

# **Prognostic Role of Routine Stress Testing in Diabetic Patients After PCI: Key Analysis from POST-PCI**

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# Disclosure

- I have nothing to disclose.

# Follow-up Strategies after PCI

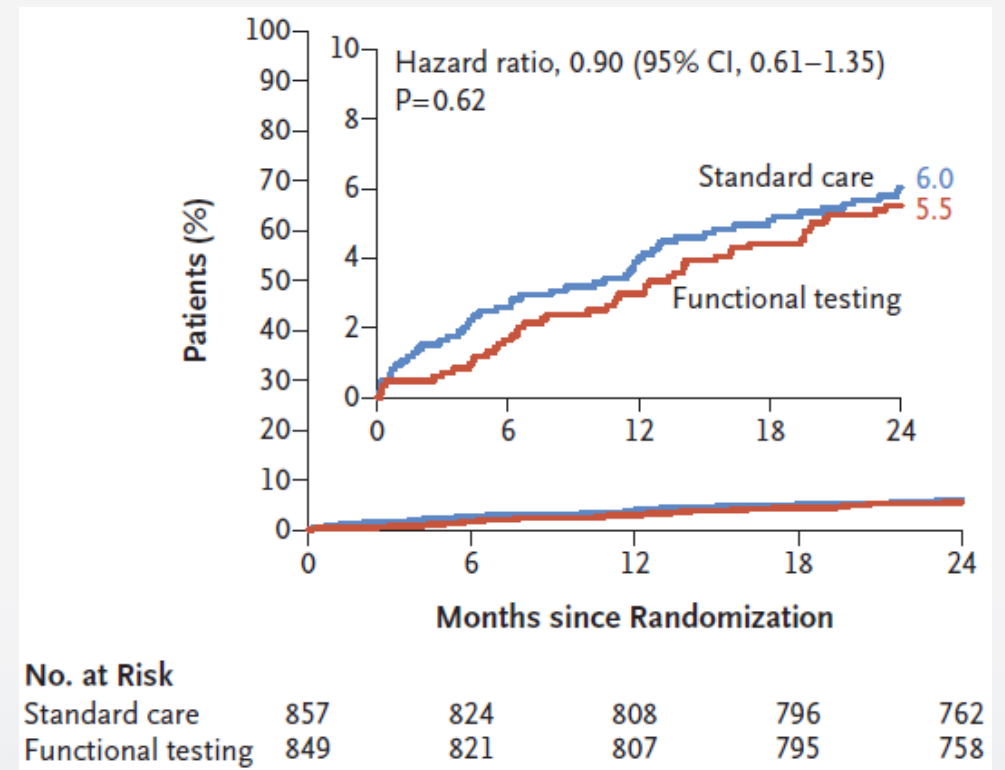
## 2018 ESC Guideline for Myocardial Revascularization

	COR	LOE
➤ Surveillance by non-invasive imaging-based stress testing <u>may be considered</u> in <b>high-risk patient</b> subsets <b>6 months</b> after revascularization	IIb	C
➤ <b>Routine</b> non-invasive imaging-based stress testing <u>may be considered</u> <b>1 year</b> after PCI	IIb	C

# The POST-PCI trial

- **DESIGN:** a multicenter, pragmatic, randomized trial conducted at 11 sites in South Korea
- **OBJECTIVE:** To compare a follow-up strategy of routine functional testing and standard care alone in patients with high-risk anatomical or clinical characteristics who had undergone PCI
- **Primary Composite Outcome:** a composite of death from any cause, myocardial infarction, or hospitalization for unstable angina) at 2 years
- A total of 1706 patients were randomly assigned to the functional testing group (n = 849) and the standard care group (n = 857)

## Primary Composite Outcome: All-cause Death, MI, or Hospitalization for UA



6.0% in Standard care vs. 5.5% in Functional Testing

Park D-W, et al. NEJM 2022;387:905-15

# Diabetes in Coronary Artery Disease

- Diabetic patients have a more aggressive form of atherosclerosis and more extensive coronary artery disease.

*Circulation 2013;128:1675-1685*

*Circulation 2015;132:923-931*

- Diabetes is a major determinant of adverse clinical events after myocardial revascularization.

*The Lancet Diabetes & Endocrinology 2013;1:317-328*

*Journal of the American College of Cardiology 2019;73:1629-1632*

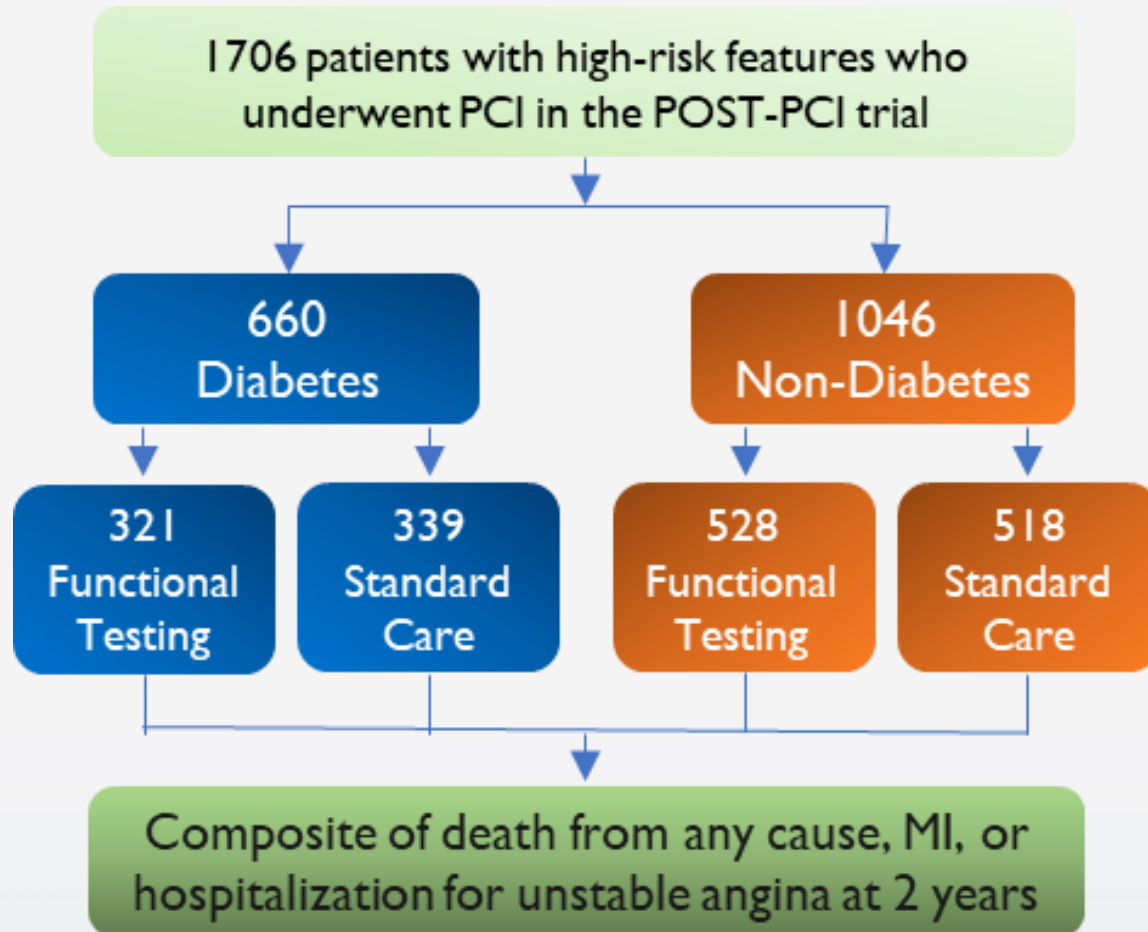
- Percutaneous coronary intervention (PCI) for diabetic patients is often being more complex and anatomically challenging.

