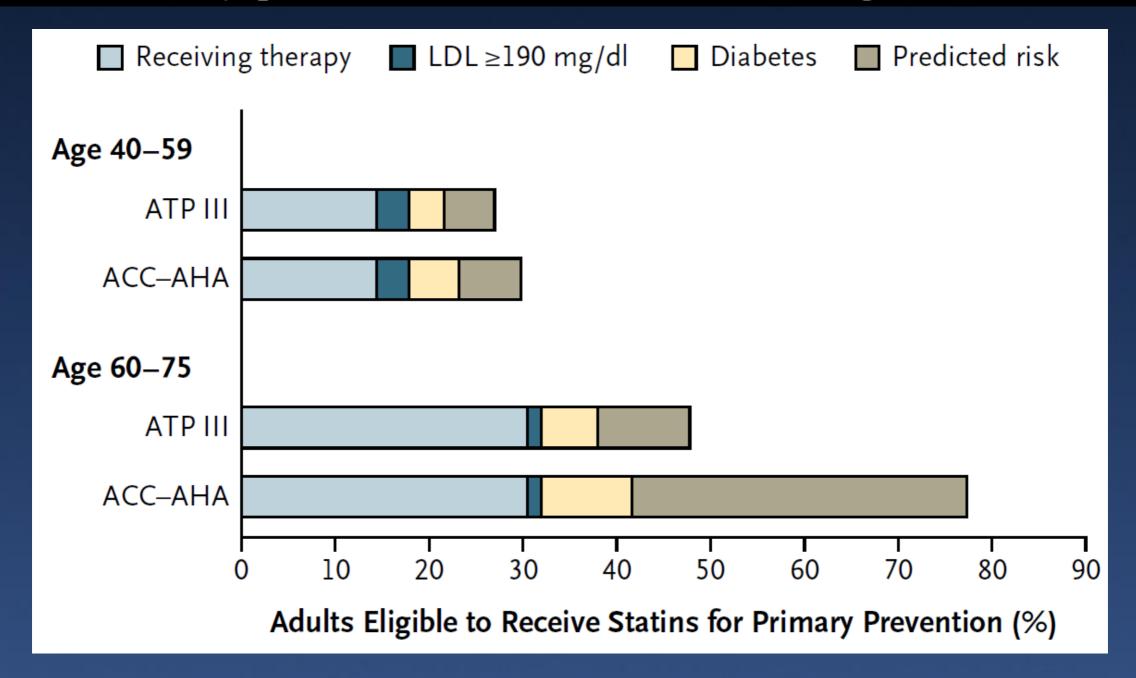




THE CATHOLIC UNIVERSITY OF KOREA

ACC/AHA guideline substantially increased the number of older adults without CVD compared with ATP III

Primary prevention for adults receiving no statin

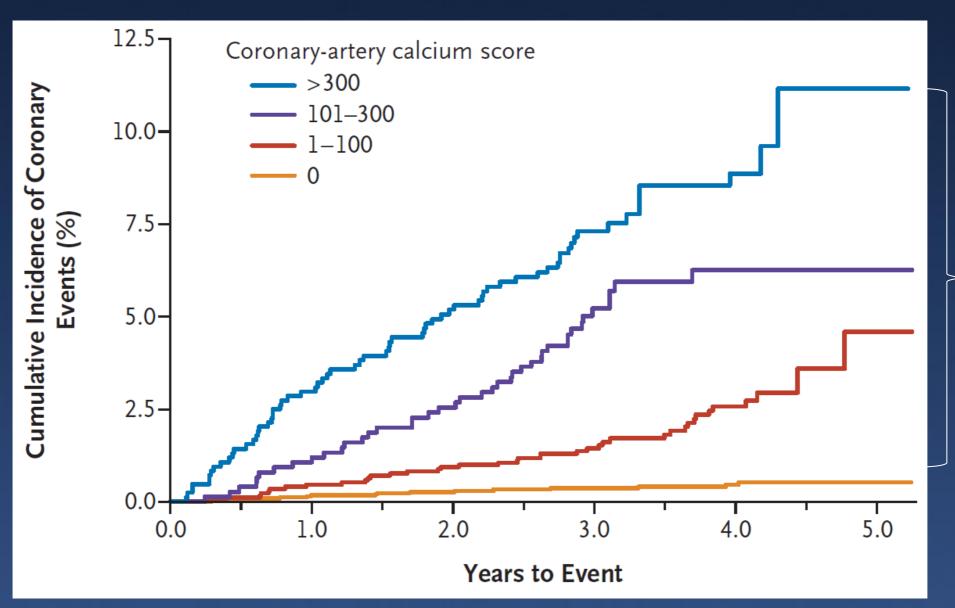






CAC (Coronary calcium score) is a strong predictor of incident coronary heart disease

MESA, Multi-Ethnic Study of Atherosclerosis 6,722 men and women without clinical CVD 3.8 years follow up



