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# PREVENT

## Preventive PCI versus Medical Therapy Alone for Treatment of Vulnerable Atherosclerotic Coronary Plaques

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# Disclosure

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- The funders did not participate in the trial design, data analysis, or manuscript preparation.

# Background

- Intracoronary imaging defined vulnerable plaque (VP) has more tendency to increase major adverse cardiac events.
- Optimal medical therapy (OMT) is the standard approach to stabilise plaque vulnerability.
- The safety and effectiveness of focal preventive percutaneous coronary intervention (PCI) of non-flow limiting VP are unknown.

# Objective

PREVENT

- To assess whether focal preventive PCI of non-flow-limiting, imaging defined vulnerable plaques improves clinical outcomes compared with OMT alone.

# Trial Organization

PREVENT

***Executive Committee*** Seung-Jung Park (Trial Chair), Duk-Woo Park (Co-PI), Gregg W. Stone (Co-PI) Jung-Min Ahn, Do-Yoon Kang

***Additional Steering Committee*** Young-Keun Ahn, Won-Jang Kim, Chang-Wook Nam

***Event Adjudication Committee*** Hanbit Park, Junghoon Lee, Ju Hyeon Kim, Jinho Lee, Hoyun Kim Yeonwoo Choi, Sangyong Jo, Kyung-Ae Kim

***Data & Safety Monitoring Board*** June-Hong Kim, Kyoung-Ha Park, Jong-Min Song, Jon Suh Elly, Jeong-youn Bae

***Participating Investigators (15 Sites in South Korea, Japan, Taiwan, and New Zealand)***

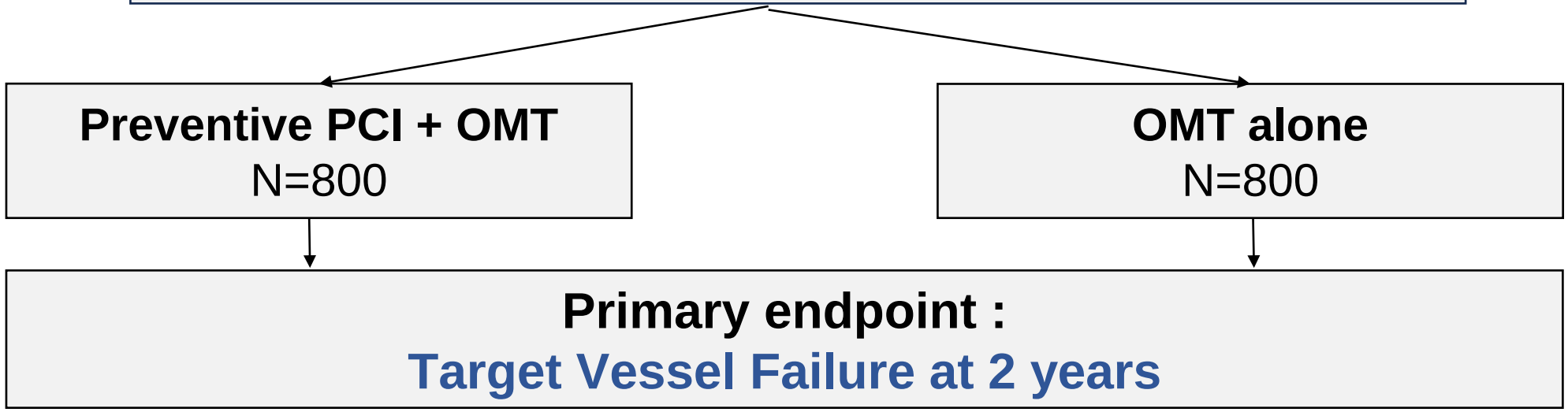
Seung-Jung Park, Jung-Min Ahn, Do-Yoon Kang, Sung-Cheol Yun, Duk-Woo Park (Asan Medical Center); Young-Keun Ahn (Chonnam National University Hospital); Won-Jang Kim, Se Hun Kang (CHA Bundang Medical Center); Chang-Wook Nam (Keimyung University Dongsan Hospital); Jin-Ok Jeong, Si-Wan Choi (Chungnam National University Hospital); In-HoChae (Seoul National University Bundang Hospital); Hiroki Shiomi (Kyoto University Hospital); Hsien-Li Kao (National Taiwan University Hospital); Joo-Yong Hahn (Samsung Medical Center); Sung-Ho Her, Gyu-Seop Lee (The Catholic University of Korea, Daejeon ST. Mary's Hospital); Bong-Ki Lee (Kangwon national University Hospital); Tae Hoon Ahn, Woong Chol Kang (Gachon University Gil Medical Center); Ki-Yuk Chang (The Catholic University St. Mary's Hospital); Jei Keon Chae (Jeonbuk National Univetsity Hospital); David Smyth (Christchurch Hospital).

# Trial Design

PREVENT

**Coronary Stenosis (>50%) with Negative FFR (≥ 0.80) and meeting two of the following (Imaging defined VP)**

1. MLA ≤4.0mm$^2$
2. Plaque Burden >70%
3. TCFA by OCT or RF-IVUS
4. Lipid-Rich Plaque by NIRS ($_{max}LCBI_{4mm}$>315)



# Major Inclusion Criteria

PREVENT

1. Men or women at least age ≥ 18 years.
2. Patients with angiographically significant stenosis (>50%) with negative FFR (>0.80) and meeting two of the following, (Imaging defined vulnerable plaque)
   1) MLA < 4mm$^2$
   2) Plaque burden >70%
   3) TCFA detected by RF-IVUS or OCT
   4) Large lipid-rich plaque on NIRS (maxLCBI$_{4mm}$ >315)
4. Eligible for PCI with Absorb BVS or EES
5. Reference vessel diameter 2.75 – 4.0 mm
6. Lesion length ≤40 mm

# Major Exclusion Criteria

PREVENT

1. Patients in whom the preferred treatment is CABG.
2. Previously stented lesion
3. Bypass graft lesion
4. Patients with 3 or more target lesions
5. Patients with 2 target lesions in the same coronary artery
6. Heavily calcified or angulated lesion
7. Bifurcation lesion requiring 2-stent technique
8. Contraindication to or planned discontinuation of dual antiplatelet therapy within 1 year