*Circulation: Cardiovascular Interventions 2015;8:e001944*

# Background

- It is still unclear whether diabetic patients who undergo PCI could benefit from routine surveillance stress testing during follow-up.

# Diabetic subgroup analysis of the POST-PCI trial



## ***Primary outcome***

- Composite of death from any cause, MI, or hospitalization for unstable angina at 2 years

## ***Secondary outcome***

- Individual component of primary outcome
- Any hospitalization for cardiac or noncardiac causes
- Invasive coronary angiography
- Repeat revascularization

# Inclusion and Exclusion Criteria

*All patients enrolled in the Original POST-PCI trial were included in this prespecified subgroup analysis*

## INCLUSION

- $\geq 19$  years of age.
- Patients who underwent successful PCI with contemporary drug-eluting stents, bioresorbable scaffolds, or drug-coated balloons.
- Patients **must have at least one** of the following **high-risk anatomical or clinical** characteristics:
  - **Anatomical** characteristics: left main lesion, bifurcation lesion, ostial lesion, chronic total occlusion lesion, multivessel disease ( $\geq 2$  vessels stented), re-stenotic lesion, diffuse long lesion (lesion length  $\geq 30$  mm or stent length  $\geq 32$  mm), or bypass graft disease.
  - **Clinical** characteristics: diabetes, chronic renal failure, enzyme positive acute coronary syndrome (e.g., STEMI or NSTEMI).

## EXCLUSION

- Cardiogenic shock at the index admission.
- Patients treated only with bare metal stents or balloon angioplasty without stent implantation at the index procedure.
- Pregnant and/or lactating women.
- Concurrent medical condition with a life expectancy  $< 1$  year.
- Patients who were actively participating in another drug or device investigational study and had not completed the primary endpoint follow-up period.
- Patients who were unable to provide written informed consent or participate in long-term follow-up.



# Enrollment, Randomization, and Follow-up

*Stratified by the presence of Diabetes*

1706 patients in the POST-PCI trial

660 (39%) Diabetes

1046 (61%) Non-Diabetes

321 Functional Testing

339 Standard Care

528 Functional Testing

518 Standard Care

9 Died at <12 mo  
2 Withdrew consent <12 mo  
8 Lost to follow-up at <12 mo

9 Died at <12 mo  
2 Withdrew consent at <12 mo  
3 Lost to follow-up at <12 mo

3 Died at <12 mo  
2 Withdrew consent <12 mo  
3 Lost to follow-up at <12 mo

9 Died at <12 mo  
1 Withdrew consent at <12 mo  
9 Lost to follow-up at <12 mo

13 Had angiography or  
revascularization at <12 mo

19 Had angiography or  
revascularization at <12 mo

27 Had angiography or  
revascularization at <12 mo

36 Had angiography or  
revascularization at <12 mo

260 (90.0%) of eligible patients  
underwent functional testing

19 (6.2%) of eligible patients  
underwent functional testing

463 (93.9%) of eligible patients  
underwent functional testing

48 (10.4%) of eligible patients  
underwent functional testing

310 (96.6%) completed 24-mo  
follow-up

332 (97.9%) completed 24-mo  
follow-up

522 (98.9%) completed 24-mo  
follow-up

507 (97.9%) completed 24-mo  
follow-up

321 (100%) were included in the  
final analysis

339 (100%) were included in the  
final analysis

528 (100%) were included in the  
final analysis

518 (100%) were included in the  
final analysis

# Baseline Characteristics

	Overall (n=1706)	Diabetes (n=660)	Non-Diabetes (n=1046)	P Value
<b>Age, yr</b>	64.69±10.28	66.43±9.53	63.59±10.59	<b>&lt;0.001</b>
<b>Male sex</b>	1356 (79.48)	505 (76.52)	851 (81.36)	<b>0.016</b>
Body-mass index	24.91±3.09	24.96±3.18	24.88±3.03	0.584
Cardiac risk factors and comorbidities				
<b>Hypertension</b>	1178 (69.05)	513 (77.73)	665 (63.58)	<b>&lt;0.001</b>
Dyslipidemia	1487 (87.16)	584 (88.48)	903 (86.33)	0.195
Current smoker	462 (27.08)	174 (26.36)	288 (27.53)	0.596
Family history of premature CAD	102 (5.98)	36 (5.45)	66 (6.31)	0.468
Previous myocardial infarction	113 (6.62)	43 (6.52)	70 (6.69)	0.886
<b>Previous PCI</b>	375 (21.98)	172 (26.06)	203 (19.41)	<b>0.001</b>
Previous CABG	42 (2.46)	19 (2.88)	23 (2.2)	0.377
<b>History of cerebrovascular disease</b>	109 (6.39)	52 (7.88)	57 (5.45)	<b>0.046</b>
History of peripheral-artery disease	39 (2.29)	20 (3.03)	19 (1.82)	0.102
<b>Atrial fibrillation or atrial flutter</b>	43 (2.52)	24 (3.64)	19 (1.82)	<b>0.020</b>