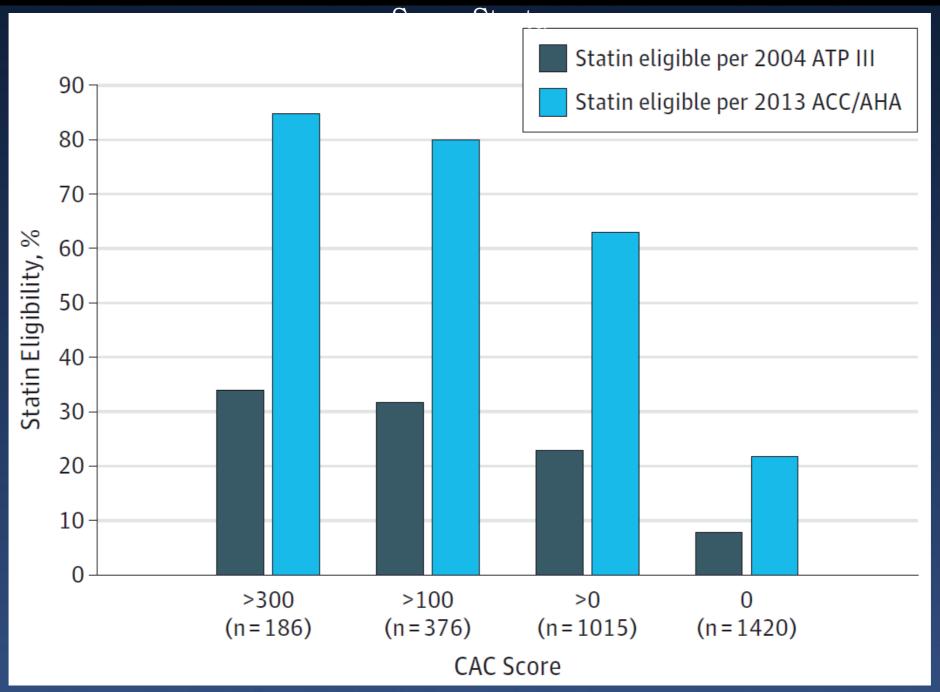
P<0.001
for differences
among all curves





Participants with CAC were more likely to be statin eligible by ACC/AHA than by ATP III

Comparison of Statin Eligibility by 2004 ATP III vs 2013 ACC/AHA Guidelines Across CAC



*CAC, Coronary calcium score as measured by the Agatston score





Estimated numbers of adults eligible for statin therapy by ATP III and ACC/AHA guideline in a Korean population

18,573 participants aged 40-75 yr in KNHNES 2008-2012

Statin eligible by ATP III vs Statin eligible by ACC/AHA 18.6% vs 35.1%

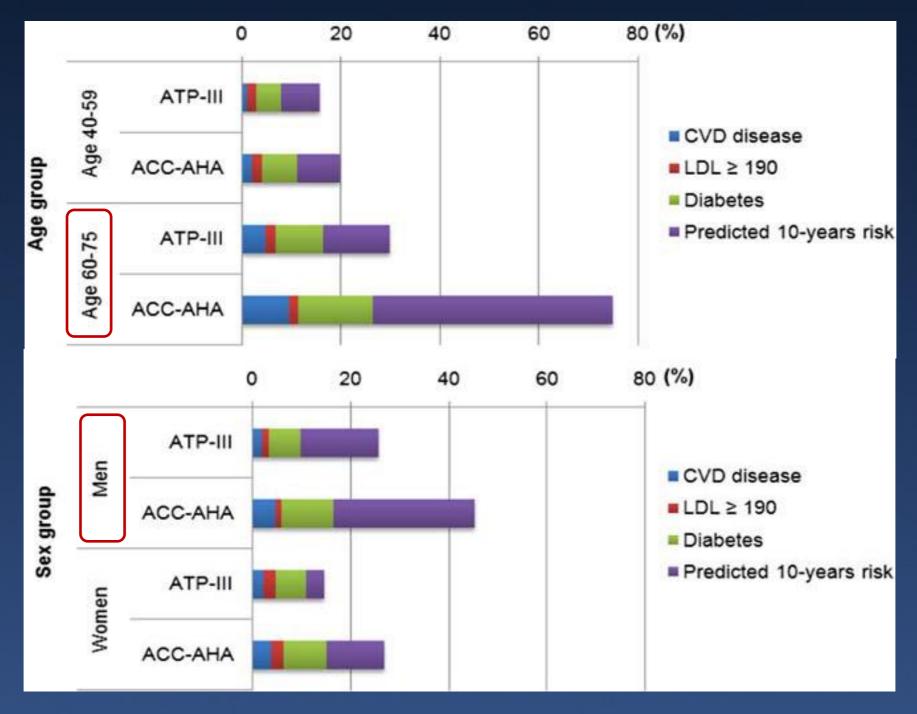
	ATP-III guidelines (N = 3730)	ACC/AHA guidelines (n = 7766)	New candidates for statin therapy† (n = 4397)
Prevalent CVD, no (%)	514 (11.4)	982 (11.7)	468 (10.5)
$LDL \ge 190 \text{ mg/dL, no.}$ (%)	388 (10.3)	388 (5.4)	0
Predicted 10-y risk, no. (%)	1561 (45.1)	4526 (56.3)	3326 (72.9)





Statin candidates by ACC/AHA guideline substantially increased among older adults and men