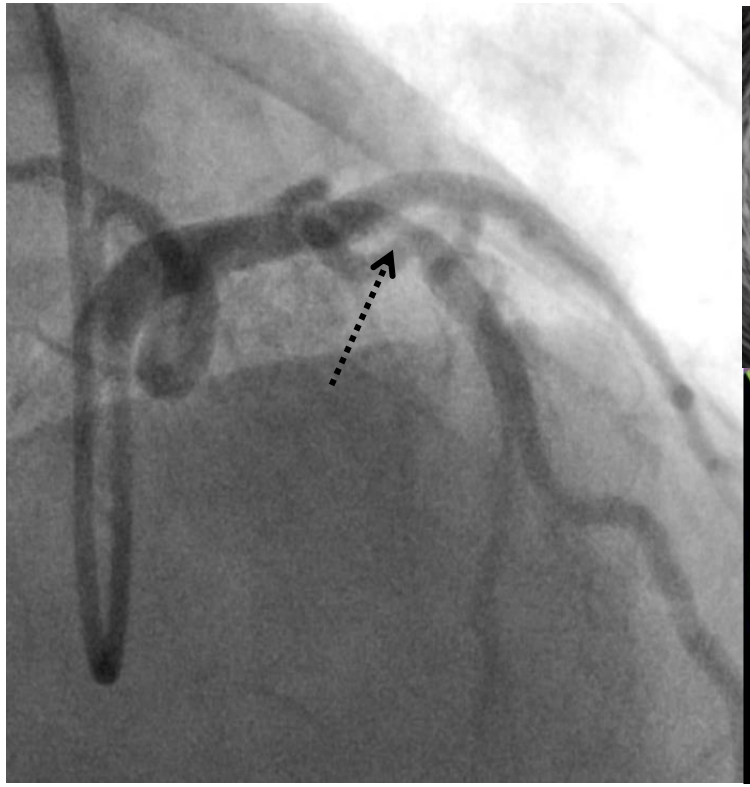
# Procedure

PREVENT

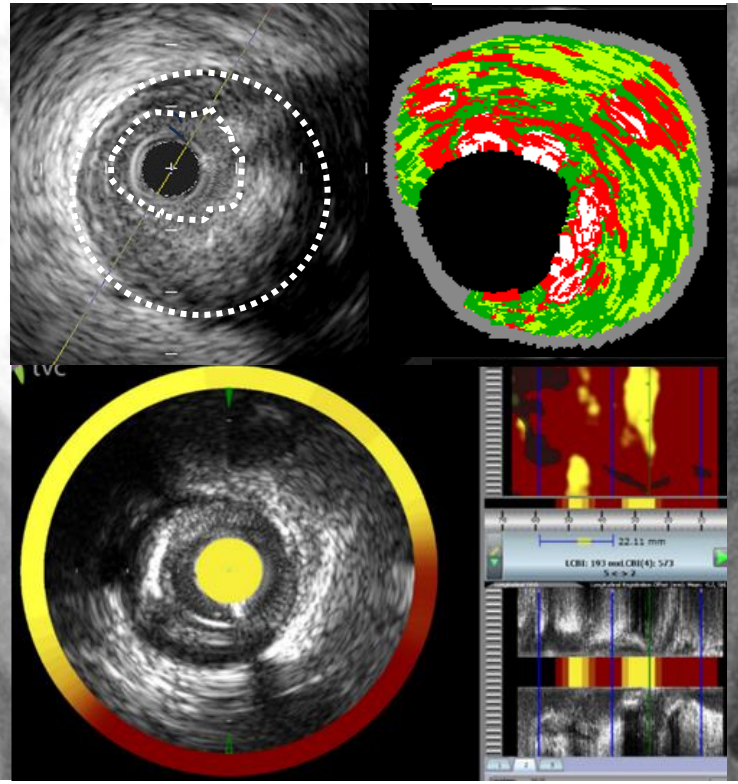
- During the initial recruitment period of the trial, PCI was performed with BVS (Absorb; Abbott). Following the withdrawal of BVS, cobalt-chromium everolimus-eluting metallic stents (Xience; Abbott) were used for the default device of PCI.
- Intravascular imaging of all target lesions was performed.
- Patients received dual antiplatelet therapy for at least 6 or 12 months after PCI according to clinical presentation and anatomical complexity.
- Clinical follow-up was done at 1, 6, 12, and 24 months and every year thereafter. Follow-up continued annually in all enrolled patients until the last enrolled patient reached 2 years after randomization.

# Procedure

PREVENT



Diameter stenosis 70%,
FFR 0.83



MLA 2.11 $mm^2$
Plaque burden 79%
TCFA by RF-IVUS
$maxLCBI_{4mm}$ 573

Absorb (BVS)
3.5 mm x 18 mm

# Primary Endpoint

PREVENT

- **Target Vessel Failure** (a composite of death from cardiac causes, target-vessel myocardial infarction, ischemia-driven target-vessel revascularization, or hospitalization for unstable or progressive angina) at 2 years after randomization

# Secondary Endpoint

PREVENT

- Individual components of the primary composite outcome
- Patient-oriented composite of all-cause death, all myocardial infarctions, or any repeat revascularization
- Procedural safety outcomes
- Stroke
- Bleeding events
- Number of anti-anginal medications used at each time point

