

# Self-Reported Health and Outcomes in Patients With Stable Coronary Heart Disease

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**Background**—The major determinants and prognostic importance of self-reported health in patients with stable coronary heart disease are uncertain.

**Methods and Results**—The STABILITY (Stabilization of Atherosclerotic Plaque by Initiation of Darapladib Therapy) trial randomized 15 828 patients with stable coronary heart disease to treatment with darapladib or placebo. At baseline, 98% of participants completed a questionnaire that included the question, “Overall, how do you feel your general health is now?” Possible responses were *excellent*, *very good*, *good*, *average*, and *poor*. Adjudicated major adverse cardiac events, which included cardiovascular death, myocardial infarction, and stroke, were evaluated by Cox regression during 3.7 years of follow-up for participants who reported excellent or very good health (n=2304), good health (n=6863), and average or poor health (n=6361), before and after adjusting for 38 covariates. Self-reported health was most strongly associated with geographic region, depressive symptoms, and low physical activity ( $P<0.0001$  for all). Poor/average compared with very good/excellent self-reported health was independently associated with major adverse cardiac events (hazard ratio [HR]: 2.30 [95% confidence interval (CI), 1.92–2.76]; adjusted HR: 1.83 [95% CI, 1.51–2.22]), cardiovascular mortality (HR: 4.36 [95% CI, 3.09–6.16]; adjusted HR: 2.15 [95% CI, 1.45–3.19]), and myocardial infarction (HR: 1.87 [95% CI, 1.46–2.39]; adjusted HR: 1.68 [95% CI, 1.25–2.27];  $P<0.0002$  for all).

**Conclusions**—Self-reported health is strongly associated with geographical region, mood, and physical activity. In a global coronary heart disease population, self-reported health was independently associated with major cardiovascular events and mortality beyond what is measurable by established risk indicators.

**Clinical Trial Registration**—URL: <http://www.ClinicalTrials.gov>. Unique identifier: NCT00799903. (*J Am Heart Assoc.* 2017;6:e006096. DOI: 10.1161/JAHA.117.006096.)

**Key Words:** coronary artery disease • general health • prognostic studies

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Received March 13, 2017; accepted June 23, 2017.

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## Clinical Perspective

### What Is New?

- In patients with stable coronary heart disease, geographic region, mood, and lifestyle risk factors are strong determinants of self-reported health.
- Self-reported general health is a strong independent predictor of cardiovascular mortality, noncardiovascular mortality, and myocardial infarction.

### What Are the Clinical Implications?

- General health should be considered in addition to traditional risk factors when estimating the risk of adverse cardiovascular events.
- It is possible that interventions that improve general health, either at the individual or general population level, will also lower cardiovascular risk.

An important goal of management of patients with stable coronary heart disease (CHD) is to improve physical, mental, and/or social well-being. Consequently, it is relevant to consider the overall general health of the patient when deciding on a management strategy. Better understanding of the determinants of general health and of how general health may influence the risk of adverse clinical outcomes has the potential to improve clinical decisions.

General health is usually considered to be a patient-centered measure.<sup>1</sup> It can be assessed by asking patients about their physical, mental, and social functioning and other aspects of quality of life using questionnaires such as the Short Form-36<sup>2</sup> and the EQ-5D.<sup>3</sup> The simplest assessment of health can be obtained by asking a single question: “How is your overall health?” In large epidemiological studies, the response to this simple question predicted both total and cardiovascular mortality.<sup>4–6</sup> Few studies, however, have evaluated the clinical importance of this simple indicator of overall health in CHD patients.<sup>7–9</sup> In addition, the primary determinants of self-reported health in patients with stable CHD are uncertain.

The aims of this study were to describe the most important factors associated with self-reported health and to evaluate its independent association with outcomes in patients with stable CHD who participated in the global STABILITY (Stabilization of Atherosclerotic Plaque by Initiation of Darapladib Therapy) trial.<sup>10,11</sup>

## Methods

### Study Population

The STABILITY trial (ClinicalTrials.gov identifier NCT007-99903) was a global outcomes trial designed to determine

whether darapladib, a specific inhibitor of lipoprotein-associated phospholipase A<sub>2</sub>, would reduce the risk of cardiovascular death, myocardial infarction, and stroke in patients with chronic CHD.<sup>10</sup> In total, 15 828 participants from 39 countries were randomized. All patients had chronic stable CHD, defined as prior myocardial infarction, prior coronary revascularization, or multivessel CHD confirmed by coronary angiography. In addition, patients had to meet at least one of the following cardiovascular risk criteria: age ≥60 years; diabetes mellitus requiring pharmacotherapy; high-density lipoprotein cholesterol <1.03 mmol/L; current or previous smoker, defined as ≥5 cigarettes per day on average; significant renal dysfunction (estimated glomerular filtration rate ≥30 and <60 mL/min per 1.73 m<sup>2</sup> or urine albumin:creatinine ratio ≥30 mg albumin/g creatinine); or polyvascular disease (CHD and cerebrovascular disease or CHD and peripheral arterial disease). Darapladib did not influence the risk of major adverse cardiac events (MACE).<sup>10,11</sup> More detailed descriptions of the study design and population were published previously.<sup>10–12</sup> All patients provided written informed consent, and the relevant ethics committees in each participating country approved the study, in accordance with the Helsinki Declaration.

### Baseline Clinical Assessment and Questionnaire

At baseline, 15 528 participants (98%) completed a lifestyle questionnaire. This included the following question: “Overall, how do you feel your general health is now?” Possible responses were *excellent*, *very good*, *good*, *average*, and *poor*. Because only a small proportion of participants responded with excellent and poor, results are presented for 3 groups (1) excellent or very good, (2) good, and (3) average or poor.

In addition to the cardiovascular risk criteria needed for study inclusion, the following information was recorded at baseline: age, sex, diagnosis of hypertension, history of congestive heart failure, prior myocardial infarction, prior percutaneous coronary intervention or coronary artery bypass grafting, and New York Heart Association functional class. Body mass index was calculated in kg/m<sup>2</sup>. Geographic regions of enrollment were North America, South America including Mexico, Western Europe including Australia and New Zealand, Eastern Europe and Asia including South Africa. These country groupings were chosen primarily by geographic location but also considered the similarity of race, culture, and gross domestic product of countries.

On the lifestyle questionnaire, patients indicated whether they lived alone and the number of years of education completed, classified as <8 years, 8 to 12 years, trade school, or college or university. Financial stress and home- and work-related stress were graded as *never or rarely*, *sometimes*, *often*, or *always*. Depressive symptoms were assessed from

the questions “How is your current mood?” (denoted as “depressed mood”) and “Have you lost interest in activities or hobbies that normally give you pleasure?” (denoted as “loss of interest”), with possible responses of *never or rarely, sometimes, often, or always*.<sup>13</sup> Physical activity was assessed from the total hours of moderate-intensity (4 metabolic equivalents) and vigorous-intensity (8 metabolic equivalents) physical activity during an average week.<sup>14,15</sup> A healthy diet was classified using a Mediterranean diet score based on responses to a simple food-frequency questionnaire.<sup>16</sup> The number of remaining teeth was recorded. Tooth loss was classified as  $\leq 25$  teeth.<sup>17</sup>

Hemoglobin, white blood cell count, creatinine, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, triglycerides, and C-reactive protein were measured at a Quest Diagnostics Clinical Laboratory. In addition, blood samples were obtained from 14 577 patients at baseline and stored until biochemical analysis. Lipoprotein-associated phospholipase A<sub>2</sub> was measured at diaDexus Inc. High-sensitivity troponin T, NT-proBNP (N-terminal pro-B-type natriuretic peptide), cystatin C, interleukin 6, and growth differentiation factor 15 were measured by an electrochemiluminescence immunoassay using a Cobas e 601 analyzer (Roche Diagnostics) at the Uppsala Clinical Research Center Laboratory in Uppsala, Sweden.