# Baseline Characteristics

	Overall (n=1706)	Diabetes (n=660)	Non-Diabetes (n=1046)	P Value
Criteria for high risk after PCI				
High-risk anatomical characteristics				
Left main disease	359 (21.04)	148 (22.42)	211 (20.17)	0.266
<b>Bifurcation disease</b>	742 (43.49)	266 (40.3)	476 (45.51)	<b>0.035</b>
Ostial lesion	255 (14.95)	99 (15)	156 (14.91)	0.961
<b>Chronic total occlusion</b>	342 (20.05)	114 (17.27)	228 (21.8)	<b>0.023</b>
<b>Multivessel disease</b>	1191 (69.81)	482 (73.03)	709 (67.78)	<b>0.021</b>
≥2 vessels stented	765 (44.84)	297 (45)	468 (44.74)	0.917
Restenotic lesion	194 (11.37)	78 (11.82)	116 (11.09)	0.644
Diffuse long lesion	1196 (70.11)	448 (67.88)	748 (71.51)	0.111
Bypass graft disease	11 (0.64)	5 (0.76)	6 (0.57)	0.759
High-risk clinical characteristics				
Diabetes on insulin	73 (4.28)	73 (11.06)	0 (0)	-
<b>Chronic renal failure</b>	87 (5.1)	70 (10.61)	17 (1.63)	<b>&lt;0.001</b>
Receipt of dialysis	49 (2.87)	39 (5.91)	10 (0.96)	<b>&lt;0.001</b>
Enzyme-positive acute coronary syndrome	331 (19.4)	116 (17.58)	215 (20.55)	0.130
Clinical indication for index PCI				
Stable angina or silent ischemia	1180 (69.17)	465 (70.45)	715 (68.36)	0.364
Unstable angina	195 (11.43)	79 (11.97)	116 (11.09)	
Non-STEMI	203 (11.9)	75 (11.36)	128 (12.24)	
STEMI	128 (7.5)	41 (6.21)	87 (8.32)	