# Statistical Considerations

PREVENT

## Power Calculation (N = 1,600)

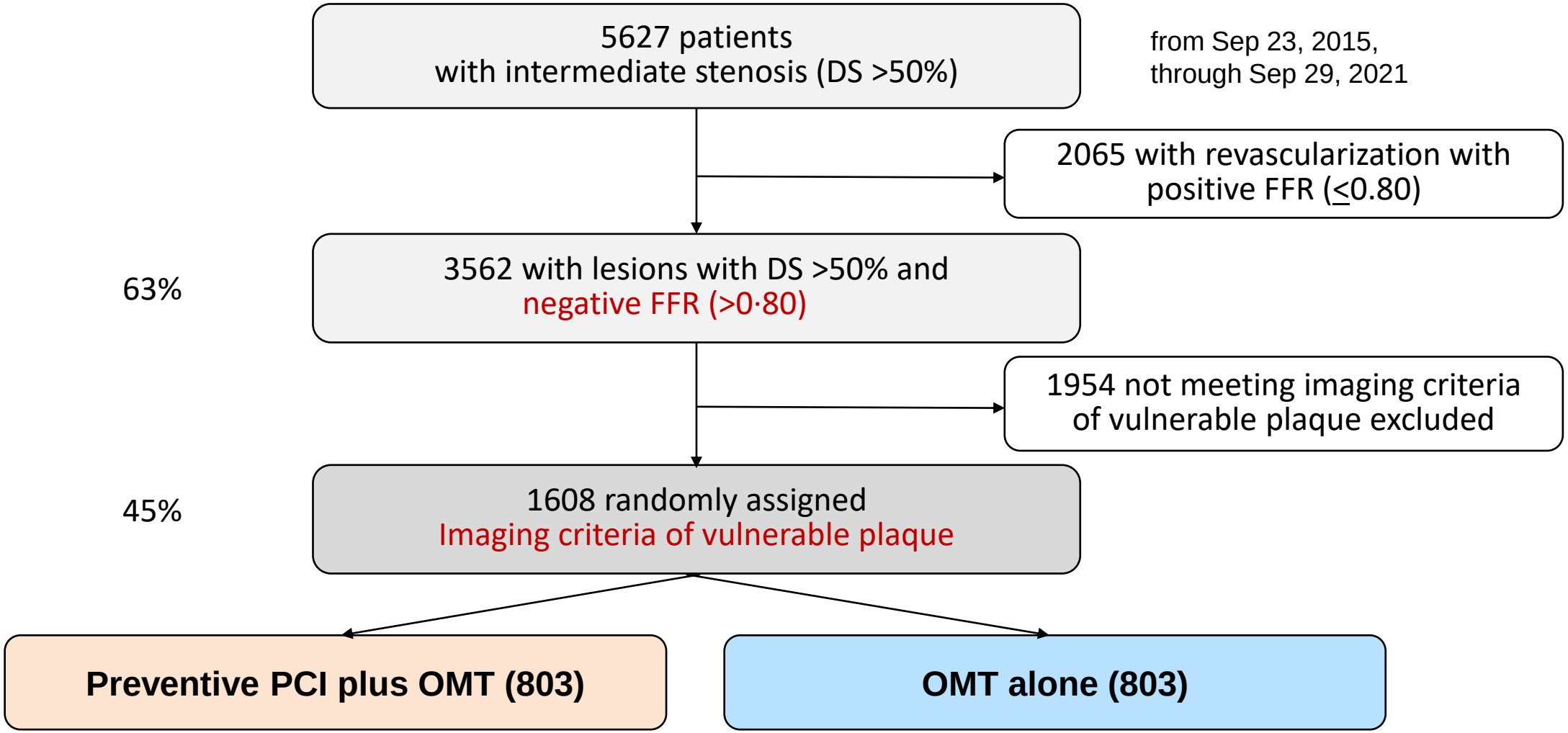
- Assuming an incidence of the primary outcome at 2-years of 8.5% for preventive PCI group and 12.0% for OMT alone group (30% relative risk reduction),
- A sample size of 1600 patients provided 80% power at a two-sided significance level of 5%, assuming a 7% loss to follow-up and crossover rate.

## Pre-Specified Statistical Analysis

- Primary intention-to-treat analysis
- Time-to-first-event estimate with Kaplan–Meier methodology
- Cox proportional hazard models to estimate the treatment effects
- Sensitivity analyses in the per-protocol and as-treated populations
- Absolute differences and 95% confidence intervals calculated at 2 years (primary outcome), 4 years (median follow-up), and 7 years (maximum follow-up)
- An interaction term between randomized groups and key subgroups for primary outcome.