## Clinical Outcomes

The primary end point of MACE was the composite of cardiovascular death, myocardial infarction, or stroke. Secondary end points were total mortality, cardiovascular mortality, noncardiovascular mortality, myocardial infarction, stroke, major coronary events, and hospital admission for heart failure. Clinical outcomes were adjudicated by a committee. The event definitions and main results of the study were presented elsewhere.<sup>10,11</sup> The median follow-up time was 3.7 years (interquartile range: 3.5–3.8 years). Vital status was complete for 99.3% of patients and 99.6% of total possible follow-up time.

## Statistical Analysis

The baseline characteristics were summarized, with categorical variables presented as count and proportion and continuous variables presented as mean and standard deviation. To investigate differences across the 3 groups of patients, the categorical variables were compared with the  $\chi^2$  test. Continuous variables were compared with Mann–Whitney nonparametric tests.

To investigate the associations between different covariates and self-reported health, multivariable ordinal logistic regressions were used due to the ordinal nature of the dependent variable (excellent or very good, good, average or

poor). The results of the regression analyses are presented as adjusted odds ratios (ORs) and 95% confidence intervals. The ORs describe the associations of different covariates with decreasing levels of self-reported health. Standardized ORs are presented for all continuous variables. All biomarkers were based on a 1-SD increase, ORs for body mass index and Mediterranean diet score were based on a 1-U increase, and ORs for physical activity (metabolic equivalent in hours per week) is based on a 50% increase. To evaluate the relative strength of association of different covariates with self-reported health,  $\chi^2$ -df was plotted.<sup>18</sup> This statistic allows comparison of predictors with different parameters, with a higher number indicating a stronger association.

Associations between self-reported health and the study outcomes were assessed using Cox proportional hazards regression models and expressed with hazard ratio and 95% confidence interval. The underlying proportional hazards assumptions of the Cox proportional hazards models were verified by Schoenfeld residual tests. Using a multivariate model, we adjusted for demographic variables (age at randomization, sex, geographic region), psychosocial measures (depressed mood, loss of interest in hobbies, financial stress, stress at work or home, years of education), lifestyle risk factors (body mass index, smoking status, physical activity,<sup>15</sup> Mediterranean diet score,<sup>16</sup> attendance at cardiac rehabilitation), disease markers at baseline (diagnosis of hypertension, congestive heart failure, significant renal dysfunction, prior myocardial infarction, prior coronary revascularization [percutaneous coronary intervention or coronary artery bypass grafting]), prior multivessel chronic heart disease, diabetes mellitus, polyvascular disease, tooth loss, New York Heart Association functional class), and biomarkers (low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, hemoglobin, high-sensitivity troponin T, interleukin 6, growth differentiation factor 15, triglycerides, estimated glomerular filtration rate [using the Chronic Kidney Disease Epidemiology Collaboration formula], creatinine, white blood cell count, high-sensitivity C-reactive protein, NT-proBNP, cystatin C, and lipoprotein-associated phospholipase A<sub>2</sub> activity). The covariates included in the model were prespecified based on previous analyses from the STABILITY trial.<sup>16,17,19,20</sup> Kaplan–Meier curves were constructed for MACE by self-reported health groups.

All analyses were performed using SAS software version 9.4 (SAS Institute). For all statistical analyses, a 2-sided  $P < 0.05$  was considered statistically significant.

## Results

The baseline characteristics of the study population are presented for participants reporting excellent or very good, good, and average or poor self-reported health in Table 1. A

**Table 1.** Demographic and Baseline Characteristics by Self-Reported General Health Levels

	Excellent or Very Good (n=2304)	Good (n=6863)	Average or Poor (n=6361)	Total (N=15 528)	Odds Ratio for one category decrease in health OR (95% CI)	P Value
<b>Demographics</b>						
Age, y						
Mean (SD)	65.2 (8.9)	64.7 (9.3)	63.7 (9.5)	64.4 (9.3)	0.88 (0.85–0.91)	<0.0001 <sup>§</sup>
Sex						
Female	294 (12.8)	1228 (17.9)	1378 (21.7)	2900 (18.7)	1.44 (1.34–1.56)	<0.0001
Race						
Black	40 (1.7)	157 (2.3)	164 (2.6)	361 (2.3)	1.40 (1.15–1.71)	<0.0001
Central, South, or Southeast Asian	104 (4.5)	531 (7.7)	528 (8.3)	1163 (7.5)	1.45 (1.30–1.63)	
East Asian or Japanese	150 (6.5)	421 (6.1)	951 (15.0)	1522 (9.8)	2.59 (2.33–2.88)	
Other	53 (2.3)	168 (2.4)	112 (1.8)	333 (2.1)	0.89 (0.72–1.09)	
White	1957 (84.9)	5586 (81.4)	4606 (72.4)	12 149 (78.2)	Reference group	
Geographic region						
Asia/Pacific	234 (10.2)	890 (13.0)	1429 (22.5)	2553 (16.4)	3.37 (3.05–3.71)	<0.0001
Eastern Europe	177 (7.7)	1436 (20.9)	1849 (29.1)	3462 (22.3)	3.30 (3.02–3.61)	
South America	217 (9.4)	662 (9.6)	440 (6.9)	1319 (8.5)	1.40 (1.25–1.58)	
Western Europe	737 (32.0)	2071 (30.2)	1546 (24.3)	4354 (28.0)	1.48 (1.36–1.60)	
North America	939 (40.8)	1804 (26.3)	1097 (17.2)	3840 (24.7)	Reference group	
<b>Psychosocial measures</b>						
Depressed mood						
Often/always	100 (4.4)	524 (7.9)	1148 (18.7)	1772 (11.7)	4.25 (3.82–4.74)	<0.0001
Sometimes	820 (36.1)	3000 (45.0)	3023 (49.2)	6843 (45.4)	1.84 (1.73–1.97)	
Never/rarely	1354 (59.5)	3142 (47.1)	1976 (32.1)	6472 (42.9)	Reference group	
Loss of interest						
Often/always	84 (3.7)	508 (7.6)	1107 (18.1)	1699 (11.3)	4.09 (3.67–4.55)	<0.0001
Sometimes	472 (20.8)	1979 (29.7)	2236 (36.6)	4687 (31.2)	2.00 (1.87–2.15)	
Never/rarely	1715 (75.5)	4174 (62.7)	2768 (45.3)	8657 (57.5)	Reference group	
Financial stress						
Often/always	205 (9.1)	895 (13.4)	1386 (22.6)	2486 (16.5)	2.44 (2.23–2.67)	<0.0001
Sometimes	633 (28.0)	2165 (32.5)	2114 (34.5)	4912 (32.6)	1.47 (1.38–1.57)	
Never/rarely	1424 (63.0)	3603 (54.1)	2630 (42.9)	7657 (50.9)	Reference group	
Lives alone						
Yes	302 (13.2)	897 (13.1)	862 (13.6)	2061 (13.3)	1.03 (0.95–1.13)	0.4556
No	1991 (86.8)	5941 (86.9)	5480 (86.4)	13 412 (86.7)	Reference group	
Stress at work or at home						
Often/always	312 (13.8)	1156 (17.3)	1513 (24.6)	2981 (19.8)	1.96 (1.80–2.14)	<0.0001
Sometimes	1027 (45.4)	3126 (46.8)	2898 (47.2)	7051 (46.7)	1.33 (1.24–1.43)	
Never/rarely	925 (40.9)	2400 (35.9)	1732 (28.2)	5057 (33.5)	Reference group	
Years of education						
9–12 y	710 (30.9)	2125 (31.1)	1897 (30.0)	4732 (30.6)	0.75 (0.69–0.82)	<0.0001
College/university	858 (37.3)	1923 (28.2)	1572 (24.9)	4353 (28.2)	0.60 (0.55–0.66)	
Trade school	347 (15.1)	1262 (18.5)	1205 (19.1)	2814 (18.2)	0.87 (0.79–0.95)	
<8 y	384 (16.7)	1513 (22.2)	1651 (26.1)	3548 (23.0)	Reference group	