18,573 participants aged 40-75 yr in KNHNES 2009-2012



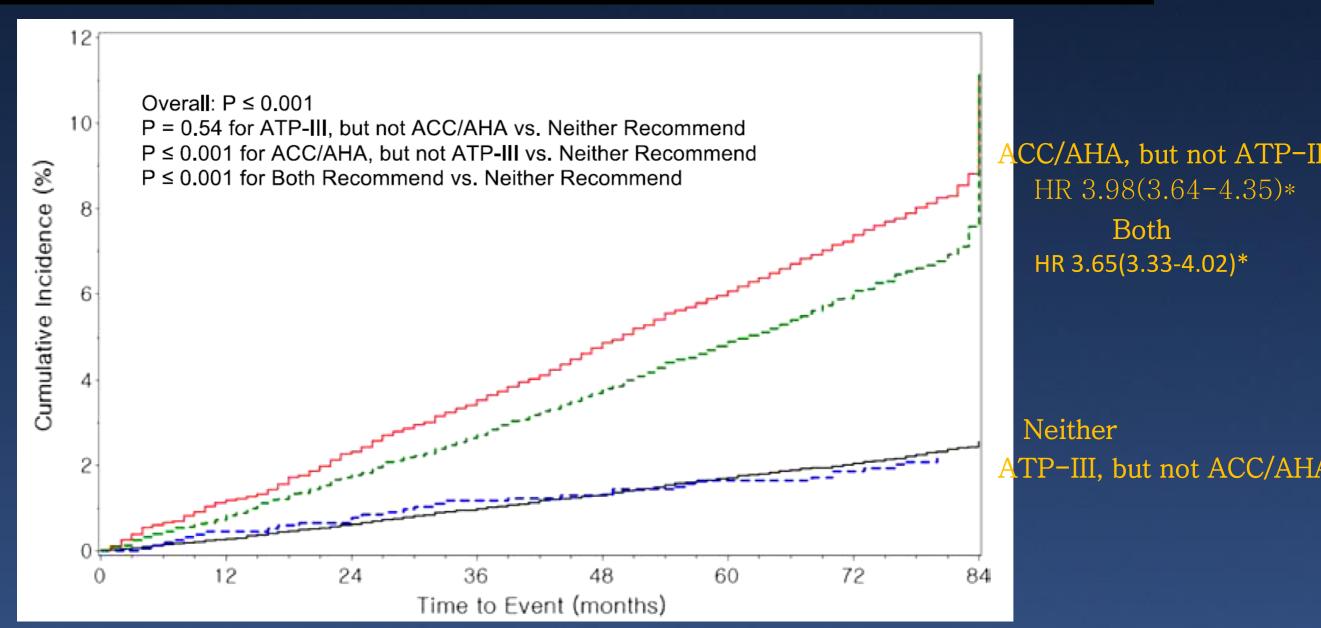




Identification of adults at higher ASCVD risk by ATP III and ACC/AHA guideline in a Korea population

18,573 participants aged 40- 75 yr in KNHNES 2008-2012 External cohort (n = 63,329) from the 2003 National Health Examination

Seven-year observed ASCVD events among Korean adults









2013 ACC/AHA guidelines is better in identifying subjects with subclinical coronary atherosclerosis

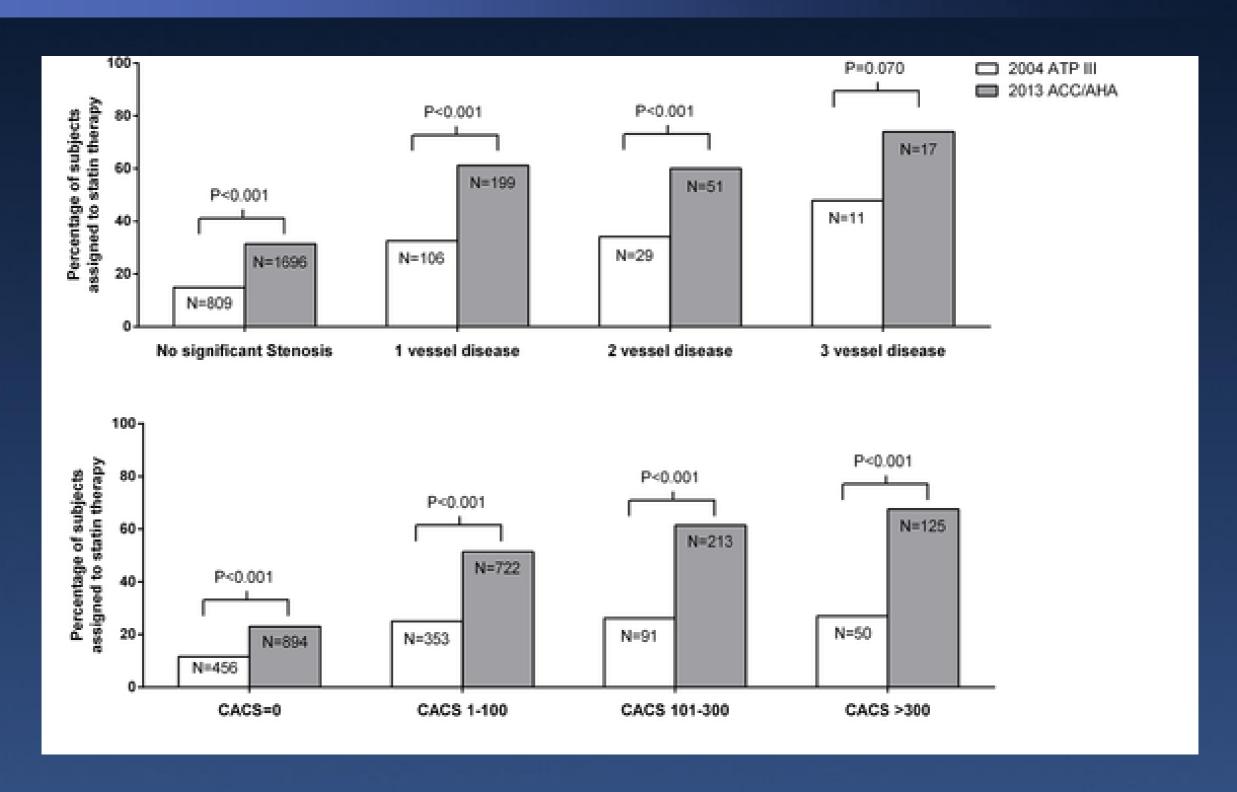
5,837 without CVD and asymptomatic subjects who underwent CCTA (mean age 53.5, men 72.1%) at Asan Medical Center between January 2007 and June 2011.