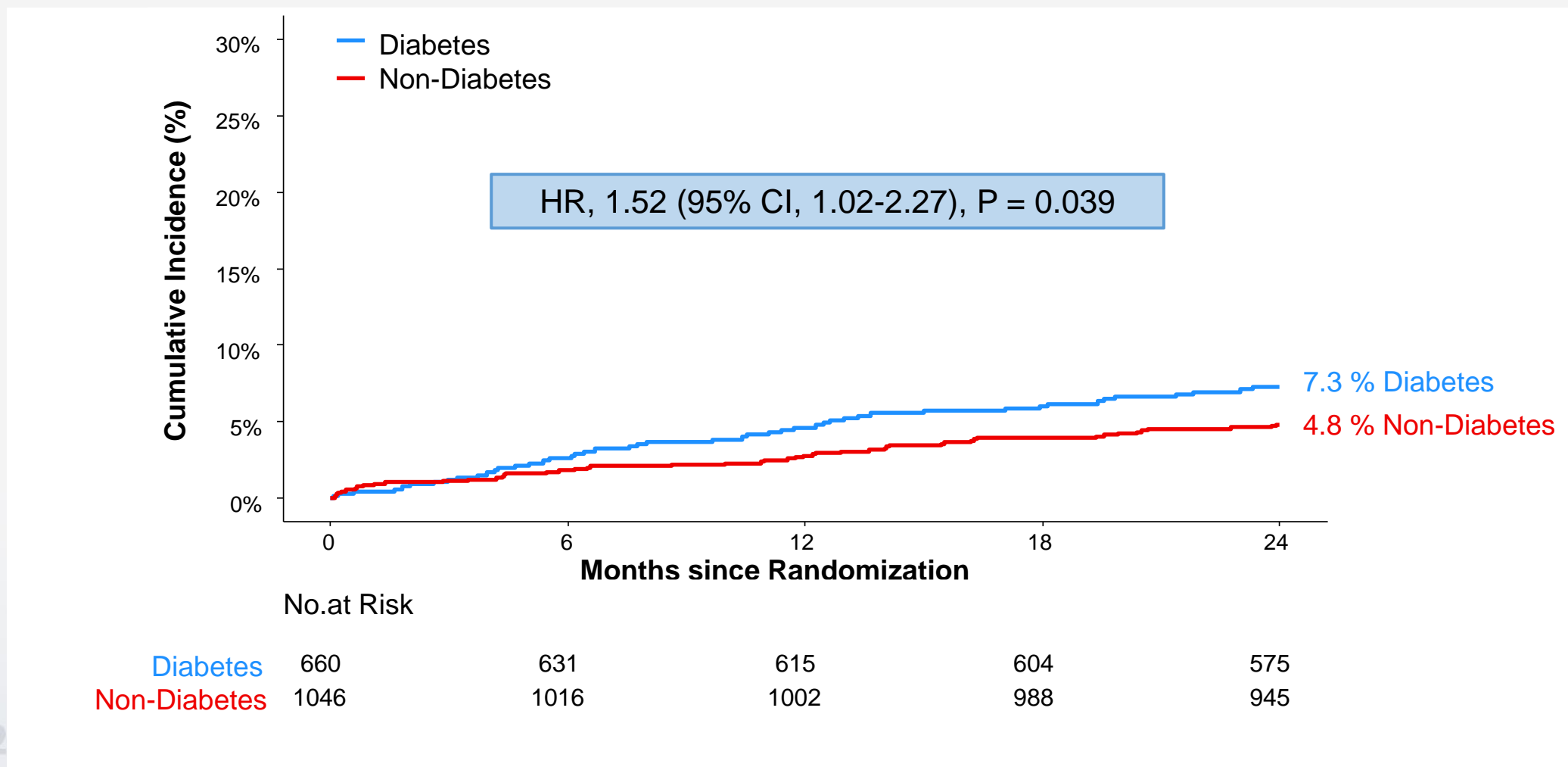
# Procedural Characteristics

	Overall (n=1706)	Diabetes (n=660)	Non-Diabetes (n=1046)	P Value
Procedural characteristics				
<b>Total no. of diseased lesions per patient</b>	2.24±1.16	2.35±1.21	2.16±1.12	<b>0.002</b>
Total no. of treated lesions per patient	1.45±0.68	1.46±0.67	1.45±0.69	0.553
Total no. of stents per patient	1.95±1.15	1.93±1.11	1.97±1.18	0.743
Total stent length per patient — mm	57.11±33.84	55.94±32.49	57.85±34.66	0.364
Use of drug-eluting stents — no. (%)	1645 (96.42)	640 (96.97)	1005 (96.08)	0.335
Use of bioabsorbable scaffold — no. (%)	16 (0.94)	2 (0.3)	14 (1.34)	0.031
Use of drug-coated balloon — no. (%)	105 (6.15)	42 (6.36)	63 (6.02)	0.776
Intravascular ultrasound guidance — no. (%)	1269 (74.38)	490 (74.24)	779 (74.47)	0.915
Fractional flow reserve assessed — no. (%)	609 (35.7)	236 (35.76)	373 (35.66)	0.967

# Primary Composite Outcome

*A composite of Death from any cause, MI, or hospitalization for unstable angina at 2 years*

**Diabetes vs. Non-Diabetes**



# Primary and Secondary Outcomes

## *Diabetic and Non-Diabetic patients*

	Diabetes (n=660)	Non-Diabetes (n=1046)	Hazard Ratio (95% CI)	P Value
Primary composite outcome	47 (7.3)	50 (4.8)	1.52 (1.02–2.27)	0.039
<b>Death from any cause</b>	28 (4.3)	23 (2.2)	1.97 (1.13–3.42)	0.016
Myocardial infarction	8 (1.3)	6 (0.6)	2.17 (0.75–6.24)	0.153
Hospitalization for unstable angina	11 (1.7)	22 (2.2)	0.81 (0.39–1.67)	0.56
Secondary outcomes				
<b>Death or myocardial infarction</b>	36 (5.6)	29 (2.8)	2.01 (1.23–3.28)	0.005
<b>Hospitalization</b>				
Any reason	187 (29.3)	214 (20.9)	1.49 (1.22–1.81)	<0.001
Cardiac reason	87 (13.8)	145 (14.2)	0.97 (0.75–1.27)	0.832
Noncardiac reason	100 (10.0)	69 (6.7)	2.45 (1.80–3.32)	<0.001
<i>Invasive coronary angiography</i>	63 (10.0)	115 (11.3)	0.89 (0.65–1.21)	0.445
Showing restenosis or obstructive CAD	44	70		
Showing no restenosis or obstructive CAD	19	45		
<i>Repeat revascularization</i>	45 (6.5)	73 (7.2)	0.91 (0.62–1.34)	0.631
Target-lesion revascularization	24 (3.8)	36 (3.5)	1.09 (0.65–1.82)	0.753
Nontarget-lesion revascularization	17 (2.7)	37 (3.6)	0.74 (0.42–1.32)	0.311