Continued

Table 1. Continued

	Excellent or Very Good (n=2304)	Good (n=6863)	Average or Poor (n=6361)	Total (N=15 528)	Odds Ratio for one category decrease in health OR (95% CI)	P Value
<b>Lifestyle risk factors</b>						
Body mass index, kg/m <sup>2</sup>						
Mean (SD)	28.5 (4.4)	28.9 (4.8)	29.2 (5.4)	28.9 (5.0)	1.09 (1.01–1.02)	<0.0001 <sup>‡</sup>
Smoking status						
Current smoker	269 (11.7)	1172 (17.1)	1362 (21.4)	2803 (18.1)	1.44 (1.32–1.58)	<0.0001
Former smoker	1298 (56.3)	3589 (52.3)	3060 (48.1)	7947 (51.2)	0.92 (0.86–0.99)	
Never smoked	737 (32.0)	2102 (30.6)	1939 (30.5)	4778 (30.8)	Reference group	
Mediterranean diet score						
Mean (SD)	12.8 (3.1)	12.0 (3.0)	11.7 (3.1)	12.0 (3.1)	0.93 (0.92–0.94)	<0.0001 <sup>‡</sup>
Physical activity (MET h/wk)						
Mean (SD)	60.7 (50.6)	55.2 (49.7)	46.8 (45.6)	52.6 (48.5)	0.90 (0.89–0.92)	<0.0001 <sup>¶</sup>
Attended cardiac rehabilitation						
Yes	966 (42.0)	2409 (35.3)	2037 (32.3)	5412 (35.1)	0.781 (0.734–0.831)	<0.0001
<b>Disease markers</b>						
Diagnosis of hypertension						
Yes	1512 (65.6)	4841 (70.5)	4759 (74.8)	11 112 (71.6)	1.34 (1.25–1.43)	<0.0001
Congestive heart failure at baseline						
Yes	223 (9.7)	1255 (18.3)	1857 (29.2)	3335 (21.5)	2.24 (2.08–2.41)	<0.0001
Significant renal dysfunction						
Yes	581 (25.2%)	2011 (29.3%)	2094 (32.9%)	4686 (30.2%)	1.27 (1.19–1.35)	<0.0001
Prior myocardial infarction						
Yes	1288 (55.9)	4069 (59.3)	3784 (59.5)	9141 (58.9)	1.07 (1.01–1.14)	0.0226
Prior coronary revascularization (PCI or CABG)						
Yes	1852 (80.4)	5222 (76.1)	4574 (71.9)	11 648 (75.0)	0.74 (0.70–0.80)	<0.0001
Prior multivessel chronic heart disease						
Yes	266 (11.5)	988 (14.4)	1084 (17.0)	2338 (15.1)	1.32 (1.22–1.44)	<0.0001
Diabetes mellitus						
Yes	677 (29.4)	2537 (37.0)	2801 (44.0)	6015 (38.7)	1.50 (1.41–1.60)	<0.0001
Polyvascular disease						
Yes	235 (10.2)	999 (14.6)	1101 (17.3)	2335 (15.0)	1.40 (1.30–1.53)	<0.0001
Tooth loss						
≤25 teeth	1593 (69.4)	5294 (77.9)	5193 (82.6)	12 080 (78.5)	1.61 (1.50–1.73)	<0.0001
26–32 (all)	701 (30.6)	1505 (22.1)	1093 (17.4)	3299 (21.5)	Reference group	
NYHA functional class						
Class II, III, or IV	120 (5.2)	856 (12.5)	1467 (23.1)	2443 (15.7)	2.63 (2.42–2.87)	<0.0001
<b>Medications at randomization</b>						
Aspirin						
Yes	2181 (94.7)	6385 (93.0)	5779 (90.9)	14 345 (92.4)	0.687 (0.613–0.770)	<0.0001
ACEI or ARB						
Yes	1632 (70.8)	5291 (77.1)	5036 (79.2)	11 959 (77.0)	1.301 (1.212–1.396)	<0.0001
Statin						
Yes	2243 (97.4)	6689 (97.5)	6174 (97.1)	15 106 (97.3)	0.892 (0.743–1.071)	0.2213

Continued

Table 1. Continued

	Excellent or Very Good (n=2304)	Good (n=6863)	Average or Poor (n=6361)	Total (N=15 528)	Odds Ratio for one category decrease in health OR (95% CI)	P Value
Beta blocker						
Yes	1728 (75.0)	5413 (78.9)	5117 (80.4)	12 258 (78.9)	1.206 (1.122–1.297)	<0.0001
P2Y <sub>12</sub> inhibitor						
Yes	718 (31.2)	2214 (32.3)	2319 (36.5)	5251 (33.8)	1.203 (1.129–1.281)	<0.0001
Biomarkers						
LDL-C, mmol/L						
Mean (SD)	2.1 (0.8)	2.2 (0.8)	2.3 (0.9)	2.2 (0.9)	1.18 (1.14–1.21)	<0.0001 <sup>  </sup>
HDL-C, mmol/L						
Mean (SD)	1.3 (0.3)	1.2 (0.3)	1.2 (0.3)	1.2 (0.3)	0.88 (0.86–0.91)	<0.0001 <sup>  </sup>
Hemoglobin, g/L						
Mean (SD)	144.5 (12.3)	142.7 (13.8)	141.8 (14.7)	142.6 (14.0)	0.89 (0.87–0.92)	<0.0001 <sup>  </sup>
High-sensitivity troponin T, ng/L						
Mean (SD)	10.8 (9.3)	11.9 (12.2)	13.7 (23.2)	12.4 (17.2)	1.19 (1.14–1.25)	<0.0001 <sup>  </sup>
Interleukin 6, ng/L						
Mean (SD)	2.4 (2.0)	2.8 (2.9)	3.1 (3.2)	2.8 (2.9)	1.18 (1.14–1.22)	<0.0001 <sup>  </sup>
GDF-15, ng/L						
Mean (SD)	1415.2 (974.0)	1532.0 (1081.4)	1669.5 (1302.6)	1569.2 (1164.0)	1.17 (1.13–1.21)	<0.0001 <sup>  </sup>
Triglycerides, mmol/L						
Mean (SD)	1.6 (1.0)	1.8 (1.2)	1.9 (1.5)	1.8 (1.3)	1.17 (1.13–1.21)	<0.0001 <sup>  </sup>
eGFR (CKD-EPI), mL/min/1.73 m <sup>2</sup>						
Mean (SD)	73.9 (16.3)	73.3 (17.1)	73.8 (18.2)	73.6 (17.4)	1.01 (0.98–1.04)	0.4384 <sup>  </sup>
Creatinine						
Mean (SD)	93.5 (19.4)	94.1 (24.1)	93.7 (23.7)	93.9 (23.3)	1.00 (0.97–1.03)	0.8168 <sup>  </sup>
White blood cell count (1 × 10 <sup>9</sup> /L)						
Mean (SD)	6.4 (1.7)	6.8 (1.9)	7.0 (1.9)	6.8 (1.9)	1.19 (1.156–1.232)	<0.0001 <sup>  </sup>
hs-CRP, mg/L						
Mean (SD)	2.4 (6.6)	2.8 (5.9)	3.4 (7.2)	3.0 (6.6)	1.12 (1.08–1.16)	<0.0001 <sup>  </sup>
NT-proBNP, ng/L						
Mean (SD)	267.6 (490.9)	345.4 (636.3)	431.9 (989.6)	368.2 (783.1)	1.21 (1.16–1.26)	<0.0001 <sup>  </sup>
Cystatin C, ng/L						
Mean (SD)	1.0 (0.3)	1.0 (0.3)	1.1 (0.3)	1.1 (0.3)	1.13 (1.10–1.17)	<0.0001 <sup>  </sup>
Lp-PLA <sub>2</sub> activity, μmol/min/L						
Mean (SD)	173.6 (44.4)	175.4 (47.2)	176.5 (50.0)	175.6 (47.9)	1.04 (1.01–1.07)	0.0177 <sup>  </sup>