2013 ACC/AHA guideline	
LDL-C \geq 190 mg/dl	90 (1.5)
Diabetes & 40-75 & LDL 70-189 mg/dL	663 (11.4)
No Diabetes & 40–75 & LDL 70–189 mg/dL& ASCVD≥ 7.5%	1210 (20.7)
Total candidates	1963 (33.6)
2004 ATP III guideline	
CHD risk equivalents*& LDL-C≥ 100 mg/dl	597 (10.2)
No Diabetes & CHD risk factor \geq 2	
CHD risk 10–20% & LDL-C \geq 130 mg/dl	263 (4.5)
CHD risk <10% & LDL-C \geq 160 mg/dl	49 (0.8)
No CHD & no Diabetes & CHD risk factor 0–1	
LDL-C ≥ 190 mg/dl	46 (0.8)
Total candidates	955 (16.4)
Subjects eligible for statins by 2013 ACC/AHA guideline only	1110 (19.0)
Subjects eligible for statins by 2004 ATP III guideline only	102 (1.7)
Subjects eligible for statins by both guidelines	853 (14.6)





2013 ACC/AHA guidelines is better in identifying subjects with subclinical coronary atherosclerosis







2013 ACC/AHA guidelines is better in identifying subjects with subclinical coronary atherosclerosis

MDCT findings	N (%)	2004 ATP III		2013 ACC/AHA		P value*	P value [†]
		Sensitivity	Specificity	Sensitivity	Specificity		
Significant stenosis	432 (7.4%)	33.8 (29.5–38.4)	85.0 (84.1–86.0)	61.8 (57.1–66.3)	68.6 (67.4–69.9)	<.001	<.001
CACS>0	1945 (33.4%)	25.5 (23.6–27.5)	88.3 (87.2–89.3)	54.7 (52.5–56.9)	77.0 (75.7–78.3)	<.001	< .001
CACS>100	533 (9.2%)	26.5 (22.9–30.4)	84.7 (83.7–85.6)	63.6 (59.4–67.6)	69.4 (68.2–70.7)	<.001	< .001
Any plaque	2330 (39.9%)	24.7 (23.0–26.5)	89.2 (88.1–90.2)	52.3 (50.2–54.3)	78.8 (77.4–80.1)	<.001	< .001





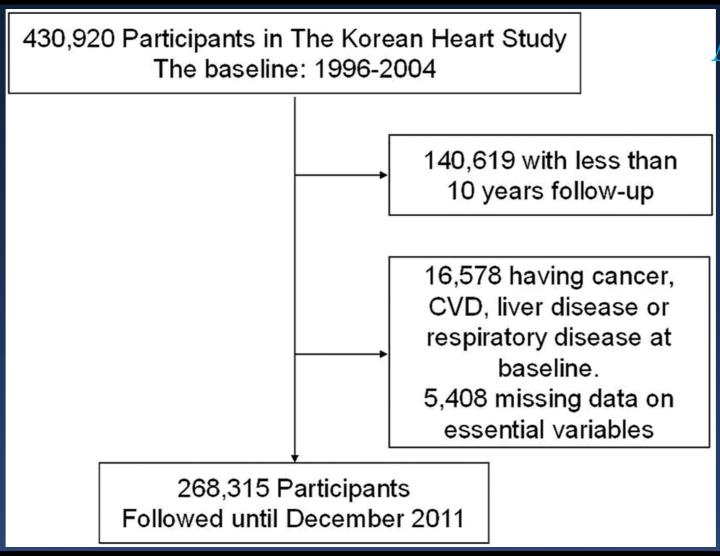
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A coronary heart disease prediction model : the Korean Heart Study

Study population



Aged 30-74 yr No CHD

Variable & Outcome

Variable: Age, BP, total and high-density lipoprotein-cholesterol (HDL-C), diabetes smoking

