Personality Disorder and Cardiovascular Disease: Results From a National Household Survey

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Objective: Little is known about the physical health of personality-disordered people. This study investigated associations between personality disorder and cardiovascular disease in a large, nationally representative sample from Great Britain.

Method: A random sample of 8580 adults aged 16 to 74 years, living in England, Wales, and Scotland in 2000 was screened for the presence of personality disorders using the screening questionnaire of the *Structured Clinical Interview for DSM-IV Axis II Personality Disorders*. Self-reported stroke or ischemic heart disease was ascertained. Age, sex, social class (by occupation), self-reported hypertension or diabetes, smoking history, and alcoholism were entered into regression models as potential confounding/mediating factors.

Results: Participants screening positive for any personality disorder were more likely to report experiencing a stroke and ischemic heart disease (age- and sex-adjusted odds ratios [ORs] were 2.1 [95% CI, 1.2 to 3.8] and 1.5 [95% CI, 1.1 to 2.1], respectively). After adjusting for potential confounders, significant associations were found between any personality disorder and stroke (OR = 1.9; 95% CI, 1.0 to 3.5) and any personality disorder and ischemic heart disease (OR = 1.4; 95% CI, 1.0 to 1.9). After adjustment, avoidant (OR = 4.0; 95% CI, 1.2 to 13.3), obsessive-compulsive (OR = 2.9; 95% CI, 1.3 to 6.6), and borderline personality disorders (OR = 8.5; 95% CI, 1.0 to 72.8) were significantly associated with stroke. Ischemic heart disease was significantly associated with avoidant (OR = 2.2; 95% CI, 1.1 to 4.5), paranoid (OR = 2.1; 95% CI, 1.0 to 4.3), schizotypal (OR = 3.6; 95% CI, 1.5 to 8.6), schizoid (OR = 1.6; 95% CI, 1.1 to 2.4), and borderline personality disorders (OR = 7.2; 95% CI, 2.1 to 24.3).

Conclusion: People at risk for personality disorder are also at increased risk for cardiovascular disease. This increased risk is not explained by differences in socioeconomic status or lifestyle. Dysfunctional personality traits may have a direct role in the etiology of cardiovascular disease.

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Personality disorders are common and burdensome mental disorders. In the United States, the prevalence of personality disorder was recently reported to be as high as 14.8%[1] (equivalent to 30.8 million afflicted people). Personality-disordered individuals are more vulnerable to other psychiatric disorders, and the prevalence of personality disorders is substantially elevated among psychiatric populations, with prevalence estimates varying from 30% in general outpatients[2] to 80% among populations with substance misuse.[3] The management of mental illness is made more complex by the presence of personality disorder,[4] and patients with personality disorder place high demands on health and social services.[5] As a broad group, personality-disordered individuals are also more likely to harm themselves[6] and to commit suicide,[7] and they are also at increased risk for death by homicide and accidents.[8]

Associations have been found between some personality disorder categories and disability.[1,9,10] However, comparatively little is known about the physical health of people with personality disorder. In a recent Australian community survey, participants screening positive for personality disorder were more likely to report having a

> ### TAKE-HOME POINTS
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> ◆ People with personality disorder are at higher risk for cardiovascular disease.
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> ◆ The increased risk for cardiovascular disease is independent of the effects of other vascular risk factors, such as hypertension, diabetes, smoking, and alcohol misuse.
>
> ◆ People with personality disorder might particularly benefit from primary prevention strategies for cardiovascular disease.

physical condition.[11] Whether there are associations between specific physical health problems and subtypes of personality disorder is, however, unknown.

Cardiovascular disease, principally heart disease and stroke, is the leading cause of mortality for both men and women among all racial and ethnic groups in the United States.[12] Although there is a long history of research into cardiovascular risk and personality styles,[13,14] it is unclear whether the former is associated with personality disorder. Some personality-disordered individuals (particularly those belonging to the cluster B group) may engage excessively in unhealthy behaviors such as smoking, excessive alcohol use, and reduced physical activity.[15,16] These behaviors may, in turn, predispose to higher rates of cardiovascular disease in this subpopulation, although this question has not been formally addressed.

The main objective of this study was to investigate the cross-sectional associations between specific categories of personality disorder and cardiovascular disease in a large, nationally representative sample from Great Britain. It was hypothesized that people screening positive for a personality disorder would be more likely to report a history of stroke and ischemic heart disease. Furthermore, in the light of literature suggesting an association between borderline personality disorder and unhealthy lifestyle, we hypothesized that this disorder would be most strongly associated with cardiovascular disease.