Values are mean (SD) and n (%) for categorical variables. Percentages refer to the percentage of patients in each level of self-reported health and of all patients who have the given characteristic. ACEI indicates angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; CABG, coronary artery bypass grafting; CI, confidence interval; CKD-EPI, Chronic Kidney Disease Epidemiology Collaboration; eGFR, estimated glomerular filtration rate; GDF-15, growth differentiation factor-15; HDL-C, high-density lipoprotein cholesterol; hs-CRP, high-sensitivity C-reactive protein; LDL-C, low-density lipoprotein cholesterol; LpPLA<sub>2</sub>, lipoprotein-associated phospholipase A<sub>2</sub>; MET, metabolic equivalent; NT-proBNP, N-terminal pro-B-type natriuretic peptide; NYHA, New York Heart Association; OR, odds ratio; PCI, percutaneous coronary intervention.

OR for 1-category decrease in self-reported health category: <sup>†</sup>OR based on 1-U increase, <sup>§</sup>OR based on 10-U increase, <sup>||</sup>OR based on 1-SD increase, <sup>¶</sup>OR based on 50% increase.

broad range of demographic, geographic, psychosocial, life-style-related, and conventional cardiovascular risk factors, disease markers, and biomarkers were associated with self-reported health. Thirty-two of these 38 covariates were

associated with self-reported health in univariate analysis, with  $P < 0.0001$ .

Patients who self-reported poorer health were slightly more likely to be on an angiotensin-converting enzyme

inhibitor or angiotensin II receptor antagonist, a beta-blocker, or a P2Y<sub>12</sub> antagonist compared with those with better self-reported health (Table 1). Aspirin use was slightly less in patients reporting poorer general health. Statin use was similar by self-reported health. There was no difference in self-reported health at baseline according to allocation to darapladib or placebo, as expected by randomization.

Variables independently associated with self-reported health in a multivariable adjusted model are displayed in Table 2. The statistical strength of associations between different variables and self-reported health is compared in Figure 1. The strongest independent associations were with geographic region, depressed mood, and low physical activity. The geographic region with the best self-reported health was North America, followed by South America, Western Europe, Eastern Europe, and Asia (Table 1). After adjusting for other covariates associated with self-reported health, persons from South America and North America had the best self-reported health, participants from Western Europe reported slightly worse general health, and those from Eastern Europe and Asia were much more likely to report poorer health (Table 2). A less healthy diet, obesity, smoking, diabetes mellitus, hypertension, exertional dyspnea, cardiovascular disease markers, and tooth loss were each associated with poorer self-reported health. Blood markers independently associated with poorer self-reported health were high-sensitivity cardiac troponin T, growth differentiation factor 15, interleukin 6, low-density lipoprotein cholesterol, and low hemoglobin. Age and sex were not associated with self-reported health in the fully adjusted model. Attendance at cardiac rehabilitation was not associated with self-reported health after adjusting for covariates (Table 2).

There was a stepwise increase in the risk of MACE with worsening self-reported health (Figure 2). The hazard ratios for adverse outcomes by self-reported health before and after adjustment for covariables are displayed in Figure 3A and 3B, respectively. Poorer self-reported health was associated with increased cardiovascular and total mortality, myocardial infarction, stroke, and hospital admission for heart failure (Figure 3A). After adjustment for all covariates, these associations were maintained for all outcomes except heart failure hospitalization and stroke (Figure 3B).

## Discussion

In this study, which evaluated a global population of patients with stable CHD on optimal secondary prevention treatment, average or poor self-reported health was independently associated with a 2- to 3-fold increased risk of cardiovascular mortality and myocardial infarction compared with patients reporting very good or excellent health. These observations indicate that self-reported health is an important incremental

risk indicator of myocardial infarction and cardiovascular mortality in patients with stable CHD, despite optimal secondary prevention treatment. The association with a large number of prognostically important variables is consistent with the conclusion that self-reported health is a global health measure that both reflects the cumulative effects of a broad range of known risk indicators and indicates the importance of additional risk indicators not measurable by conventional methods.

A number of large studies have evaluated associations between self-reported health and mortality in general populations.<sup>4,6,21</sup> In the UK Biobank cohort, which included nearly 500 000 volunteers and evaluated multiple clinical, biomarker, and genetic risk factors, self-reported health was the strongest single predictor of all-cause mortality in men and the third strongest mortality predictor in women after a cancer diagnosis and illness or injury.<sup>4</sup> Meta-analyses of smaller studies have also been consistent in reporting associations between poorer self-reported health and cardiovascular and all-cause mortality.<sup>5,22</sup> In a large Swedish general population cohort, poorer self-reported health was associated with a higher prevalence of multiple cardiovascular risk factors, and with an increased risk of myocardial infarction during follow-up over  $\approx 13$  years.<sup>21</sup>

A systematic review of studies reporting the relationship between self-reported health and fatal and nonfatal cardiovascular outcomes<sup>22</sup> identified 3 studies<sup>8,9,23</sup> including 10 648 patients with known cardiovascular or ischemic heart disease. In this meta-analysis, patients with poor health compared with good or excellent health had a  $\approx 2.4$  times higher risk of cardiovascular death, consistent with the current study. However these studies have limitations, including poor measurement of baseline risk factors and cardiovascular disease status, lack of detail on study methods, and poor ascertainment of disease status or severity.

Most previous studies reporting self-reported health have been undertaken in a single country. In the current study, which included patients from 39 countries and multiple regions of the world, self-reported health was strongly associated with geographic region and country of residence. These observations suggest that cultural or regional norms need to be considered when interpreting self-reported health. In addition, the large geographic differences in self-reported health changed after adjustment for covariates, suggesting that geographic differences in self-reported health reflect both differences in the burden of disease or symptoms and different perceptions of their impact on health. Socioeconomic<sup>24</sup> and international gradients<sup>25</sup> in adverse outcomes for patients with CHD persist despite adjustment for conventional cardiovascular risk factors and are well described. It is possible these could be explained in part by differences in general health.