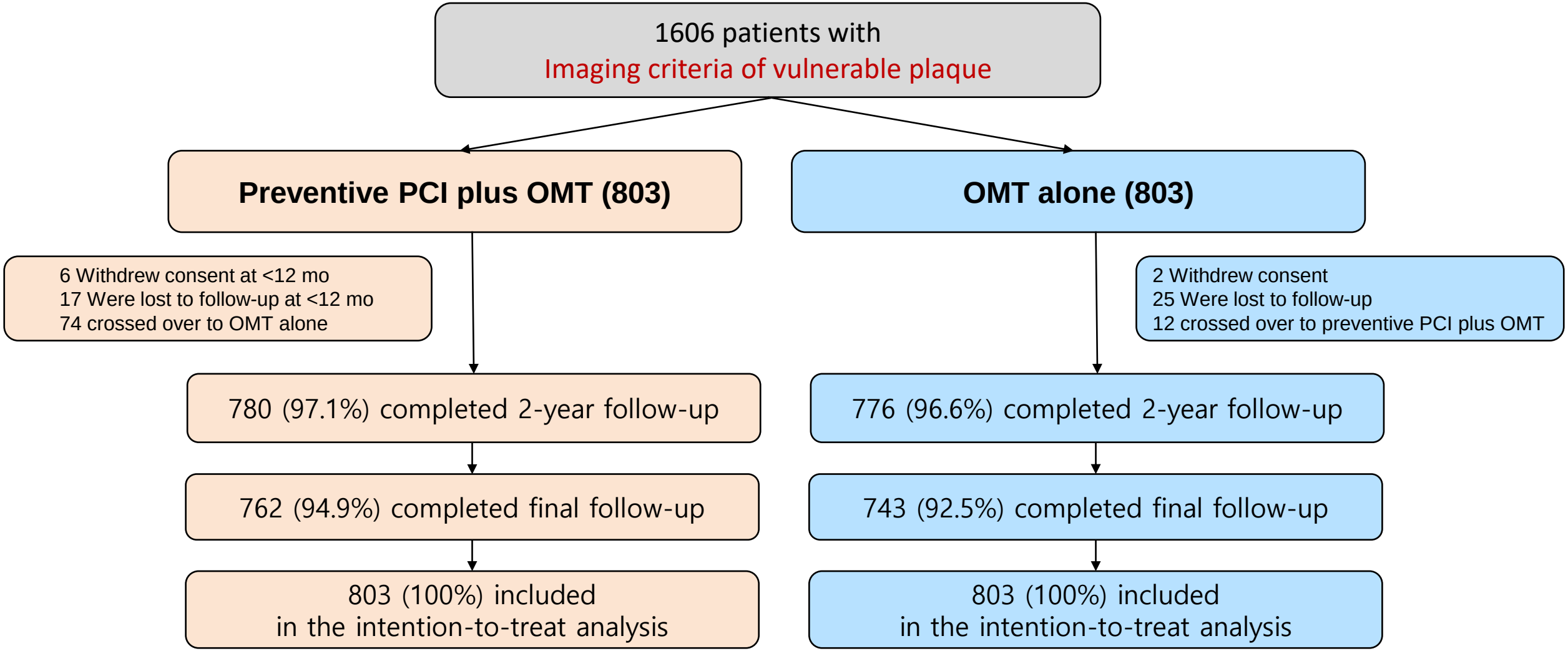
# Patient Flow and Follow Up

PREVENT



# Patient Flow and Follow Up

PREVENT



# Baseline Characteristics

PREVENT

| | Preventive PCI plus OMT (N=803) | OMT alone (N=803) |
|---|---|---|
| Age — years | 64 (58 – 71) | 65 (59 – 71) |
| Female sex | 197 (25%) | 232 (29%) |
| Body-mass index — $kg/m^2$ | 24.6 (22.9 – 26.5) | 24.7 (22.9 – 26.4) |
| Diabetes mellitus — no. (%) | 244 (30%) | 246 (31%) |
| Hypertension — no. (%) | 519 (65%) | 536 (67%) |
| Dyslipidemia — no. (%) | 721 (90%) | 709 (88%) |
| Current smoking — no. (%) | 136 (17%) | 139 (17%) |
| Previous PCI — no. (%) | 109 (14%) | 85 (11%) |
| History of cerebrovascular disease — no. (%) | 52 (6%) | 50 (6%) |
| Left ventricular ejection fraction [%], (N=843)† | 63 (60 – 66) | 63 (60 – 66) |
| Clinical presentation — no. (%) | | |
| Stable angina or silent ischemia | 670 (83%) | 677 (84%) |
| Unstable angina | 106 (13%) | 91 (11%) |
| Non-ST elevation myocardial infarction | 18 (2%) | 28 (3%) |
| ST-elevation myocardial infarction | 9 (1%) | 7 (1%) |

Data are median (inter-quartile range), or n (%). †Preventive percutaneous coronary intervention group n=485; optimal medical therapy group n=358.

# Anatomic Characteristics

PREVENT

| | Preventive PCI plus OMT (N=831) | OMT alone (N=841) |
|---|---|---|
| **Qualifying criteria for target lesions†** | N=831 | N=841 |
| MLA <4.0 $mm^2$ by gray-scale IVUS or OCT | 809 / 831 (97%) | 817 / 841 (97%) |
| Plaque burden >70% by gray-scale IVUS | 792 / 815 (97%) | 805 / 831 (97%) |
| Large lipid-rich plaque by NIRS ($maxLCBI_{4mm}$>315) | 99 / 348 (28%) | 94 / 369 (26%) |
| TCFA defined by OCT or radiofrequency IVUS | 39 / 571 (7%) | 40 / 679 (6%) |
| **Target lesion location** | | |
| Left anterior descending artery | 416 (50%) | 400 (48%) |
| Left circumflex artery | 170 (20%) | 147 (17%) |
| Right coronary artery | 245 (29%) | 294 (35%) |
| **Median FFR values of target lesions** | 0.87 (0.83 – 0.90) | 0.86 (0.83 – 0.90) |
| **QCA of target lesions** | | |
| Diameter stenosis — % | 56.6 (9.2) | 52.6 (9.8) |
| Minimal lumen diameter — mm | 1.3 (0.3) | 1.5 (0.4) |
| Reference vessel diameter — mm | 3.1 (0.4) | 3.1 (0.5) |
| Lesion length — mm | 23.6 (8.5) | 19.3 (8.3) |

Data are median (inter-quartile range), or n (%). †Preventive percutaneous coronary intervention group n=485; optimal medical therapy group n=358.

# Core Lab-Imaging Analysis

PREVENT

| | Preventive PCI plus OMT (N=831) | OMT alone (N=841) |
|---|---|---|
| **IVUS measurements** | N = 811 | N = 830 |
| Lesion length — mm | 23.7 (8.7) | 22.6 (9.1) |
| Minimal lumen area — $mm^2$ | 2.78 (0.87) | 2.83 (0.87) |
| Minimal lumen area ≤4.0 $mm^2$ | 784 / 811 (97%) | 801/830 (97%) |
| Plaque burden — % | 75.9 (6.9) | 76.4 (4.4) |
| Plaque burden >70% | 718 / 809 (89%) | 753 / 829 (91%) |
| **NIRS measurements** | N = 348 | N = 369 |
| Plaque-level $maxLCBI_{4mm}$ > 315 | 144 (41%) | 138 (37%) |
| **RF-IVUS measurements** | N = 456 | N = 575 |
| TCFA defined by RF-IVUS | 57 / 465 (13%) | 73 / 575 (13%) |
| **OCT measurements** | N = 63 | N = 21 |
| TCFA defined by OCT | 11 / 63 (18%) | 7 / 21 (33%) |
| **No· of high-risk plaque features†** | | |
| Lesions with ≥2 of 4 high-risk features | 736 (89%) | 760 (90%) |
| Lesions with ≥3 of 4 high-risk features | 163 (20%) | 177 (21%) |
| Lesions with 4 of 4 high-risk features | 12 (1%) | 13 (2%) |

Data are median (inter-quartile range), or n (%). †Preventive percutaneous coronary intervention group n=485; optimal medical therapy group n=358.

# Procedural Characteristics

PREVENT

| | Preventive PCI plus OMT (N=803) | OMT alone (N=803) |
|---|---|---|
| **PCI of target lesion, per patient, any†** | 729 / 803 (91%) | 12 / 803 (1%) |
| Drug-eluting stent implantation | 491 / 729 (67%) | 7 / 12 (58%) |
| Bioabsorbable scaffold implantation | 237 / 729 (33%) | 5 / 12 (42%) |
| Number of stents or scaffolds implanted | 1 (1 – 1) | 0 (0 – 0) |
| Stent or scaffold diameter — mm | 3.5 (3.0 – 3.5) | 3.25 (3.0 – 3.5) |
| Total stent or scaffold length — mm | 23 (18 – 28) | 23 (18 – 28) |
| Intravascular imaging used to optimize stent or scaffold implantation | 729 / 729 (100%) | 12 / 12 (100%) |
| **PCI of non-target lesions, per patient, any** | 290 / 803 (36%) | 286 / 803 (36%) |
| Number of lesions treated | 0 (0 – 1) | 0 (0 – 1) |
| Number of stents implanted | 0 (0 – 1) | 0 (0 – 1) |
| Stent diameter — mm | 3.25 (3.0 – 3.5) | 3.25 (3.0 – 3.5) |
| Total stent length — mm | 38 (23 – 51) | 38 (28 – 51) |

Data are median (inter-quartile range), or n (%). †One patient underwent balloon angioplasty only.