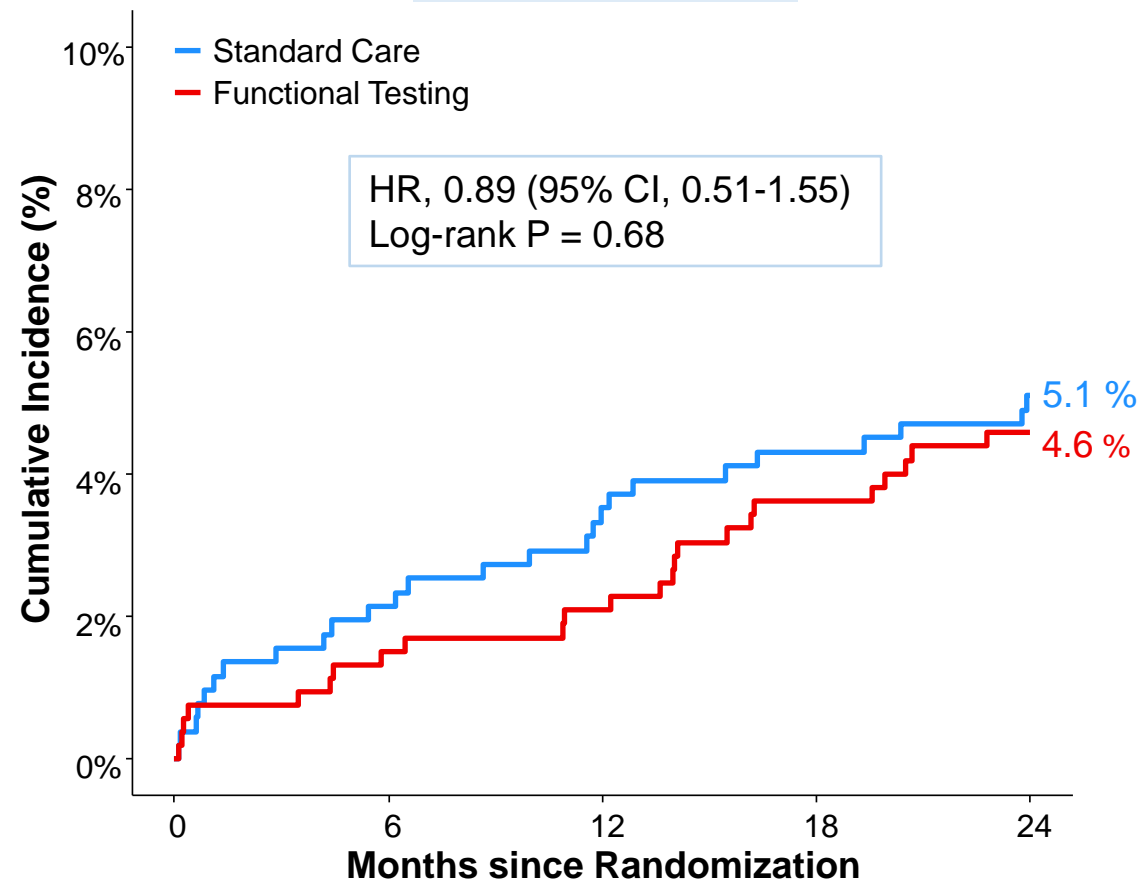
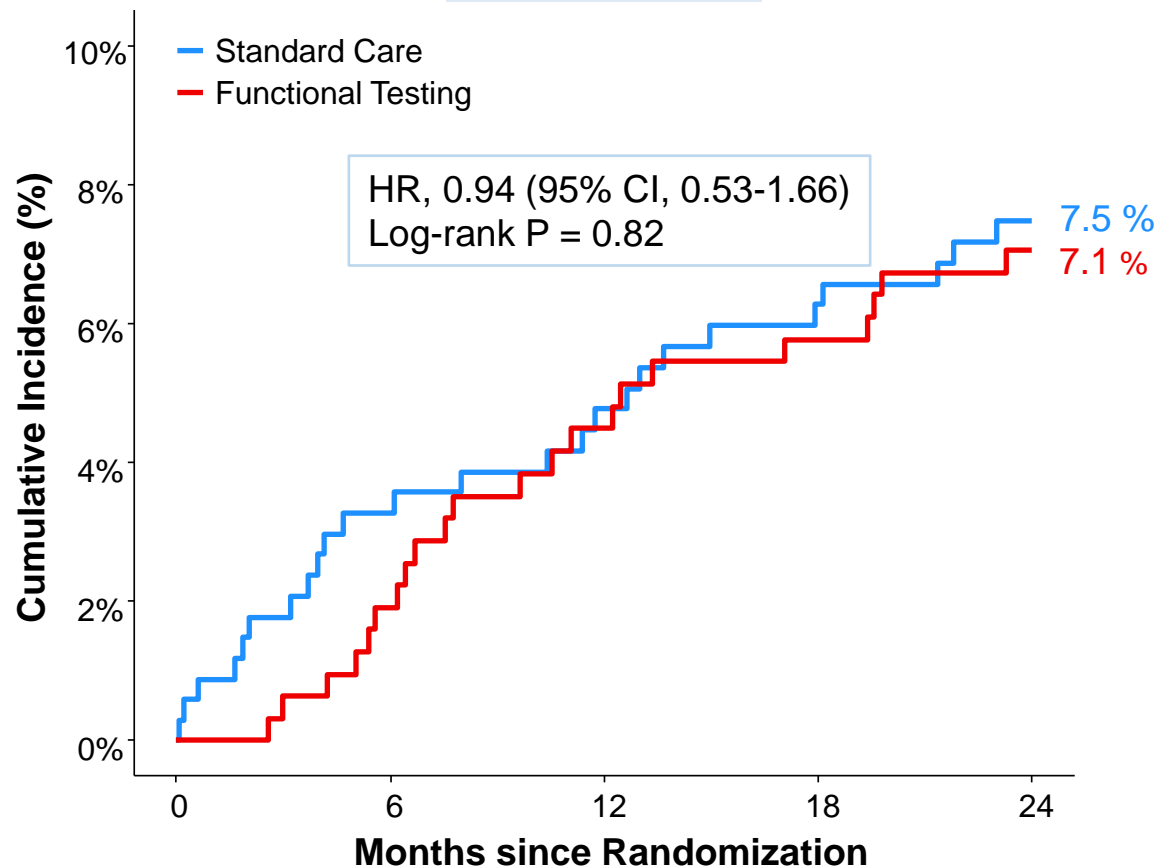
# Primary Composite Outcome

*Stratified by Diabetes status and Randomization Group*

P for interaction = 0.91

**Diabetics**

**Non-Diabetics**



	No. at Risk	0	6	12	18	24
Standard Care	339	324	318	311	293	
Functional Testing	321	307	297	293	282	

	No. at Risk	0	6	12	18	24
Standard Care	518	500	490	485	469	
Functional Testing	528	516	512	503	476	