Outcome: Non-fatal or fatal CHD





HRs for CHD risk factors in men in the Korean Heart Study

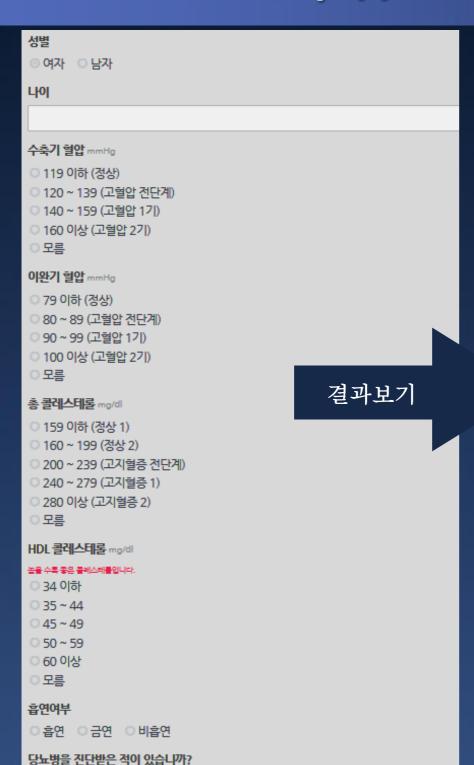
		Basic model HR (95% CI)	Model 1 HR (95% CI)	Model 2 HR (95% CI)	Model 3 HR (95% CI)
	Age	1.13 (1.09 to 1.18)	1.13 (1.08 to 1.18)	1.13 (1.08 to 1.18)	1.13 (1.08 to 1.18)
	Blood pressure				
	Nomal	1.00	1.00	1.00	1.00
	Prehypertension	1.30 (1.16 to 1.46)	1.29 (1.15 to 1.45)	1.32 (1.17 to 1.48)	1.28 (1.14 to 1.43)
	Stage-1 hypertension	1.74 (1.53 to 1.97)	1.72 (1.52 to 1.96)	1.78 (1.57 to 2.02)	1.68 (1.48 to 1.91)
	Stage-2 hypertension	2.22 (1.91 to 2.57)	2.20 (1.90 to 2.56)	2.28 (1.97 to 2.65)	2.13 (1.84 to 2.48)
	Total cholesterol, mg/dL				
	<160	1.00	1.00	1.00	1.00
	160–199	1.26 (1.07 to 1.49)	1.34 (1.14 to 1.59)	1.09 (0.90 to 1.32)	1.21 (1.02 to 1.43)
	200–239	1.81 (1.53 to 2.13)	2.02 (1.71 to 2.38)	1.23 (0.99 to 1.53)	1.67 (1.42 to 1.98)
	240–279	2.42 (2.01 to 2.92)	2.77 (2.30 to 3.34)	1.34 (1.04 to 1.73)	2.19 (1.81 to 2.65)
	≥280	3.79 (2.93 to 4.91)	4.45 (3.44 to 5.76)	2.02 (1.47 to 2.77)	3.37 (2.59 to 4.38)
	Smoking				
	Never	1.00	1.00	1.00	1.00
	Former	1.01 (0.88 to 1.16)	1.02 (0.89 to 1.17)	1.02 (0.89 to 1.17)	1.00 (0.87 to 1.15)
	Current	1.93 (1.72 to 2.17)	1.86 (1.65 to 2.09)	1.96 (1.75 to 2.21)	1.87 (1.66 to 2.11)
	Diabetes	4.00	4.00	4.00	1.00
	No	1.00	1.00	1.00	1.00
	Yes	1.69 (1.51 to 1.89)	1.63 (1.46 to 1.82)	1.72 (1.53 to 1.92)	1.65 (1.48 to 1.85)
	HDL-cholesterol, mg/dL		1.00		
	<35		1.00 0.66 (0.57 to 0.75)		
	35–44 45–49	HDL-C	0.56 (0.48 to 0.65)		
	50–59		0.45 (0.48 to 0.65) 0.45 (0.39 to 0.52)		
	≥60		0.34 (0.28 to 0.41)		
	LDL-cholesterol, mg/dL		0.54 (0.28 to 0.41)		
	<100			1.00	
	100–129			1.23 (1.06 to 1.43)	
	130–149			1.50 (1.25 to 1.80)	
	≥150			1.97 (1.61 to 2.40)	
	Triglycerides, mg/dL			1.57 (1.01 to 2.40)	
	<100				1.00
	100–149				1.21 (1.07 to 1.37)
	150–199				1.35 (1.18 to 1.54)
	200–249				1.39 (1.19 to 1.63)
	≥250				1.30 (1.11 to 1.52)
	ROC (95% CI)	0.756 (0.745 to 0.766)	0.764 (0.752 to 0.774)	0.758 (0.747 to 0.769)	0.757 (0.746 to 0.768)
RSIT	Continuous NRI (95% CI)	Referent model	0.284 (0.231 to 0.339)	0.185 (0.124 to 0.246)	0.109 (0.051 to 0.162)
	V'S HOSDITAI		(INVASCUIIAT (ANTAR