METHOD

Sample

This study was a secondary analysis of existing data collected as part of a large community survey of British adults aged 16 to 74 years. The methodology of this survey has been described in detail elsewhere.[17] The second National Survey of Psychiatric Morbidity sampled adults living in private households and was carried out in England, Wales, and Scotland in 2000 by the Office for National Statistics.[17] The main findings from this survey relating to the prevalence of personality disorder have been published elsewhere.[18] The London Multi-Centre Research Ethics Committee approved the study, and all relevant local research ethics committees were informed. Participants gave their informed consent after the study procedures were fully explained. The primary sampling units (postal sec-

tors) were selected from the Small Users Postcode Address File, stratified for region and social class composition to generate a nationally representative sample. Households were randomly selected from within each unit, and 1 person was randomly selected and invited to participate from each household containing at least 1 person aged between 16 and 74 years. A total of 12,792 adults were selected, resulting in 8580 participants (a 67% response rate).

Procedures

Measurement of personality disorder and mental disorder. Possible cases of DSM-IV personality disorder (PD) were identified using the screening questionnaire of the *Structured Clinical Interview for Axis II Personality Disorders* (SCID-II).[19] Clinical (SCID-II) interviews were also carried out on a limited subsample of 623 participants, 63 of whom had any PD and 560 of whom did not. However, cardiovascular events in this subsample were too rare for adequately quantifying associations. Principal analyses were therefore carried out using the SCID-II screening data on the larger sample, and second-stage clinical data were used for confirmatory secondary analyses. Participants gave *yes* or *no* responses to 116 screening questions, which they entered on a laptop computer. Categories of Axis II disorder derived from this instrument were created by applying algorithms developed during a previous survey.[20]

Outcome measures. Participants were asked to report any long-standing health problems. From the responses given, stroke and ischemic heart disease were generated as 2 binary variables. Ischemic heart disease was defined on the basis of reported heart attack, angina, or coronary artery bypass surgery.

Other independent variables. Age and sex were recorded. Socioeconomic status was classified from occupational status into 7 standard categories[21] and was entered into regression models as a fixed variable with missing values (N = 328) as a dummy category. Diabetes and hypertension were also defined from reports of health problems. Smoking status was classified into 3 groups (current, previous, never). Alcohol misuse was ascertained using the Alcohol Use Disorders Identification Test (AUDIT) questionnaire,[22] and participants were categorized into 3 groups according to standard scores for problem drinking and alcoholism (0–7, 8–15, 16–40).

Table 1. Associations Between Personality Disorder (PD) and Reported Stroke and Ischemic Heart Disease

| | | Stroke | | Ischemic Heart Disease | |
| | | Prevalence,[a] | | Prevalence,[a] | |
PD Category	N (Weighted %)	N (%)	OR[b] (95% CI)	N (%)	OR[b] (95% CI)
No PD	5937 (70.6)	31 (0.4)	1.0 (reference)	126 (1.7)	1.0 (reference)
Any PD	2462 (28.7)	25 (0.8)	2.1 (1.2 to 3.8)	75 (2.4)	1.5 (1.1 to 2.1)
Paranoid	600 (7.2)	5 (0.6)	3.1 (1.2 to 8.4)	14 (1.9)	2.4 (1.2 to 4.7)
Schizotypal	222 (2.7)	1 (0.3)	1.5 (0.2 to 11.2)	10 (2.9)	4.3 (1.9 to 9.6)
Schizoid	1146 (12.9)	17 (1.1)	2.2 (1.1 to 4.5)	50 (3.7)	1.7 (1.2 to 2.5)
Histrionic	51 (0.7)	0	NA	0	NA
Narcissistic	35 (0.5)	0	NA	0	NA
Borderline	111 (1.3)	1 (1.2)	13.8 (1.9 to 97.7)	4 (3.0)	9.7 (3.0 to 31.8)
Antisocial	312 (3.6)	2 (0.6)	4.6 (1.0 to 21.1)	6 (1.0)	1.7 (0.7 to 4.5)
Avoidant	404 (4.6)	4 (1.1)	5.1 (1.6 to 16.1)	11 (1.9)	2.5 (1.3 to 4.8)
Dependent	100 (1.2)	1 (1.0)	4.0 (0.5 to 32.1)	2 (2.4)	2.6 (0.4 to 15.0)
Obsessive-compulsive	845 (10.2)	9 (1.2)	2.7 (1.2 to 6.3)	21 (2.0)	1.1 (0.7 to 1.7)

[a]All prevalence figures are weighted percentages.
[b]All ORs are adjusted for age and sex.
Abbreviations: NA = not applicable, OR = odds ratio.