# Primary and Secondary Outcomes

*Stratified by Diabetes status and Randomization Group*

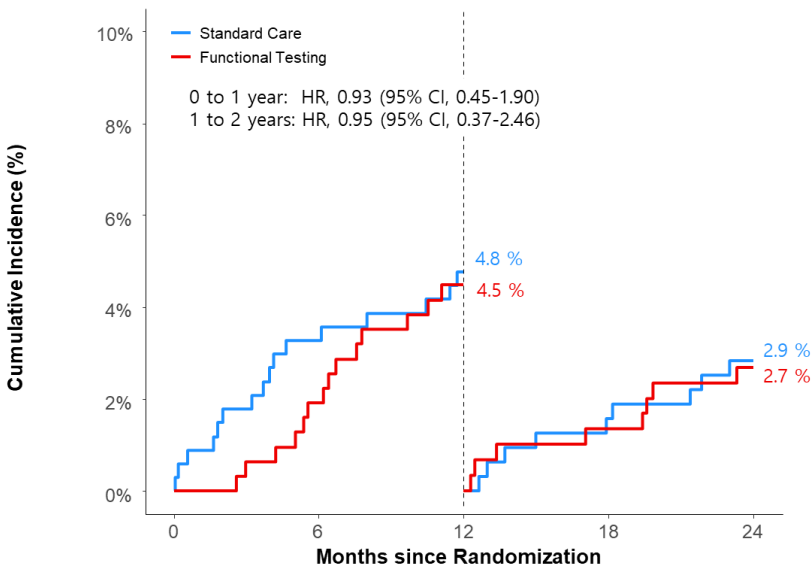
	Diabetes				Non-Diabetes				P for Interaction
	Functional Testing (n=321)	Standard Care (n=339)	Hazard Ratio (95% CI)	P Value	Functional Testing (n=528)	Standard Care (n=518)	Hazard Ratio (95% CI)	P Value	
Primary composite outcome	22 (7.1)	25 (7.5)	0.94 (0.53–1.66)	0.818	24 (4.6)	26 (5.1)	0.89 (0.51–1.55)	0.684	0.906
Death from any cause	14 (4.5)	14 (4.2)	1.07 (0.51–2.24)	0.86	9 (1.7)	14 (2.8)	0.62 (0.27–1.43)	0.264	0.34
Myocardial infarction	2 (0.7)	6 (1.9)	0.36 (0.07–1.76)	0.21	2 (0.4)	4 (0.8)	0.48 (0.09–2.62)	0.397	0.80
Hospitalization for unstable angina	6 (2.0)	5 (1.5)	1.28 (0.39–4.19)	0.684	13 (2.5)	9 (1.8)	1.40 (0.60–3.27)	0.442	0.907
Secondary outcomes									
Death or myocardial infarction	16 (5.1)	20 (6.0)	0.85 (0.44–1.64)	0.633	11 (2.1)	18 (3.5)	0.59 (0.28–1.25)	0.166	0.467
Hospitalization									
Any reason	101 (32.8)	86 (26.1)	1.30 (0.97–1.73)	0.076	110 (21.1)	104 (20.7)	1.01 (0.77–1.32)	0.939	0.213
Cardiac reason	46 (15.0)	41 (12.6)	1.19 (0.78–1.81)	0.427	76 (14.6)	69 (13.8)	1.06 (0.76–1.46)	0.743	0.67
Noncardiac reason	55 (18.0)	45 (13.7)	1.35 (0.91–2.01)	0.134	34 (6.5)	35 (7.0)	0.93 (0.58–1.50)	0.775	0.238
<i>Invasive coronary angiography</i>	<b>38 (12.6)</b>	<b>25 (7.7)</b>			<b>63 (12.1)</b>	<b>52 (10.4)</b>			
Showing restenosis or obstructive CAD	28 (73.7)	16 (64.0)			41 (65.1)	29 (55.8)			
Showing no restenosis or obstructive CAD	10 (26.3)	9 (36.0)			22 (34.9)	23 (44.2)			
<i>Repeat revascularization</i>	<b>24 (8.0)</b>	<b>17 (5.2)</b>			<b>42 (8.1)</b>	<b>31 (6.2)</b>			
Target-lesion revascularization	13 (4.3)	11 (3.4)			21 (4.1)	15 (3.0)			
Nontarget-lesion revascularization	11 (3.7)	6 (1.8)			21 (4.1)	16 (3.2)			