# Procedural Safety Outcomes : As-treated population

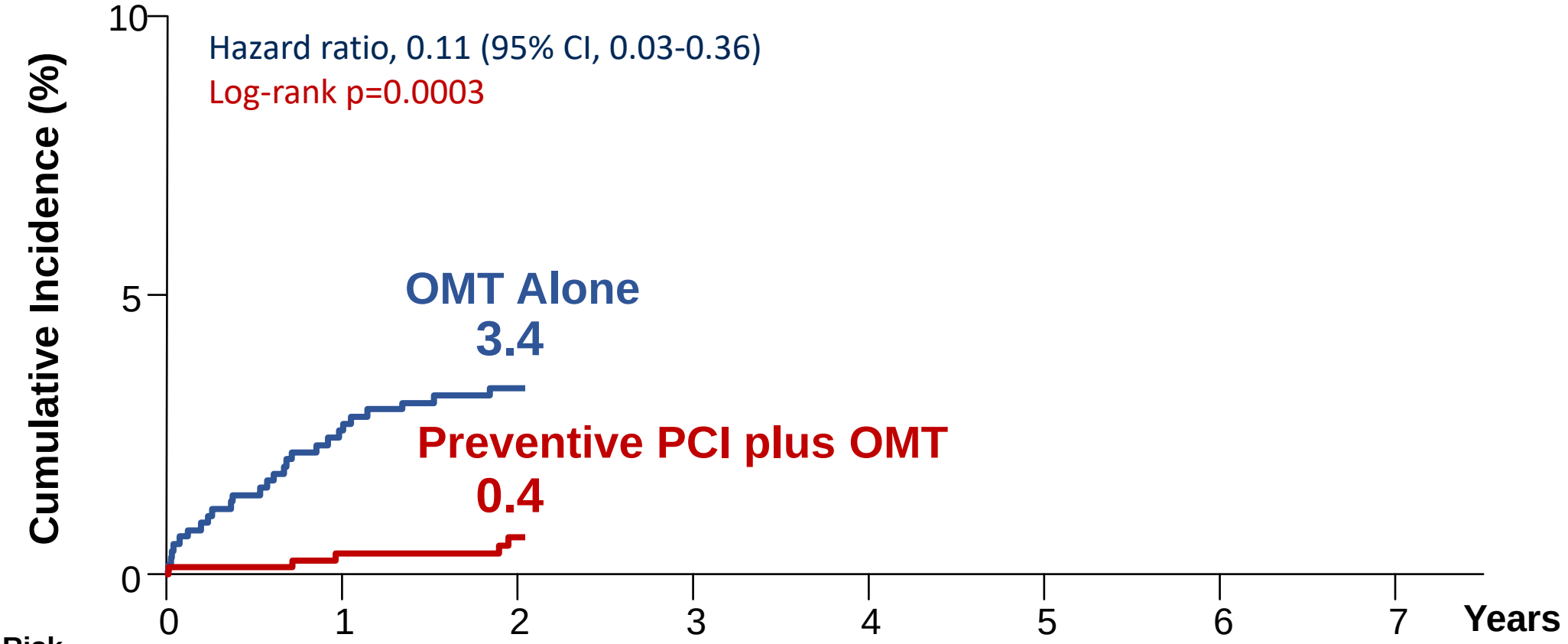
PREVENT

| | Preventive PCI (N=741) | OMT alone (N=865) |
|---|---|---|
| **Patients without non-target vessel PCI** | N=461 | N=569 |
| Total PCI time — min | 29 (18 – 45) | 0 |
| Total amount of contrast media used — mL | 150 (120 – 200) | 0 |
| **Patients with non-target vessel PCI** | N=280 | N=296 |
| Total PCI time — min | 57 (40 – 73) | 46 (25 – 65) |
| Total amount of contrast media used — mL | 250 (200 – 300) | 200 (150 – 250) |
| **Preventive PCI-related acute adverse events no. (%)** | | |
| Acute stent or scaffold thrombosis | 1 (<1%) | 0 |
| Distal dissection of at least type B | 1 (<1%) | 0 |
| Side branch occlusion | 2 (<1%) | 0 |
| Distal embolization | 1 (<1%) | 0 |
| Coronary perforation | 0 | 0 |

Data are median (inter-quartile range), or n (%).