**Table 2.** Covariates Independently Associated With Self-Reported Health in a Model Adjusting for All Other Covariates

Variables	Contrast	OR (95% CI)	Overall P Value
<b>Demographics</b>			
Age at randomization, y		1.080 (1.006–1.159) <sup>†</sup>	0.0330
Sex	Female vs male	1.175 (0.989–1.395)	0.0664
Geographic region	Asia/Pacific vs North America	4.795 (4.142–5.549)	<0.0001
	Eastern Europe vs North America	3.015 (2.651–3.427)	
	South America vs North America	0.866 (0.732–1.025)	
	Western Europe vs North America	1.647 (1.477–1.837)	
<b>Psychosocial measures</b>			
Depressed mood	Often/always vs never/rarely	2.214 (1.897–2.583)	<0.0001
	Sometimes vs never/rarely	1.408 (1.292–1.535)	
Lost interest in hobbies	Often/always vs never/rarely	2.625 (2.270–3.036)	<0.0001
	Sometimes vs never/rarely	1.502 (1.378–1.638)	
Financial stress	Often/always vs never/rarely	1.455 (1.287–1.645)	<0.0001
	Sometimes vs never/rarely	1.150 (1.054–1.255)	
Lives alone	Yes vs no	1.009 (0.905–1.126)	0.8676
Stress at work or at home	Often/always vs never/rarely	1.222 (1.081–1.382)	0.0024
	Sometimes vs never/rarely	1.136 (1.040–1.242)	
Years of education	9–12 vs <8 y	0.873 (0.783–0.974)	<0.0001
	Trade school vs <8 y	0.968 (0.856–1.094)	
	College/university vs <8 y	0.785 (0.700–0.881)	
<b>Lifestyle risk factors</b>			
Body mass index, kg/m <sup>2</sup>		1.028 (1.019–1.037)*	<0.0001
Smoking status	Current smoker vs never/former smoker	1.285 (1.153–1.432)	<0.0001
Mediterranean diet score		0.959 (0.947–0.972)*	<0.0001
Physical activity, MET h/wk		0.916 (0.901–0.931) <sup>§</sup>	<0.0001
Cardiac rehabilitation	Yes vs no	0.962 (0.888–1.043)	0.3514
<b>Disease markers</b>			
Diagnosis of hypertension	Yes vs no	1.285 (1.181–1.399)	<0.0001
Congestive heart failure at baseline	Yes vs no	1.141 (1.001–1.301)	0.0481
Significant renal dysfunction	Yes vs no	1.061 (0.965–1.165)	0.2194
Prior myocardial infarction	Yes vs no	0.895 (0.825–0.971)	0.0076
Prior coronary revascularization (PCI or CABG)	Yes vs no	0.876 (0.797–0.962)	0.0055
Prior multivessel chronic heart disease	Yes vs no	1.228 (1.098–1.372)	0.0003
Diabetes mellitus	Yes vs no	1.229 (1.128–1.338)	<0.0001
Polyvascular disease	Yes vs no	1.272 (1.144–1.415)	<0.0001
Tooth loss	≤25 vs 26–32 (all) teeth	1.387 (1.262–1.524)	<0.0001
NYHA functional class	Class II,III, or IV vs no class/class I	1.554 (1.337–1.806)	<0.0001
<b>Biomarkers</b>			
LDL-C, mmol/L		1.092 (1.040–1.146) <sup>‡</sup>	0.0004
HDL-C, mmol/L		0.939 (0.898–0.982) <sup>‡</sup>	0.0062
Hemoglobin, g/L		0.951 (0.909–0.995) <sup>‡</sup>	0.0307

Continued



Table 2. Continued

Variables	Contrast	OR (95% CI)	Overall <i>P</i> Value
High-sensitivity troponin T, ng/L		1.081 (1.026–1.140) <sup>‡</sup>	0.0036
Interleukin 6, ng/L		1.070 (1.023–1.119) <sup>‡</sup>	0.0033
GDF-15, ng/L		1.070 (1.017–1.124) <sup>‡</sup>	0.0083
Triglycerides, mmol/L		1.050 (0.995–1.109) <sup>‡</sup>	0.0767
eGFR (CKD-EPI), mL/min/1.73 m <sup>2</sup>		1.117 (0.971–1.286) <sup>‡</sup>	0.1219
Creatinine		1.131 (0.979–1.307) <sup>‡</sup>	0.0949
White blood cell count (1 × 10 <sup>9</sup> /L)		0.988 (0.949–1.028) <sup>‡</sup>	0.5541
High-sensitivity C-reactive protein, mg/L		1.009 (0.967–1.053) <sup>‡</sup>	0.6678
NT-proBNP, ng/L		1.049 (0.995–1.105) <sup>‡</sup>	0.0750
Cystatin C, ng/L		0.943 (0.885–1.006) <sup>‡</sup>	0.0750
Lp-PLA <sub>2</sub> activity, μmol/min/L		0.965 (0.918–1.013) <sup>‡</sup>	0.1506

CABG indicates coronary artery bypass grafting; CI, confidence interval; CKD-EPI, Chronic Kidney Disease Epidemiology Collaboration; eGFR, estimated glomerular filtration rate; GDF-15, growth differentiation factor-15; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; LpPLA<sub>2</sub>, lipoprotein-associated phospholipase A<sub>2</sub>; MET, metabolic equivalent; NT-proBNP, N-terminal pro-B-type natriuretic peptide; NYHA, New York Heart Association; OR, odds ratio; PCI, percutaneous coronary intervention.

OR for 1-category decrease in self-reported health category: <sup>\*</sup>OR based on 1-U increase, <sup>†</sup>OR based on 10-U increase, <sup>‡</sup>OR based on 1-SD increase, <sup>§</sup>OR based on 50% increase.

Both psychosocial and conventional cardiovascular risk factors have been associated with self-reported health in previous studies.<sup>7,21,22</sup> In these studies, however, information on multiple covariates was more limited, and a detailed analysis of the relative importance of different factors was not undertaken. In the current study, depressive symptoms were strongly associated with self-reported health, consistent with an effect of mood on the perception of health and the impact of poorer health on mood. Stress from various causes and fewer years of education were also associated with poorer self-reported health. Other indicators of socioeconomic status were not assessed in this study. Lifestyle risk factors, including current smoking, physical activity, diet, and body weight, were relatively strong predictors of self-reported health.

The presence of clinical markers of cardiovascular disease or risk, including prior myocardial infarction, stroke, polyvascular disease, diabetes mellitus, and renal dysfunction, was associated with poorer self-reported health; however, the strength of these associations, as assessed by the  $\chi^2$  statistic, was generally less than that of psychosocial and lifestyle measures. Associations between self-reported health and blood biomarkers, some of which are powerful risk predictors, were generally weaker than those of clinical variables. Associations of self-reported health with low-density lipoprotein cholesterol, hemoglobin, interleukin 6, growth differentiation factor 15, and troponin T are consistent with an influence of multiple pathophysiological pathways.