# Landmark Analysis

## In Diabetic Patients

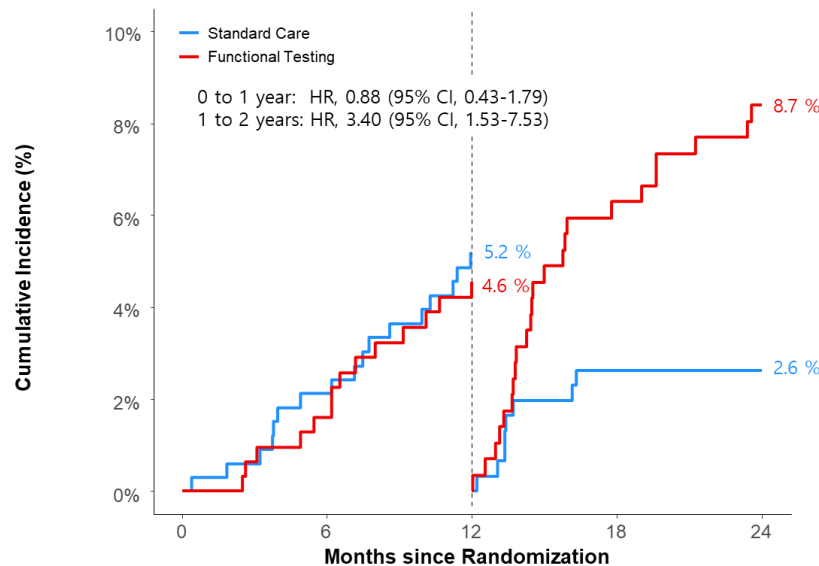
Primary Composite Outcome



No.at Risk

Standard Care	339	324	318	311	293
Functional Testing	321	307	297	293	282

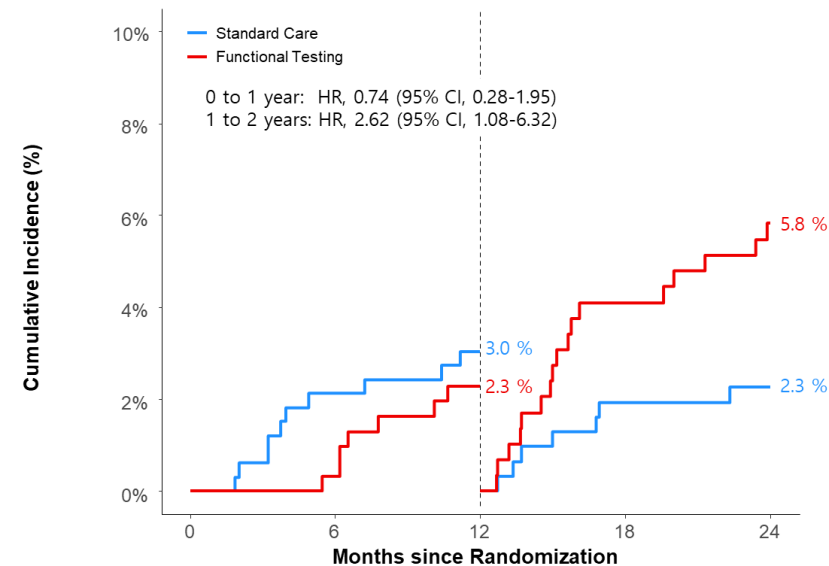
Invasive Coronary Angiography



No.at Risk

Standard Care	339	322	308	295	282
Functional Testing	321	303	288	268	253

Repeat Revascularization



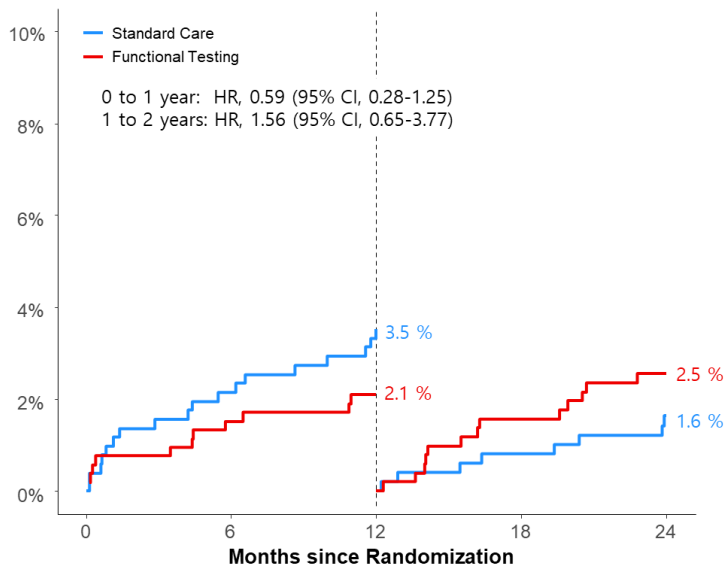
No.at Risk

Standard Care	339	322	315	304	288
Functional Testing	321	307	295	280	266

# Landmark Analysis

## In Non-Diabetic Patients

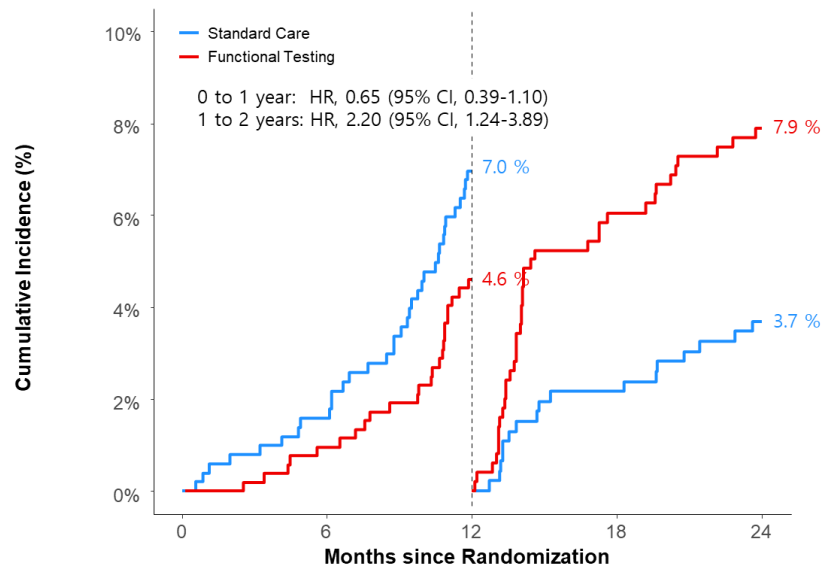
### Primary Composite Outcome



No.at Risk

	0	6	12	18	24
Standard Care	518	500	490	485	469
Functional Testing	528	516	512	503	476

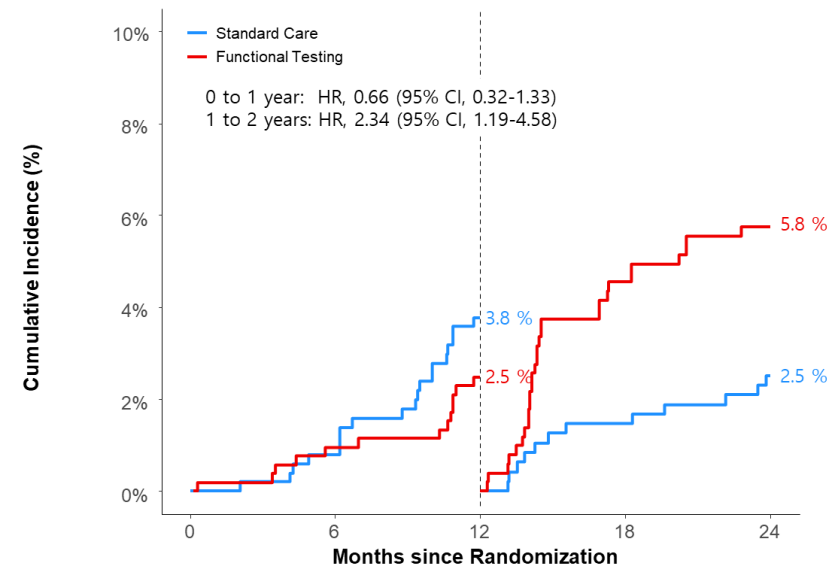
### Invasive Coronary Angiography



No.at Risk

	0	6	12	18	24
Standard Care	518	496	464	451	434
Functional Testing	528	516	496	462	433