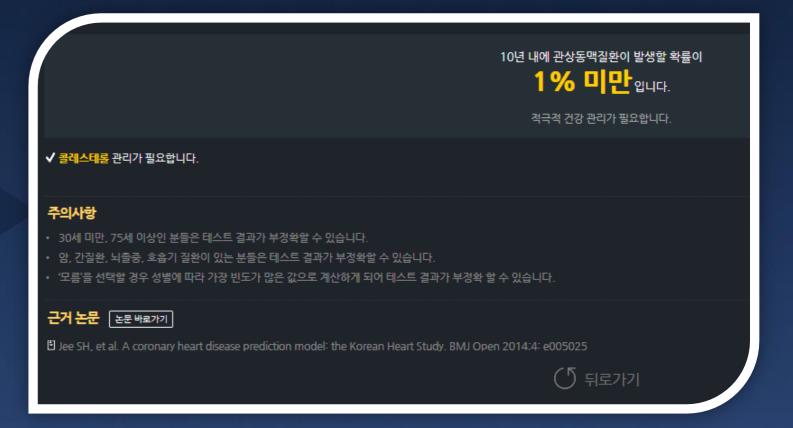


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관상동맥질환위험 예측모형

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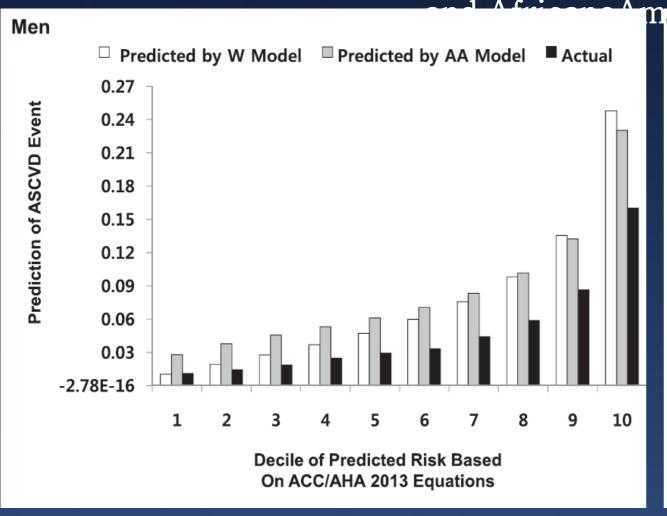


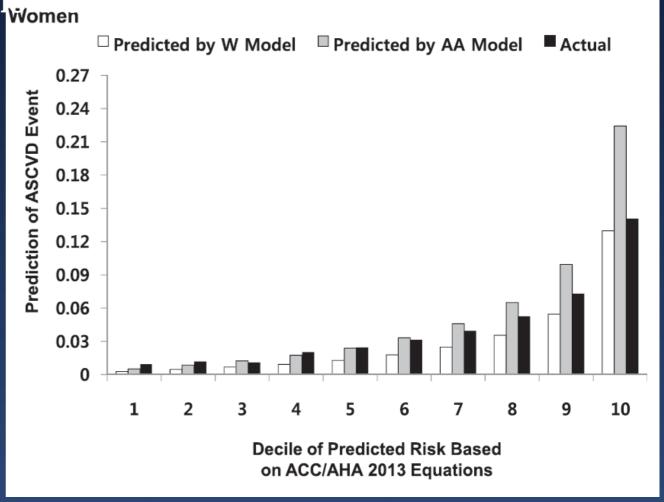


이 이 아니오

Evaluation of predictive ability of the ACC/AHA 2013 Pooled Cohort Equations for the KHS population

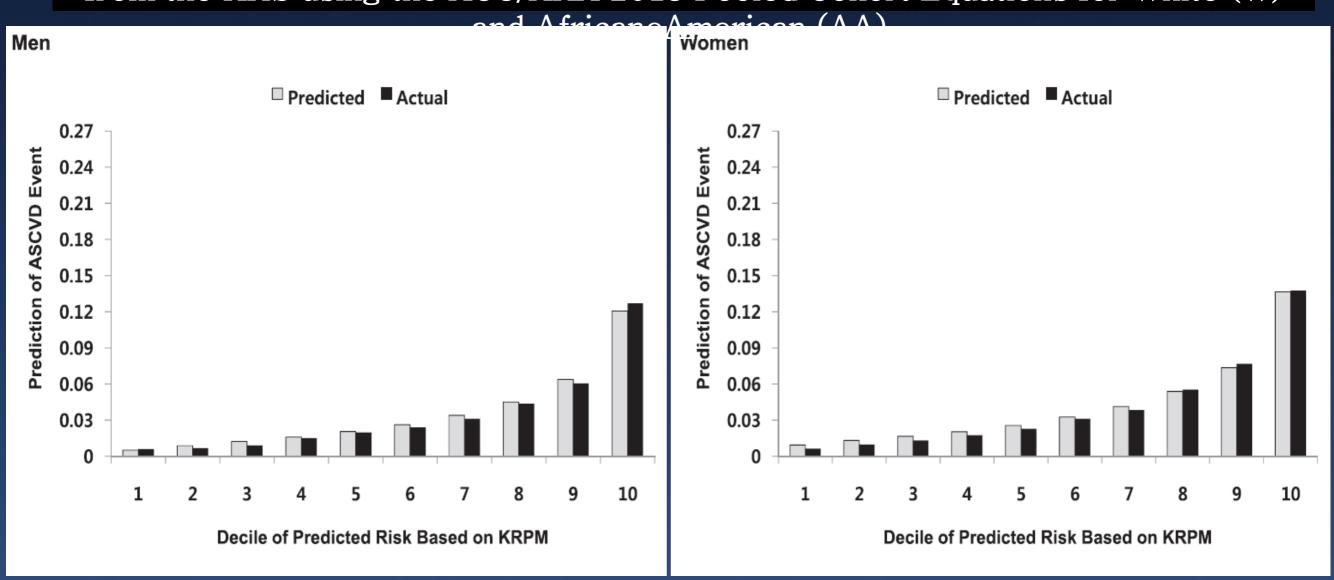
Ten-Year Probability of Predicted and Actual ASCVD Events in Men and Women from the KHS using the ACC/AHA 2013 Pooled Cohort Equations for White (W)