# Primary Composite Outcome:
## Target Vessel Failure at 2 Year F/U

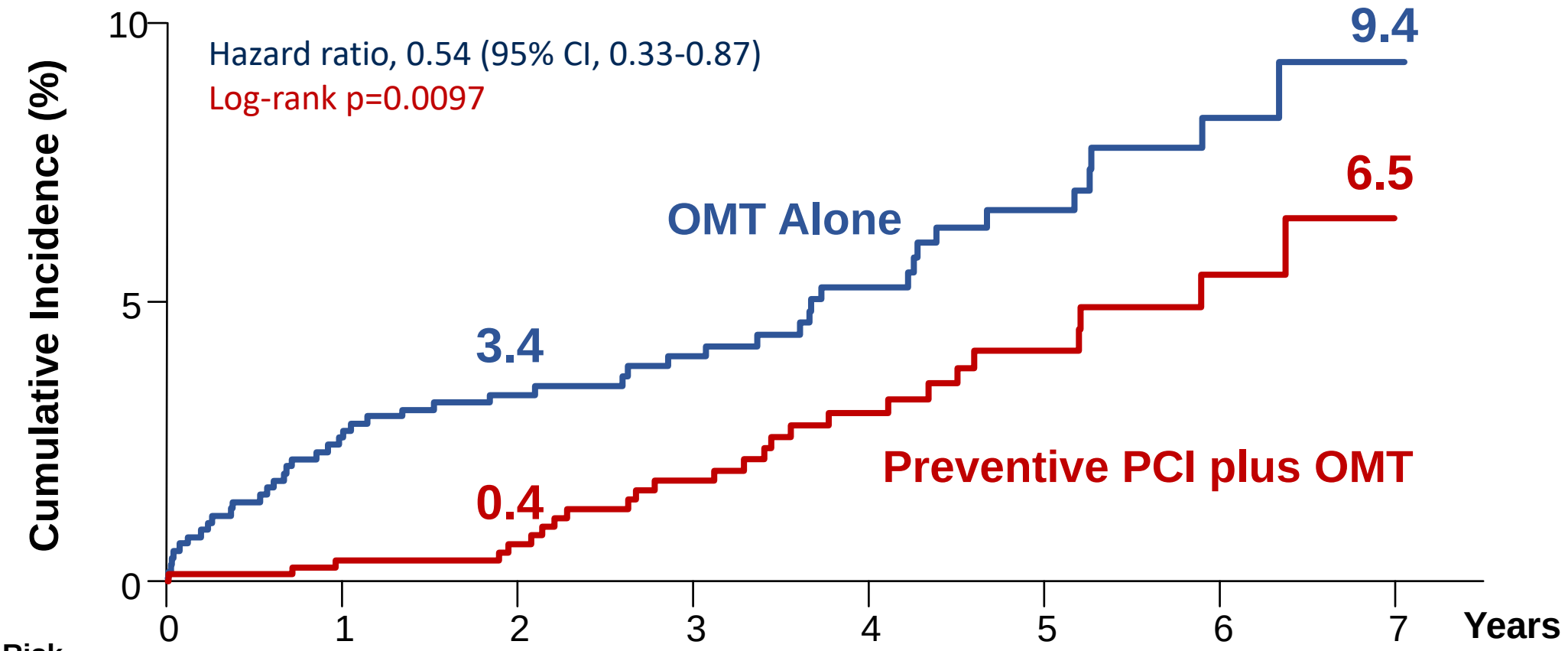
PREVENT




| No. at Risk | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| OMT Alone | 803 | 765 | 710 | 544 | 432 | 308 | 198 | 61 |
| Preventive PCI Plus OMT | 803 | 792 | 745 | 570 | 450 | 320 | 198 | 77 |

# Primary Composite Outcome:
## Target Vessel Failure at 7 Year F/U

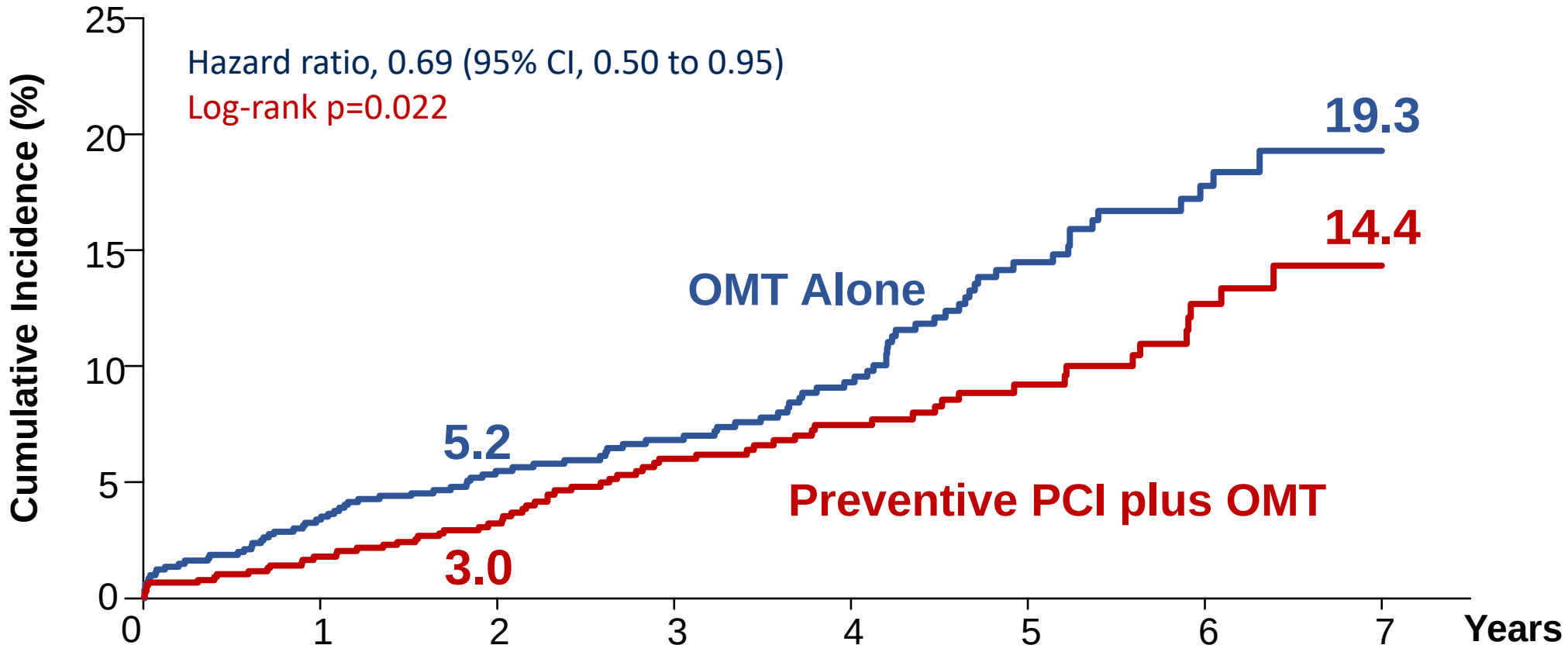
PREVENT




| No. at Risk | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| OMT Alone | 803 | 765 | 710 | 544 | 432 | 308 | 198 | 61 |
| Preventive PCI Plus OMT | 803 | 792 | 745 | 570 | 450 | 320 | 198 | 77 |

# Patient-Oriented Composite Outcome:
## Death from Any cause, Any MI, or Any RR

PREVENT




| No. at Risk | | | | | | | |
|---|---|---|---|---|---|---|---|
| OMT Alone | 803 | 761 | 700 | 536 | 424 | 297 | 190 | 58 |
| Preventive PCI Plus OMT | 803 | 781 | 728 | 551 | 431 | 302 | 187 | 72 |

# Individual Components of the Primary Composite Outcome

PREVENT

| Endpoints | Preventive PCI plus OMT (N=803) | OMT alone (N=803) | Difference in event rates (95% CI) | Hazard ratio (95% CI) |
|---|---|---|---|---|
| ***Primary composite outcome*** | | | | **0·54 (0·33 to 0·87)** |
| At 2 years‡ | 3 (0·4%) | 27 (3·4%) | -3·0 (-4·4 to -1·8) | **0·11 (0·03 to 0·36)** |
| At 4 years | 17 (2·8%) | 37 (5·4%) | -2·6 (-4·7 to -0·4) | |
| At 7 years | 26 (6·5%) | 47 (9·4%) | -2·9 (-7·3 to 1·5) | |
| ***Death from cardiac causes*** | | | | 0·87 (0·31 to 2·39) |
| At 2 years | 1 (0·1%) | 6 (0·8%) | -0·6 (-1·3 to 0·02) | |
| At 4 years | 5 (0·8%) | 7 (0·9%) | -0·1 (-1·1 to 0·9) | |
| At 7 years | 7 (1·4%) | 8 (1·3%) | 0·1 (-1·4 to 1·5) | |
| ***Target-vessel related MI*** | | | | 0·62 (0·20 to 1·90) |
| At 2 years | 1 (0·1%) | 6 (0·8%) | -0·6 (-1·3 to 0·02) | |
| At 4 years | 4 (0·6%) | 7 (10%) | -0·3 (-1·3 to 0·6) | |
| At 7 years | 5 (1·0%) | 8 (1·4%) | -0·3 (-1·7 to 1·1) | |

Event rates (%) shown are Kaplan–Meier estimates in the intention-to-treat population.