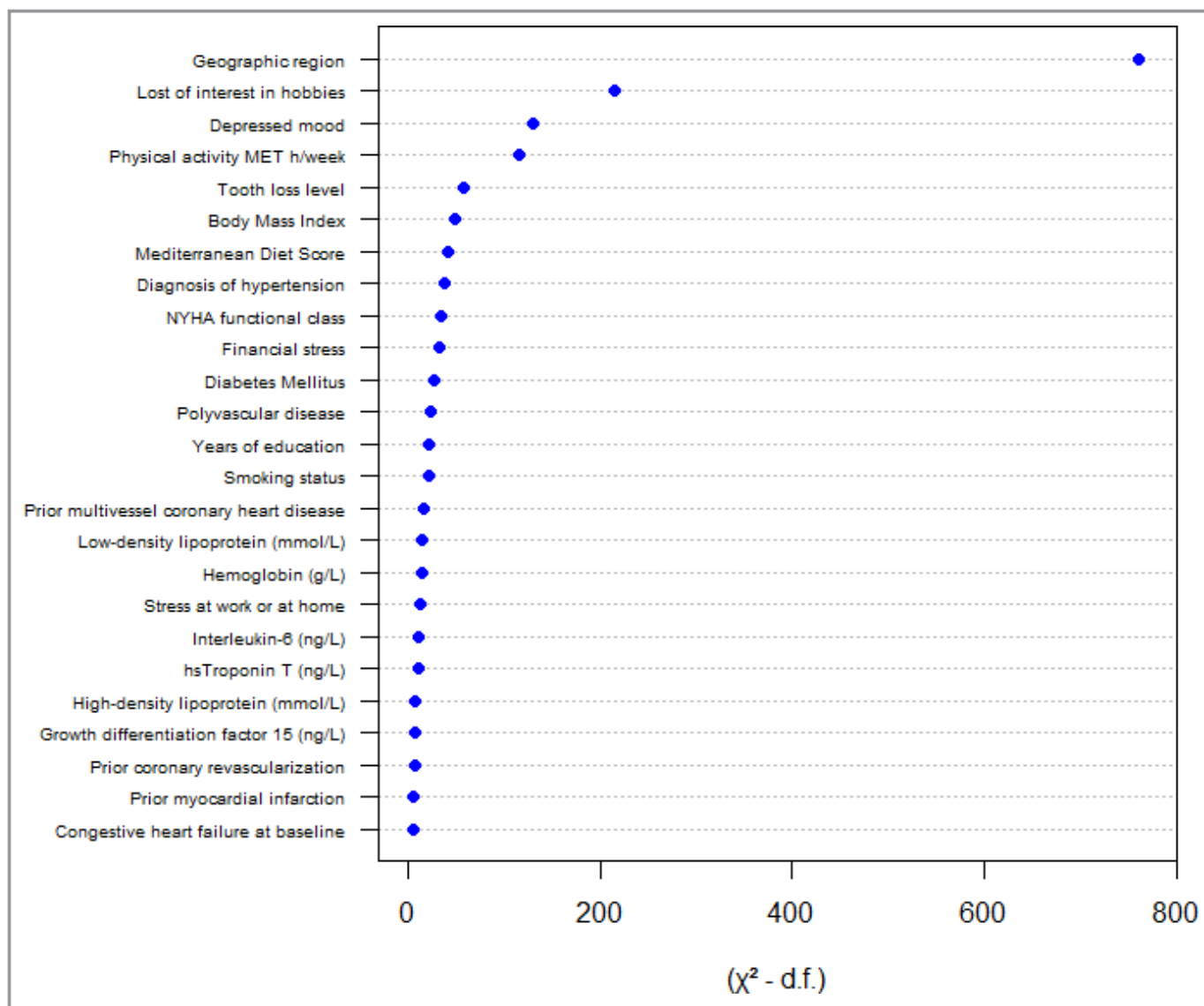
There were modest differences in use of several evidence-based medications by self-reported health, but the reasons for these differences cannot be determined reliably in this observational study. Differences in medication use could be

explained by treatment indication, such as impaired left ventricular function, which is a stronger indication for beta blockers and angiotensin-converting enzyme inhibitors or angiotensin receptor antagonists, or effects of treatment on general health (eg, if beta blockers caused fatigue). A common association between medication use and other factors that influence health, such as socioeconomic conditions, geography, or medical care, is also possible.<sup>12</sup>

### Study Limitations

The current study has a number of limitations. The degree to which the observed associations are causal cannot be established in this observational study. Despite the availability of a wide array of clinical and biochemical risk indicators and risk factors, there are still additional unmeasured risk factors, for example, details on all comorbidities, extent of coronary lesions, and genetic factors that were not included in the database. Furthermore, participants selected to participate in a clinical trial may not be representative of all CHD patients; however, the large geographically and culturally diverse study population and the internal consistency of the data suggest that results are likely to be broadly applicable. Additional strengths of the current analysis include the standardized assessment of multiple clinical, psychosocial, and lifestyle variables and near-complete ascertainment of outcomes.

This study described associations between self-reported health and a broad range of prognostically important variables. Our observation that many of these associations remained statistically significant after multivariable adjustment indicates that self-reported health captures a broad range of conditions affecting sense of well-being.



**Figure 1.** Relative strength of association with self-reported health of each variable included in the full model, as measured by the Wald  $\chi^2$  test minus the predictor degrees of freedom:  $(\chi^2 - df) = \chi^2 - \text{predictor } df$ . Higher values on the x-axis indicate a stronger association with self-reported health. hs indicates high sensitivity; MET, metabolic equivalent; NYHA, New York Heart Association.

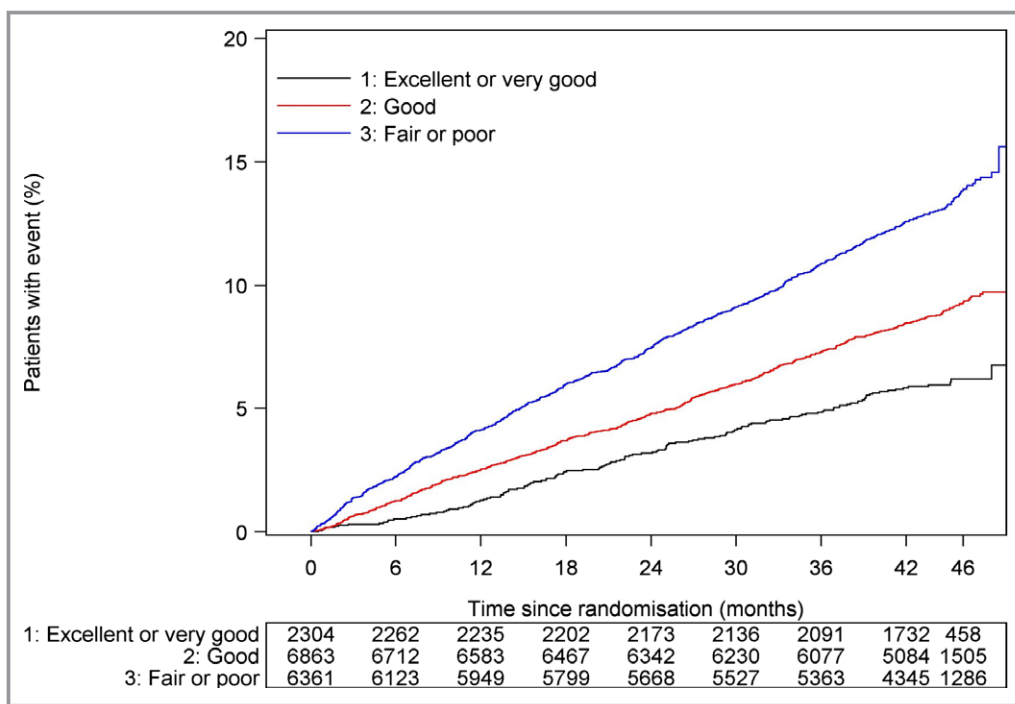
Broad geographic regions were prespecified for the analysis, but chosen groupings are relatively crude indicators of the importance of cultural, medical, and socioeconomic differences between and within countries—a limitation that is likely to diminish estimates of the importance of geographic factors. Despite this, geographic region was a strong independent predictor of both self-reported health and MACE.

## Study Implications

An assessment of self-reported health can be undertaken simply as part of almost any consultation. Poor or worsening self-reported health may occur for many reasons, both cardiac and noncardiac. This study suggests that poorer general health, whatever the reason, is associated with a higher risk of

MACE in patients with stable CHD. This raises the possibility that interventions that improve overall health could reduce cardiovascular risk.

Disease-specific patient-centered outcome measures, such as the Quality of Life After Myocardial Infarction Questionnaire<sup>26</sup> or the Seattle Angina Questionnaire,<sup>27</sup> may be more sensitive to the impact of cardiovascular disease on quality of life than on overall health.<sup>1</sup> Self-reported overall health is influenced by many factors. Compared with disease-specific tools, general health may be less sensitive to changes in symptoms directly related to, for example, CHD. Nevertheless, disease-specific measures have some disadvantages. They generally include more questions, are less comparable for patients with different medical problems, are more time consuming to administer, and may not



**Figure 2.** Kaplan–Meier plot of major adverse cardiovascular events by self-reported health at baseline.

capture the impact of non–disease-related factors on general health.