10-Year Probability of Predicted and Actual ASCVD Events by Korean Risk Prediction Model

Ten-Year Probability of Predicted and Actual ASCVD Events in Men and Women from the KHS using the ACC/AHA 2013 Pooled Cohort Equations for White (W)



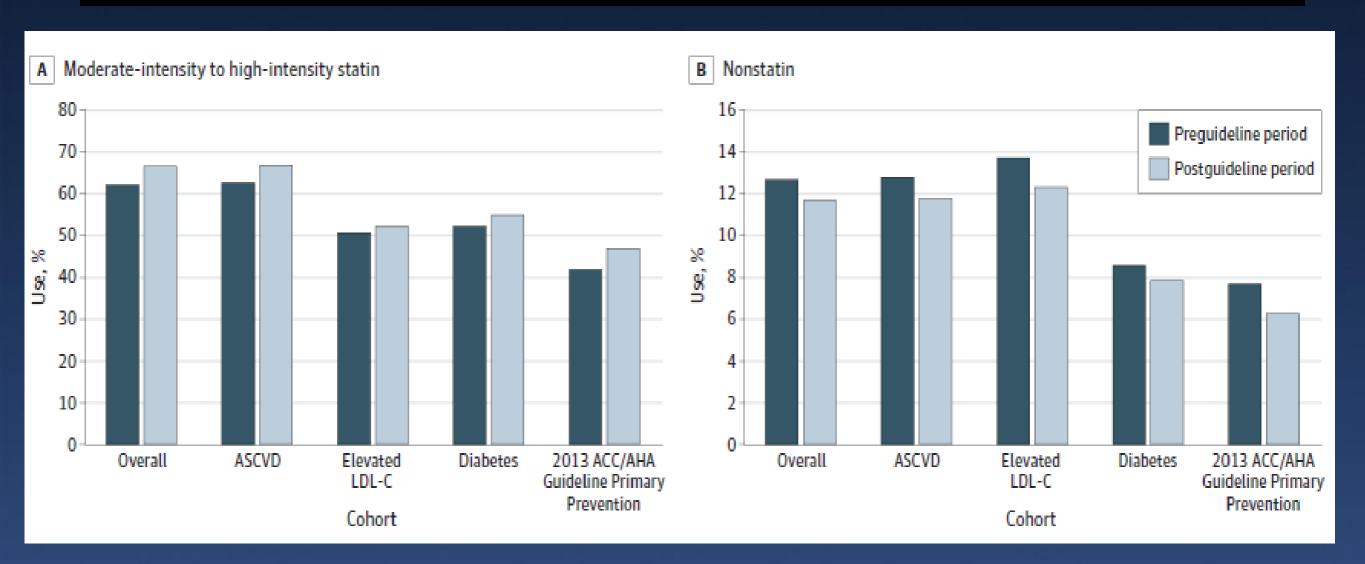
Calibration for χ^2 : 25.90, P = 0.002 for men; 14.69, P = 0.100 for women





A trend toward increasing use of moderate-intensity to high intensity statins overall and in the ASCVD cohort

Overall Use for the Pre-guideline and Post-guideline Periods



Adoption of the 2013 ACC/AHA Cholesterol Management Guideline in cardiology practices



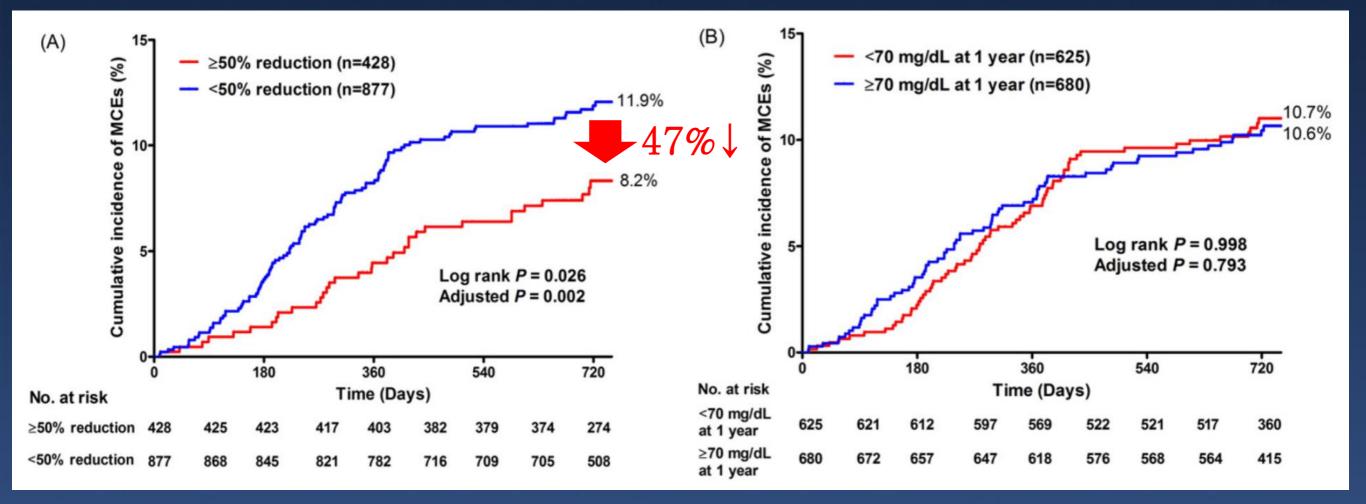


50% Reduction vs. LDL Target 70 mg/dL in AMI pts.