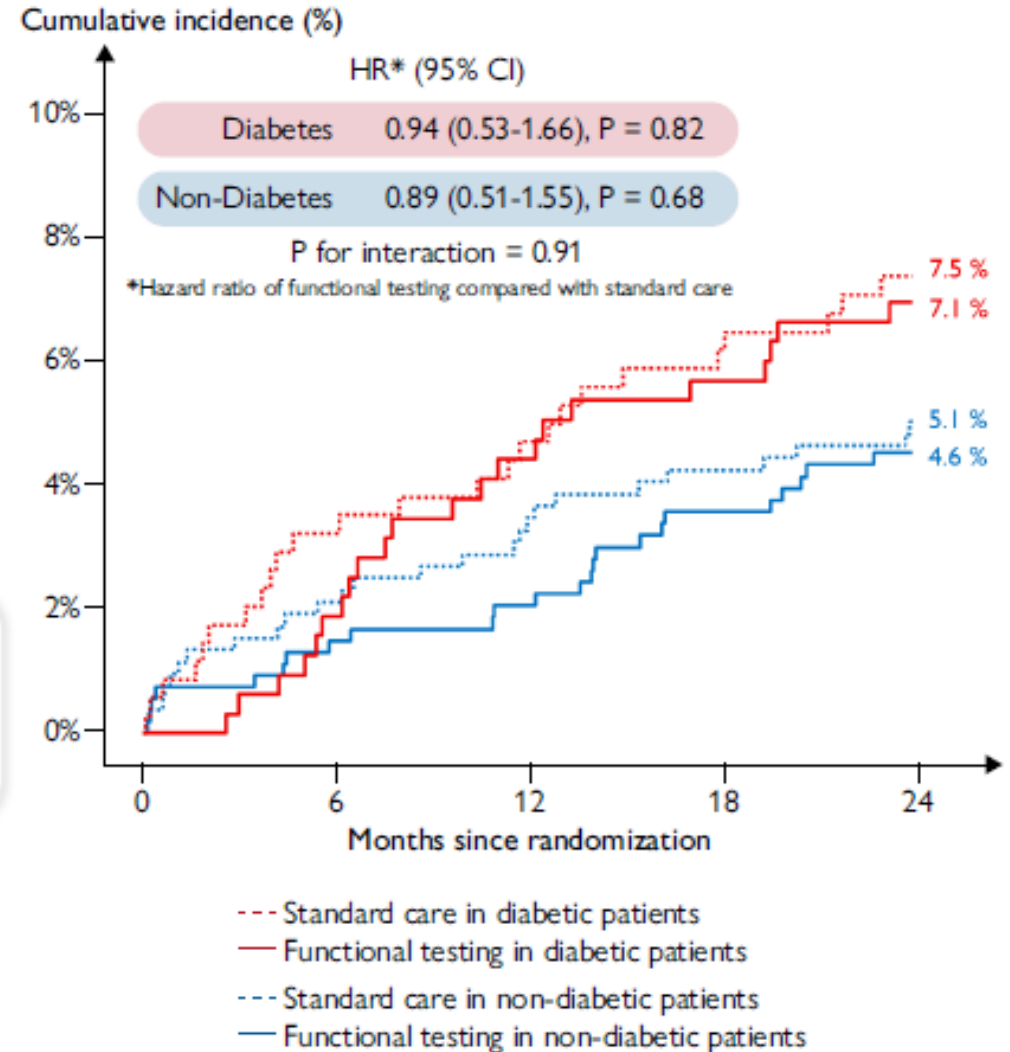
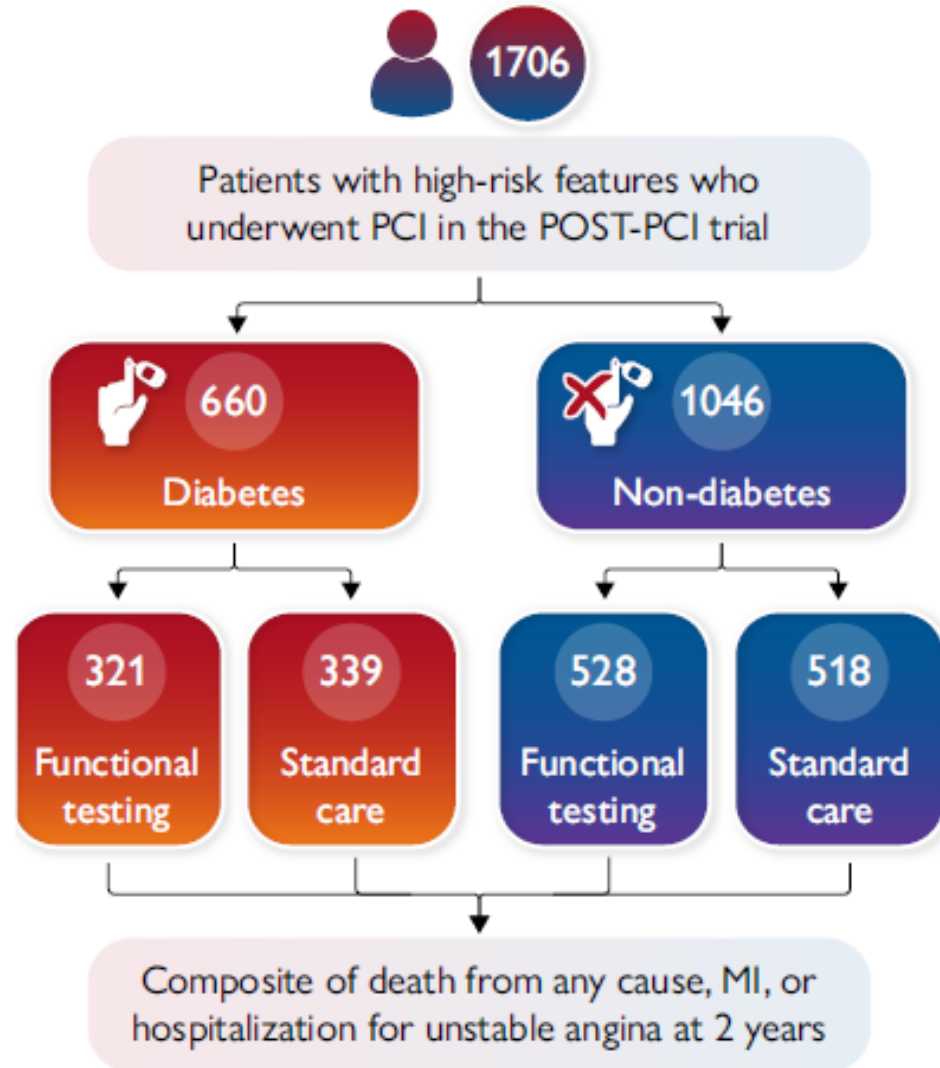
### Repeat Revascularization



No.at Risk

	0	6	12	18	24
Standard Care	518	500	480	470	453
Functional Testing	528	516	507	479	450

## A pre-specified subgroup analysis of the POST-PCI trial



# Conclusion

- Patients with Diabetes had an increased risk of adverse cardiovascular events at 2 years.
- The adverse cardiovascular events rate did not differ between the routine functional-testing group and the standard-care group both in patients with and without diabetes.
- Invasive coronary angiography and repeat revascularization after 1 year occurred more frequently in the functional-testing group, irrespective of diabetes status. However, this additional invasive management did not reduce major adverse cardiovascular events or mortality.