Because self-reported overall health is a powerful risk marker, considering it could better inform decisions about treatment or delivery of health care and discussions about risks to future health. Few studies have evaluated whether and how response to different treatments relates to self-reported health. Further research is needed to evaluate the effectiveness of targeting health care based on assessment of self-reported general health.

### Conclusions

In a global stable CHD population, self-reported health was strongly associated with geographical region, psychosocial variables, and lifestyle risk factors. Self-reported health was independently associated with MACE when adjusting for baseline characteristics including a wide array of prognostic biomarkers. These data support the conclusion that self-perceived health and psychosocial and lifestyle-related factors contribute to cardiovascular events beyond what is measurable by established risk indicators.

### Author Contributions

Stewart, Held, Wallentin, and White designed the lifestyle questionnaire administered to STABILITY trial participants, which included the question on self-reported health, and

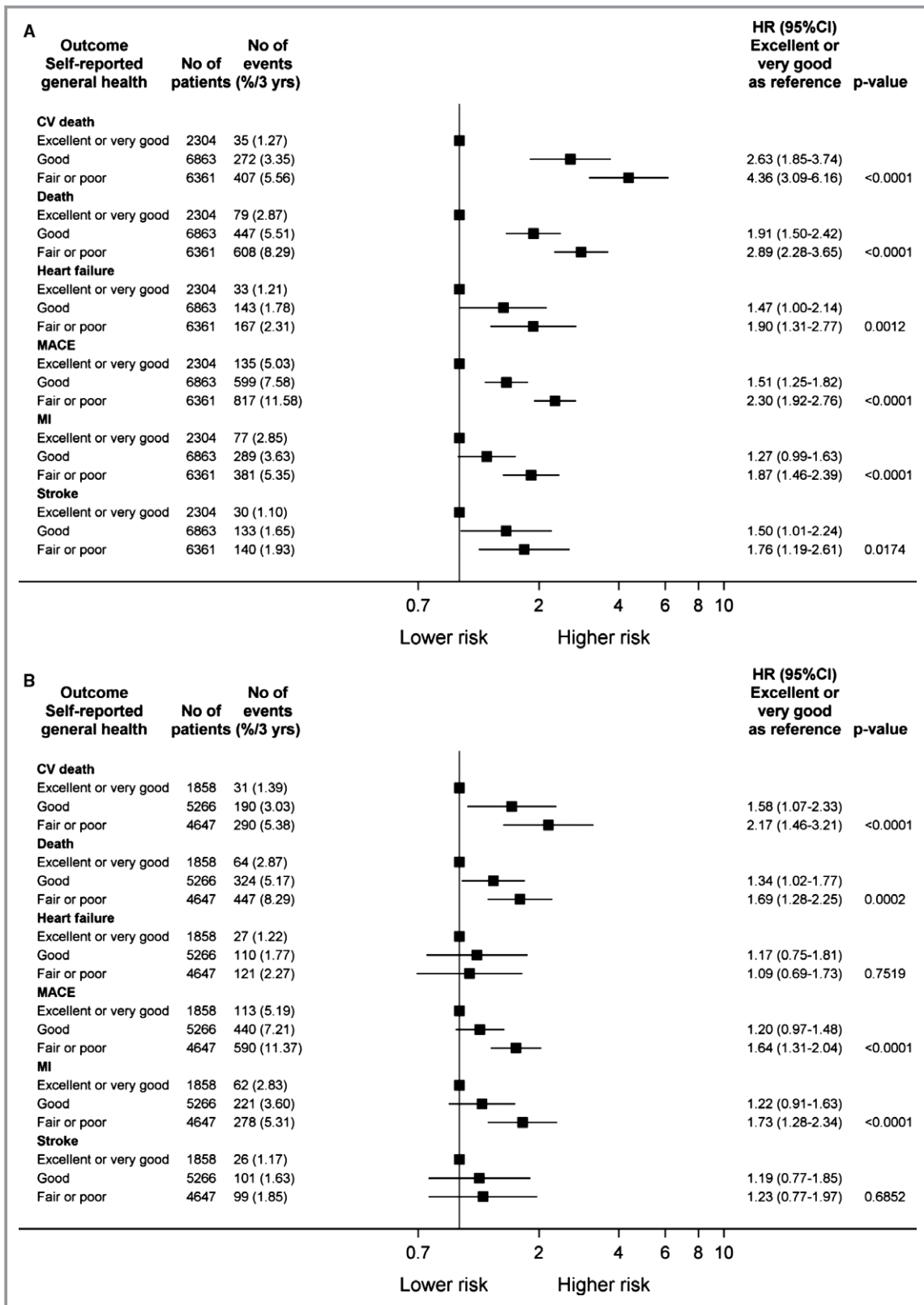
proposed the study analysis. Statistical analysis was undertaken by Hadziosmanovic. The manuscript was drafted by Stewart. All coauthors contributed to the design and management of the STABILITY trial. All authors contributed to critical review of the manuscript. Additional Contributions: Editorial assistance was provided by Susanna Thörnqvist, PhD, Uppsala Clinical Research Center (UCR), Uppsala University, Sweden, through funds from GlaxoSmithKline and secretarial assistance was provided by Michelle D’Souza, Auckland City Hospital.

### Sources of Funding

This work was supported by the STABILITY trial funded by GlaxoSmithKline. The design, statistical analysis, and drafting of the manuscript were all undertaken independently by the study investigators.

### Disclosures

Stewart has received nonfinancial support from GlaxoSmithKline. Hagström is an expert committee member, receiving lecture fees, and institutional research grants from Sanofi, and Amgen; institutional research grants from AstraZeneca, and GlaxoSmithKline; he is also an expert committee member for Ariad and MSD. Held has received an institutional research grant and speaker’s bureau from AstraZeneca; institutional research grants from Bristol-Myers Squibb, Merck & Co, GlaxoSmithKline, Roche. Armstrong has received grants from



**Figure 3.** Adverse events by self-reported health at baseline adjusted (A) for treatment allocation only and (B) for all covariates. Hazard ratios (HRs) and 95% confidence intervals (CIs) are presented for each outcome for patients reporting good and average or poor health compared with the reference group that reported very good or excellent health. *Heart failure* refers to hospitalization for heart failure. CV indicates cardiovascular; MACE, major adverse cardiac events; MI, myocardial infarction.