Primary endpoint: 2 year major cardiac event including cardiac death, non-fatal myocardial infraction, percutaneous coronary intervention, and coronary artery by bypass grafting after

KAGANIR! discharge

mean LDL-C: 126mg/dL





Korean Data: MUSTANG Study

Clinical Investigations



Current Statin Usage for Patients With Acute Coronary Syndrome Undergoing Percutaneous Coronary Intervention: Multicenter Survey in Korea

Mi-Jeong Kim, MD; Doo Soo Jeon, MD; Hyeon-Cheol Gwon, MD; Soo-Joong Kim, MD; Kiyuk Chang, MD; Hyo-Soo Kim, MD; Seung-Jea Tahk, MD; for Korean MUSTANG Investigators

Cardiovascular Center (M.-J. Kim, Jeon), Incheon St. Mary's Hospital, The Catholic University, Incheon, Republic of Korea; Cardiac and Vascular Center (Gwon), Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Republic of Korea; Division of Cardiology (S.-J. Kim), College of Medicine, Kyung Hee University, Seoul, Republic of Korea; Cardiovascular Center (Chang), Seoul St. Mary's Hospital, The Catholic University, Seoul, Republic of Korea; Cardiac Catheterization Laboratory and Coronary Intervention (H.-S. Kim), Department of Internal Medicine, Seoul National University Hospital, Seoul, Republic of Korea; Department of Cardiology (Tahk), Ajou University Hospital, Suwon, Republic of Korea

3362 patients with ACS underwent PCI

- diagnosed with unstable angina, (UA) non-ST-elevated MI(NSTEMI), or ST-elevated MI(STEMI)
- High-dose statin treatment was defined as <u>atorvastatin ≥40 mg</u> or rosuvastatin ≥20 mg/day.
- The patterns of statin usage were investigated for 30 days after the index PCI.

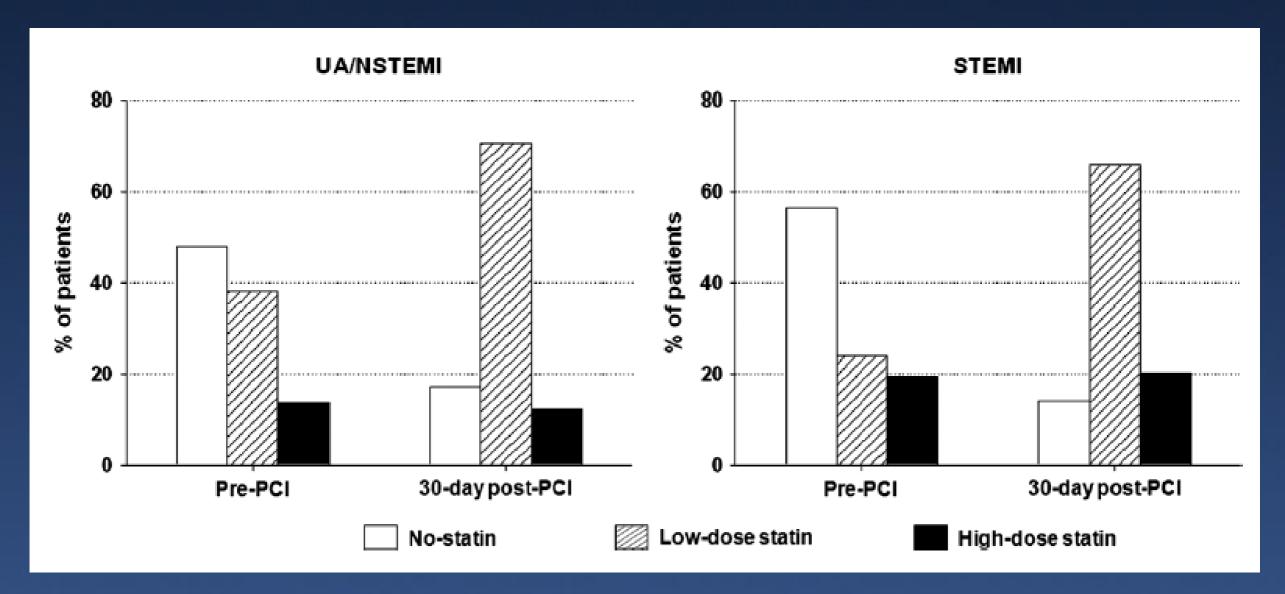




About half were never treated with statin prior to PCI

Statin dosage used in pre-PCI and post-PCI period in patients with UA/NSTEMI and STEMI

The usage of low-dose statin sharply increased after PCI compared with pre-PCI, but that of high-dose remained similar between the pre-PCI and post-PCI period





Conclusion

- 2013 ACC/AHA guideline substantially increased the number of statin Tx candidates, esp. the number of a predicted 10 year risk group
- 2013 ACC/AHA guideline has good performance for identifying subjects with subclinical coronary atherosclerosis
- Korean risk prediction model has superiority in predicting CVD risks in Korean general population.
- High intensity statin therapy in patients with ACS is less prescribed than we imagine.