Statistical Analysis

All analyses were carried out using STATA software[23] with standard weighting procedures to allow for the stratified, clustered sampling and nonresponse. Prevalence rates of the 2 outcomes were compared between participants with or without any screen-positive PD. The reference group for all analyses comprised participants screening negative for any PD. Odds ratios (ORs) were calculated and adjusted for age (in years) and sex in logistic regression models. Further logistic regression analyses were carried out to investigate potential mediating/confounding effects of social class, hypertension, diabetes, smoking and alcohol status, and comorbid personality disorder. In order to investigate the associations with PD trait counts, dimensional analyses were carried out as a secondary procedure. Quartiles of PD traits were generated for the overall PD trait score and also for cluster A, B, and C trait scores. Age- and sex-adjusted ORs were calculated using the group of participants in the lowest quartile of trait score as the reference group. Finally, a confirmatory secondary analysis was carried out using data from the 623 people who were clinically assessed for PD.

RESULTS

Characteristics of the Study Sample

The mean age of the sample was 42.6 (SE = 0.2) years, and 50% of the sample was male. Previous stroke was reported by 0.6%, ischemic heart disease by 2.0%, hypertension by 4.1%, and diabetes by 2.6% of the sample. Reported ischemic heart disease was significantly associated with increased age (p < .001), male sex (p < .001), lower social class (p = .009), reported hypertension (p < .001), diabetes (p < .001), and previous smoking status (p = .012). Ischemic heart disease was negatively associated with AUDIT score (p = .029). Reported stroke was sig-

nificantly associated with increased age (p < .001) and diabetes (p = .006) but not with other variables.

Data on personality disorder were available for 8399 participants (98%). Of these, 2462 screened positive for any PD (weighted prevalence of 28.7%). The most common subcategories of personality disorder were schizoid, obsessive-compulsive, and paranoid. Histrionic and narcissistic PDs were too rare to allow further analysis as independent variables. Those screening positive for PD were younger than the remainder (mean difference of 0.9 years) and were more likely to be male (54% compared with 48% of the remainder). Participants screening positive were also more likely to be current smokers (37% compared with 27% of the remainder) and to have a high (> 7) AUDIT score (30% compared with 25% of the remainder).

The overall weighted prevalence of screen-positive DSM-IV personality disorders and the associations with vascular outcomes (adjusted for age and sex) are summarized in Table 1.

Previous stroke was reported approximately twice as frequently by participants with any PD than by the remainder and, after adjustment for age and sex, was significantly associated with all subcategories except dependent and schizotypal PD. Ischemic heart disease was reported approximately 50% more frequently by participants with any PD than by the remainder and was significantly associated, after adjustment for age and sex, with all subcategories except dependent, obsessive-compulsive, and antisocial PD (p < .05).

The results of further adjustment for potential mediating factors are displayed in Tables 2 and 3.

After adjusting for all other covariates, participants screening positive for any personality disorder were significantly more likely to report experiencing a stroke (OR = 1.9; 95% CI, 1.0 to 3.5) and ischemic heart disease (OR = 1.4; 95% CI, 1.0 to 1.9). No substantial mediating

Table 2. Adjusted Associations Between Personality Disorder (PD) and Reported Stroke[a]