Merck, Sanofi-Aventis, Bayer; lecture fees from AstraZeneca; consulting fees from Merck, Bayer, Axio/Orexigen, Eli Lilly, Bayer, Mast Therapeutics Inc. Aylward has received grants, personal fees and other from GlaxoSmithKline, AstraZeneca, Merck; grants and personal fees from Sanofi-Aventis; personal fees from Boehringer Ingelheim, Pfizer, Eli Lilly, The Medicines Company, Amgen. Cannon has received grants and personal fees from AstraZeneca, Takeda, Boehringer Ingelheim, Merck, Bristol-Myers Squibb, Arisaph, GlaxoSmithKline; personal fees from Alnylam, Pfizer, Kowa, Lipimedix, Regeneron, Sanofi, Amgen, Boehringer Ingelheim/Eli Lilly; grants from Janssen. Koenig has received lecture and consultancy fees from Novartis, Amgen, AstraZeneca; lecture fees from Actavis, Berlin-Chemie; consultancy fees from GlaxoSmithKline, The Medicines Company, Pfizer, Merck Sharpe & Dohme and Kowa; research grants from Roche Diagnostics, Abbott, Singulex, Beckmann. López-Sendón has received grants and personal fees from Pfizer, Novartis, Servier, Menarini, and Sanofi; personal fees from Boehringer Ingelheim, grants from Bayer, grants from GlaxoSmithKline. Mohler has received grants and honoraria from GlaxoSmithKline. Hadziolosmanovic has received institutional research grant from GlaxoSmithKline. Krug-Gourley is an employee of and having stock ownership in GlaxoSmithKline. Siddique has received personal fees and non-financial support from GlaxoSmithKline, Novartis, Bayer, Pfizer, Sanofi-Aventis, Servier; non-financial support from Ferozsons/Boston Scientific, Pharmevo, Horizon Pharma, Highnoon, Atco Laboratories. Steg has received personal fees from GlaxoSmithKline, Amarin, Bayer, Boehringer-Ingelheim, Bristol-Myers-Squibb, Daiichi-Sankyo, Eli Lilly, Merck-Sharp-Dohme, Novartis, Pfizer, The Medicines Company, CLS-Behring, Janssen; grants, personal fees and other from Sanofi and Servier; personal fees and other from AstraZeneca. White has received research grants and personal fees from GlaxoSmithKline, research grants from Sanofi-Aventis, Eli Lilly, National Institute of Health, George Institute, Omthera Pharmaceuticals, Pfizer New Zealand, Intarcia Therapeutics Inc., Elsal Inc., Dal-GenE and research grants and advisory board member for AstraZeneca, Honoraria and lecture fees from Sirtex and Acetilion. Wallentin has received institutional research grants, consultancy fees, lecture fees, and travel support from Bristol-Myers Squibb/Pfizer, AstraZeneca, GlaxoSmithKline, Boehringer Ingelheim; institutional research grants from Merck & Co, Roche; consultancy fees from Abbott; holds 2 patents involving GDF-15. The remaining authors have no disclosures to report.

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# **Supplemental Material**

## **Appendix**

### **STABILITY Trial – Organizational**

#### **STABILITY Executive Steering Committee members**

##### *Co-chairmen:*

Harvey D White (Green Lane Cardiovascular Service, Auckland City Hospital, and Auckland University, Auckland, NZ; member of the VIGOUR Organization)

Lars Wallentin (Department of Medical Sciences and Uppsala Clinical Research Center, Uppsala University, Uppsala, SE; member of the VIGOUR Organization)

##### *Members:*

Andrzej Budaj (Grochowski Hospital, Warsaw, PL)

Christopher P Cannon (TIMI Study Group, Brigham and Women's Hospital, Boston, MA, US)

Robert A Harrington (Stanford University, Stanford, CA, US; member of the VIGOUR Organization)

Ph Gabriel Steg (INSERM-Unité, AP-HP; Hôpital Bichat; and Université Paris-Diderot, Paris, FR; Royal Brompton Hospital, London, UK; member of the VIGOUR Organization)

##### *GlaxoSmithKline Members:*

Richard Davies (GlaxoSmithKline, King of Prussia, PA, US)

Elizabeth Tarka (GlaxoSmithKline, King of Prussia, PA, US)

#### **STABILITY Executive Operations Committee members**

Harvey D White (Green Lane Cardiovascular Service, Auckland City Hospital, and Auckland University, Auckland, NZ; member of the VIGOUR Organization)

Lars Wallentin (Department of Medical Sciences and Uppsala Clinical Research Center, Uppsala University, Uppsala, SE; member of the VIGOUR Organization)

Claes Held (Department of Medical Sciences and Uppsala Clinical Research Center, Uppsala University, Uppsala, SE; member of the VIGOUR Organization)

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Sue Krug-Gourley (GlaxoSmithKline, King of Prussia, PA, US)  
Jerry Rudman (GlaxoSmithKline, King of Prussia, PA, US) (Posthumous)  
Peter Smith (GlaxoSmithKline, Research Triangle Park, NC, US)  
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**STABILITY Steering Committee members/ National Coordinators**

Diego Ardissino (Azienda Ospedaliero-Universitaria di Parma, Parma, IT)  
Paul W Armstrong (University of Alberta, Edmonton, CA, US; member of the VIGOUR Organization)  
Alvaro Avezum (Dante Pazzanese Institute of Cardiology, São Paulo, BR)  
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Alfonso Bryce (Cardiogolf/Clinica El Golf, Lima, PE)  
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Ming-Fong Chen (National Taiwan University Hospital, Taipei, TW)  
Ramon Corbalan (Pontificia Universidad Catolica de Chile, Santiago, CL)  
Anthony JDalby (Milpark Hospital, Johannesburg, ZA)  
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Rafael Diaz (ECLA Estudios Cardiológicos, Latinoamérica, Rosario, AR)  
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### **Clinical End Point Classification (CEC) - Cardiology**

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*Co-chairman - CEC Cardiology:* Kenneth W Mahaffey, Duke Clinical Research Institute, Durham, NC, US

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*Coordinating Sites – CEC Cardiology*

Uppsala Clinical Research Center (UCR), Uppsala University, Uppsala, SE (*Lead coordinating site*)  
Duke Clinical Research Institute (DCRI), Durham, NC, US  
GLCC Research Organization Ltd, Auckland, NZ

*Staff Members – CEC Cardiology*

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Kimberly O'Malia, Grace Ryan, Patsy Smitheran, Maunette Tait, and Sachin Vyas (CEC Monitors);  
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and Laura Mackay (CEC Monitors)

### **Clinical End Point Classification (CEC) - Oncology**

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Wolfram Goessling (Brigham and Women's Hospital, Boston, MA, US)

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#### *Coordinating Site – CEC Oncology*

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### **Statistical Centers and Involved Statisticians**

Allison Barnes (GlaxoSmithKline, Research Triangle Park, NC, US)

Rebekkah Brown (GlaxoSmithKline, Research Triangle Park, NC, US)

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### **Central Laboratory**

Quest Diagnostics Clinical Laboratories, Inc., Valencia, CA, US

### **Data Coordination**

*Data management:* GlaxoSmithKline, R&D Projects Clinical Platforms & Sciences, King of Prussia, PA, US

*Registration And Medication Ordering System [RAMOS] interactive voice response system:*  
GlaxoSmithKline, R&D Platform Technology & Science, Upper Providence, PA, US

*Web-based Data Capture Vendor:* Oracle Health Sciences, Boston, MA, US

### **STABILITY Investigators by country**

Listed are investigators recruiting at least 1 patient. Number of patients included is listed in brackets.  
FPI = Former Principal Investigator at site

#### **Argentina**

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Cartasegna, Luis R, Hospital Italiano de La Plata, Buenos Aires (6); Chekherdemian, Sergio, Complejo Médico de la Policia Federal Argentina Churrucá-Visca, Ciudad Autonoma de Buenos Aires (16);  
Cuello, Jose L, Instituto de Investigaciones Clinicas Bahia Blanca, Buenos Aires (42); Elías, Pedro, INSARES, Mendoza (22); Giordano, Jorge, Clinica Instituto Medico Adrogué, Buenos Aires (23);  
Hirschson, Alfredo, CENIT- Centro de Neurociencias y Tratamiento- Buenos Aires, Buenos Aires (14);  
Hominal, Miguel Angel, Centro de Investigaciones Clinicas del Litoral S.R.L., Santa Fe, Santa Fe (47);  
Ibañez, Julio O, Instituto de Hipertension y Corazon, Corrientes (21); Jure, Horacio O, Clinica Chutro SRL, Córdoba (49); Litvak, Marcos, Instituto Medico Especializado, Ciudad Autonoma de Buenos Aires (25);  
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#### **Australia**

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## **Belgium**

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## **Brazil**

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## **Bulgaria**

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## **Canada**

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## **Chile**

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## Estonia

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## France

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