# Individual Components of the Primary Composite Outcome

PREVENT

| Endpoints | Preventive PCI plus OMT (N=803) | OMT alone (N=803) | Difference in event rates (95% CI) | Hazard ratio (95% CI) |
|---|---|---|---|---|
| ***Ischemia-driven target-vessel revascularization*** | | | | **0·44 (0·25 to 0·77)** |
| At 2 years | 1 (0·1%) | 19 (2·4%) | -2·3 (-3·4 to -1·2) | |
| At 4 years | 10 (1·7%) | 29 (4·4%) | -2·7 (-4·6 to -0·8) | |
| At 7 years | 17 (4·9%) | 38 (8·0%) | -3·2 (-7·4 to 1·1) | |
| ***Hospitalization for unstable or progressive angina*** | | | | **0·19 (0·06 to 0·54)** |
| At 2 years | 1 (0·1%) | 12 (1·5%) | -1·4 (-2·3 to -0·5) | |
| At 4 years | 4 (0·7%) | 16 (2·4%) | -1·7 (-3·0 to -0·4) | |
| At 7 years | 4 (0·7%) | 21 (4·9%) | -4·2 (-7·17 to -1·4) | |

# Secondary Endpoint Outcomes

PREVENT

| Endpoints | Preventive PCI plus OMT (N=803) | OMT alone (N=803) | Difference in event rates (95% CI) | Hazard ratio (95% CI) |
|---|---|---|---|---|
| ***Death from any cause*** | | | | 0·61 (0·35 to 1·06) |
| At 2 years | 4 (0·5%) | 10 (1·3%) | -0·8 (-1·7 to 0·2) | |
| At 4 years | 11 (1·8%) | 17 (2·6%) | -0·8 (-2·4 to 0·8) | |
| At 7 years | 20 (5·2%) | 32 (7·4%) | -2·3 (-6·0 to 1·5) | |
| ***Non-target-vessel myocardial infarction*** | | | | 0·91 (0·39 to 2·15) |
| At 2 years | 8 (1.0%) | 12 (1·5%) | 0·1 (-0·8 to 1·1) | |
| At 4 years | 10 (1.3%) | 8 (1.1%) | 0·3 (-0·9 to 1·4) | |
| At 7 years | 10 (1.3%) | 11 (2.2%) | -0·9 (-2·6 to 0·8) | |
| ***Non-target-vessel revascularization*** | | | | 0·88 (0·51 to 1·52) |
| At 2 years | 13 (1·6%) | 13 (1·7%) | -2·2 (-4·1 to -0·2) | |
| At 4 years | 22 (3·1%) | 19 (2·7%) | -1·8 (-4·7 to 1·2) | |
| At 7 years | 24 (4·8%) | 27 (5·6%) | -4·9 (-10·8 to 1·1) | |

# Secondary Endpoint Outcomes

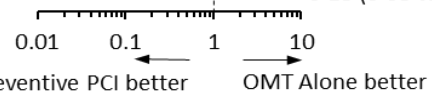
PREVENT

| Endpoints | Preventive PCI plus OMT (N=803) | OMT alone (N=803) | Difference in event rates (95% CI) | Hazard ratio (95% CI) |
|---|---|---|---|---|
| ***Definite stent or scaffold thrombosis*** | | | | 0·66 (0·11 to 3·95) |
| At 2 years | 1 (0.1%) | 3 (0·4%) | -0·3 (-0·8 to 0·3) | |
| At 4 years | 2 (0·3%) | 3 (0·4%) | 0·2 (-1·1 to 1·5) | |
| At 7 years | 2 (0.3%) | 3 (0·4%) | -0·4 (-2·3 to 1·5) | |
| ***Stroke*** | | | | 0·99 (0·43 to 2·29) |
| At 2 years | 5 (0·6%) | 6 (0.8%) | -0·1 (-1·0 to 0·7) | |
| At 4 years | 10 (1.5%) | 9 (1.3%) | 0·3 (-0·9 to 1·4) | |
| At 7 years | 11 (1.8%) | 11 (2.2%) | -0·9 (-2·6 to 0·8) | |
| ***Bleeding events (Major)*** | | | | 0·90 (0·38 to 2·11) |
| At 2 years | 5 (0·6%) | 4 (0.5%) | -0·8 (-1· 8 to 0·2) | |
| At 4 years | 8 (1·4%) | 6 (0.9%) | -0·3 (-1·4 to 0·9) | |
| At 7 years | 10 (1.9%) | 6 (0.9%) | 0·4 (-1·1 to 1·8) | |