PD Category	Model 1 [adjusted for age and sex], OR (95% CI)	Model 2 [model 1 + socioeconomic status], OR (95% CI)	Model 3 [model 2 + hypertension and diabetes], OR (95% CI)	Model 4 [model 3 + smoking and alcohol], OR (95% CI)	Model 5 [model 1 + comorbid PD], OR (95% CI)
Any PD	2.1 (1.2 to 3.8)	2.0 (1.9 to 3.6)	1.9 (1.1 to 3.6)	1.9 (1.0 to 3.5)	NA
Paranoid	3.1 (1.2 to 8.4)	2.7 (1.0 to 7.5)	2.7 (1.0 to 7.5)	2.6 (0.9 to 7.3)	1.3 (0.5 to 3.5)
Schizotypal	1.5 (0.2 to 11.2)	1.1 (0.1 to 8.7)	1.1 (0.1 to 8.9)	1.1 (0.1 to 8.2)	0.3 (0.02 to 3.9)
Schizoid	2.2 (1.1 to 4.5)	2.0 (0.9 to 4.4)	2.0 (0.9 to 4.3)	2.0 (0.9 to 4.3)	1.6 (0.8 to 3.3)
Borderline	13.8 (1.9 to 97.7)	10.2 (1.2 to 83.7)	10.1 (1.2 to 87.8)	8.5 (1.0 to 72.8)	4.6 (0.5 to 46.0)
Antisocial	4.6 (1.0 to 21.1)	4.1 (0.9 to 19.3)	4.0 (0.8 to 19.2)	3.8 (0.7 to 19.7)	1.9 (0.3 to 11.0)
Avoidant	5.1 (1.6 to 16.1)	4.1 (1.2 to 13.6)	4.0 (1.2 to 13.3)	4.0 (1.2 to 13.3)	2.7 (0.9 to 7.8)
Dependent	4.0 (0.5 to 32.1)	3.4 (0.4 to 28.5)	3.3 (0.4 to 28.2)	3.2 (0.4 to 28.6)	1.1 (0.1 to 9.0)
Obsessive-compulsive	2.7 (1.2 to 6.3)	2.9 (1.2 to 6.6)	2.9 (1.3 to 6.6)	2.9 (1.3 to 6.6)	2.0 (0.9 to 4.6)

[a]The reference group for all analyses is participants screening negative for any PD, with the exception of model 5, which allows for comorbidity of PD.
Abbreviations: NA = not applicable, OR = odds ratio.

Table 3. Adjusted Associations Between Personality Disorder (PD) and Reported Ischemic Heart Disease[a]

PD Category	Model 1 [adjusted for age and sex], OR (95% CI)	Model 2 [model 1 + socioeconomic status], OR (95% CI)	Model 3 [model 2 + hypertension and diabetes], OR (95% CI)	Model 4 [model 3 + smoking and alcohol], OR (95% CI)	Model 5 [model 1 + comorbid PD], OR (95% CI)
Any PD	1.5 (1.1 to 2.1)	1.4 (1.0 to 2.0)	1.4 (1.0 to 2.0)	1.4 (1.0 to 1.9)	NA
Paranoid	2.4 (1.2 to 4.7)	2.3 (1.2 to 4.6)	2.3 (1.2 to 4.5)	2.1 (1.0 to 4.3)	1.4 (0.6 to 3.3)
Schizotypal	4.3 (1.9 to 9.6)	4.2 (1.8 to 9.6)	4.1 (1.8 to 9.4)	3.6 (1.5 to 8.6)	2.2 (0.7 to 7.6)
Schizoid	1.7 (1.2 to 2.5)	1.7 (1.1 to 2.5)	1.7 (1.1 to 2.4)	1.6 (1.1 to 2.4)	1.6 (1.1 to 2.3)
Borderline	9.7 (3.0 to 31.8)	8.8 (2.7 to 29.4)	8.2 (2.6 to 25.8)	7.2 (2.1 to 24.3)	3.8 (1.0 to 15.0)
Antisocial	1.7 (0.7 to 4.5)	1.6 (0.6 to 4.4)	1.6 (0.6 to 4.3)	1.2 (0.4 to 3.8)	0.9 (0.3 to 2.4)
Avoidant	2.5 (1.3 to 4.8)	2.2 (1.1 to 4.5)	2.3 (1.1 to 4.7)	2.2 (1.1 to 4.5)	1.2 (0.5 to 3.0)
Dependent	2.6 (0.4 to 15.0)	2.6 (0.4 to 15.6)	2.6 (0.4 to 15.5)	2.5 (0.4 to 15.1)	1.3 (0.2 to 9.9)
Obsessive-compulsive	1.1 (0.7 to 1.7)	1.0 (0.6 to 1.6)	1.0 (0.6 to 1.6)	1.0 (0.6 to 1.6)	0.8 (0.5 to 1.3)

[a]The reference group for all analyses is participants screening negative for any PD, with the exception of model 5, which allows for comorbidity of PD.
Abbreviations: NA = not applicable, OR = odds ratio.

effects were observed, with little change in the strength of association of interest following successive adjustments. Stroke was significantly associated with avoidant, obsessive-compulsive, and borderline PD. Ischemic heart disease was significantly associated with avoidant, paranoid, schizotypal, schizoid, and borderline PD. After adjusting for the presence of comorbid categories of PD, no clear patterns of association emerged between single categories of PD and stroke. Nevertheless, ischemic heart disease remained significantly associated with both borderline and schizoid PD.

Associations between exposure to quartiles of PD traits and the cardiovascular outcomes are displayed in Table 4.