PREVENT

# Subgroup Analyses of the Primary Outcome at 2-year Follow-up

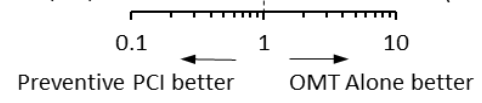
| Subgroup | Preventive PCI | OMT Alone | Hazard Ratios (95% CI) | P-for-Interaction |
|---|---|---|---|---|
| | *No. of events/no. of patients (Cumulative 2-Yr incidence, %)* | | | |
| **Age** | | | | 0·435 |
| < 65 years | 1/408 (0·3) | 15/394 (3·9) | 0·06 (0·01 to 0·47) | |
| ≥ 65 years | 2·395 (0·5) | 12/409 (3·0) | 0·17 (0·04 to 0·76) | |
| **Sex** | | | | 0·974 |
| Male | 2/606 (0·3) | 17/571 (3·0) | 0·11 (0·03 to 0·47) | |
| Female | 1/197 (0·5) | 10/232 (4·4) | 0·11 (0·02 to 0·89) | |
| **Diabetes mellitus** | | | | 0·989 |
| Yes | 0/244 (0) | 9/246 (3·7) | NC | |
| No | 3/559 (1·2) | 18/557 (3·3) | 0·16 (0·05 to 0·56) | |
| **Acute coronary syndrome** | | | | 0·989 |
| Yes | 0/133 (0) | 8/126 (6·7) | NC | |
| No | 3/670 (0·5) | 19/677 (2·8) | 0·16 (0·05 to 0·53) | |
| **PCI of non-target vessel** | | | | 0·988 |
| Yes | 0/290 (0) | 13/286 (4·6) | NC | |
| No | 3/513 (0·6) | 14/517 (2·8) | 0·21 (0·06 to 0·74) | |
| **Median diameter stenosis by QCA** | | | | 0·180 |
| ≥ 55% | 1/491 (0·2) | 14/316 (4·5) | 0·04 (0·01 to 0·34) | |
| < 55% | 2/308 (0·7) | 13/484 (2·7) | 0·24 (0·05 to 1·07) | |
| **Median fractional flow reserve value** | | | | 0·920 |
| ≤ 0·86 | 3/412 (0·7) | 14/395 (3·6) | 0·20 (0·06 to 0·71) | |
| > 0·86 | 0/389 (0) | 13/405 (3·3) | NC | |
| **Intracoronary imaging screening tools** | | | | NA |
| Gray-scale IVUS only | 3/303 (1·0) | 6/261 (2·3) | 0·41 (0·10 to 1·66) | |
| RF-IVUS | 0/506 (0) | 18/635 (2·9) | NC | |
| NIRS-IVUS | 1/333 (0·3) | 12/346 (3·5) | 0·09 (0·01 to 0·66) | |
| OCT | 1/67 (1·5) | 1/20 (5·0) | 0·30 (0·02 to 4·76) | |
| **Preventive PCI modalities** | | | | 0·772 |
| BVS era | 1/265 (0·4) | 12/281 (4·3) | 0·09 (0·01 to 0·67) | |
| CoCr-EES era | 2/538 (0·4) | 15/522 (2·9) | 0·13 (0·03 to 0·55) | |



PREVENT

# Subgroup Analyses of the Primary Outcome at 7-year Follow-up

| Subgroup | Preventive PCI | OMT Alone | Hazard Ratios (95% CI) | P-for-Interaction |
|---|---|---|---|---|
| | *No. of events/no. of patients (%)* | | | |
| **Age** | | | | 0·619 |
| < 65 years | 13/408 (3·2) | 25/394 (6·4) | 0·48 (0·25 to 0·94) | |
| ≥ 65 years | 13/395 (3·3) | 22/409 (5·4) | 0·61 (0·31 to 1·20) | |
| **Sex** | | | | 0·996 |
| Male | 19/606 (3·1) | 32/571 (5·6) | 0·54 (0·31 to 0·96) | |
| Female | 7/197 (3·6) | 15/232 (6·5) | 0·53 (0·22 to 1·31) | |
| **Diabetes mellitus** | | | | 0·696 |
| Yes | 8/244 (3·3) | 13/246 (5·3) | 0·62 (0·26 to 1·50) | |
| No | 18/559 (3·2) | 34/557 (6·1) | 0·51 (0·29 to 0·89) | |
| **Acute coronary syndrome** | | | | 0·380 |
| Yes | 4/133 (3·0) | 11/126 (8·7) | 0·33 (0·11 to 1·05) | |
| No | 22/670 (3·3) | 36/677 (5·3) | 0·60 (0·35 to 1·01) | |
| **PCI of non-target vessel** | | | | **0·007** |
| **Yes** | 5/290 (1·7) | 24/286 (8·4) | 0·19 (0·07 to 0·51) | |
| No | 21/513 (4·1) | 23/517 (4·4) | 0·91 (0·50 to 1·64) | |
| **Median diameter stenosis by QCA** | | | | **0·014** |
| **≥ 55%** | 11/491 (2·2) | 23/316 (7·3) | 0·28 (0·14 to 0·58) | |
| < 55% | 15/308 (4·9) | 24/484 (5·0) | 0·95 (0·50 to 1·81) | |
| **Median fractional flow reserve value** | | | | 0·771 |
| ≤ 0·86 | 16/412 (3·9) | 25/395 (6·3) | 0·59 (0·32 to 1·11) | |
| > 0·86 | 10/389 (2·6) | 22/405 (5·4) | 0·46 (0·22 to 0·97) | |
| **Intracoronary imaging screening tools** | | | | NA |
| Gray-scale IVUS only | 10/306 (3·3) | 14/261 (5·4) | 0·50 (0·22 to 1·12) | |
| RF-IVUS | 15/506 (3·0) | 31/635 (4·9) | 0·55 (0·29 to 1·01) | |
| NIRS-IVUS | 15/333 (4·5) | 24/346 (6·9) | 0·63 (0·33 to 1·20) | |
| OCT | 5/67 (7·5) | 3/20 (15·0) | 0·41 (0·10 to 1·71) | |
| **Preventive PCI modalities** | | | | **0·018** |
| BVS era | 19/265 (7·2) | 22/281 (7·8) | 0·89 (0·48 to 1·65) | |
| **CoCr-EES era** | 7/538 (1·3) | 25/522 (4·8) | 0·25 (0·11 to 0·59) | |



# Study Limitations

PREVENT

- The study was open-label, introducing the risks of placebo effects and ascertainment bias.
- The observed rates of the primary outcome were substantially lower than expected in both groups.
- The selection of imaging modality to assess plaque vulnerability was left to operator discretion.
- 9% in the preventive PCI group and 1% in the OMT alone group crossed over.
- The study did not collect data to examine the cost-effectiveness of a preventive PCI strategy.
- DAPT use was greater in the preventive PCI group.

# Summary of Key Findings

PREVENT

- The PREVENT trial is the first large-scale, randomized controlled study comparing preventive PCI plus OMT versus OMT alone for the treatment of non-flow-limiting imaging defined vulnerable plaques.
- In the PREVENT trial, preventive PCI reduced the composite risk of death from cardiac causes, target-vessel MI, ischemia-driven TVR, or hospitalization for unstable or progressive angina at 2 years.
- Preventive PCI also reduced the composite patient-oriented outcome of risk of all-cause death, any MI, or any repeat revascularization.
- This benefit was sustained throughout the 7-year follow-up period.

# Conclusions

PREVENT

- In the PREVENT trial, preventive PCI plus OMT resulted in a lower incidence of major adverse cardiac events compared with OMT alone in patients with non-flow-limiting vulnerable plaques

- Our key findings might provide novel insights on the role of preventive PCI on non-flow-limiting high-risk vulnerable plaques in the future.

# *Thank You !*

## Further Details in the Lancet Simultaneous Publication

THELANCET-D-24-00558R4
S0140-6736(24)00413-6
Embargo: April 8, 2024 - 16:00 (BST)
Doctopic: Primary Research
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