For stroke, compared with the lowest quartile group, the adjusted OR for any PD trait was 1.70 (95% CI, 0.69 to 4.15) for quartile 2, 1.76 (95% CI, 0.70 to 4.42) for quartile 3, and 3.52 (95% CI, 1.44 to 8.58) for quartile 4. For ischemic heart disease, compared with the lowest quartile group, the adjusted OR for any PD trait was 1.26 (95% CI, 0.78 to 2.03) for quartile 2, 1.22 (95% CI, 0.76 to 1.97) for quartile 3, and 2.45 (95% CI, 1.64 to 3.67) for quartile 4. The per-quartile ORs represent the mean

increase in risk of cardiovascular outcomes across all 4 quartiles of PD traits. For both stroke and ischemic heart disease, there was a significant gradient of risk of cardiovascular disease associated with the degree of exposure to PD traits. For clusters A, B, and C, the per-quartile ORs for stroke and ischemic heart disease were all significant and of a similar magnitude.

In a secondary analysis of the 623 people assessed clinically for PD, stroke was reported by 1 of the 63 participants with any PD compared with 4 of the 560 participants with no PD (unweighted OR = 2.2). Ischemic heart disease was reported by 2 of the participants with any PD compared with 11 participants with no PD (unweighted OR = 1.6).

DISCUSSION

In this analysis of a large national dataset, people screening positive for personality disorder were more likely to report stroke or ischemic heart disease. Adjusting for established cardiovascular risk factors resulted in little attenuation of these associations. Dimensional analyses revealed that there was a significant gradient

Table 4. Adjusted Associations Between Quartiles of Personality Disorder (PD) Traits and Stroke and Ischemic Heart Disease

PD Type	Stroke, OR[a,b] (95% CI)	Ischemic Heart Disease, OR[a,b] (95% CI)
Any PD		
2nd quartile	1.70 (0.69 to 4.15)	1.26 (0.78 to 2.03)
3rd quartile	1.76 (0.70 to 4.42)	1.22 (0.76 to 1.97)
4th quartile	3.52 (1.44 to 8.58)	2.45 (1.64 to 3.67)
Per quartile	1.47 (1.11 to 1.93)	1.31 (1.14 to 1.51)
Cluster A		
2nd quartile	1.36 (0.64 to 2.92)	1.09 (0.72 to 1.65)
3rd quartile	2.53 (1.18 to 5.39)	1.42 (0.93 to 2.17)
4th quartile	2.0 (0.86 to 4.65)	2.24 (1.48 to 3.38)
Per quartile	1.31 (1.04 to 1.67)	1.31 (1.14 to 1.49)
Cluster B		
2nd quartile	1.79 (0.77 to 4.17)	1.23 (0.80 to 1.89)
3rd quartile	1.85 (0.83 to 4.11)	1.31 (0.87 to 1.97)
4th quartile	3.53 (1.62 to 7.68)	1.68 (0.99 to 2.87)
Per quartile	1.45 (1.13 to 1.86)	1.17 (1.0 to 1.37)
Cluster C		
2nd quartile	1.75 (0.74 to 4.18)	1.19 (0.77 to 1.84)
3rd quartile	1.66 (0.71 to 3.88)	1.25 (0.78 to 2.01)
4th quartile	2.47 (1.01 to 6.02)	2.17 (1.50 to 3.14)
Per quartile	1.30 (1.0 to 1.70)	1.28 (1.13 to 1.45)

[a]All ORs are adjusted for age and sex.
[b]The reference group for all analyses is participants who are within the first quartile of PD symptoms. The per quartile ORs represent the average increase in risk of cardiovascular outcomes across all 4 quartiles of PD symptoms.
Abbreviation: OR = odds ratio.

of risk of cardiovascular disease associated with the degree of exposure to PD traits. To the best of our knowledge, this is the first time that such findings have been reported.

Methodological issues need to be considered. The SCID-II questionnaire is not a diagnostic instrument for personality disorder and requires a second-stage interview in order to improve the likelihood of detecting cases of PD. In addition, PD questionnaires are susceptible to reporting bias,[24] and physically unwell participants may have been more likely to report personality pathology, leading to differential misclassification of PD. These limitations notwithstanding, self-report questionnaires have been used in other community surveys of PD[11] and our use of a brief questionnaire made it possible for us to gather personality data on a large sample of participants. Furthermore, the findings from the smaller sample assessed with the SCID-II interview showed very similar strengths of association between any PD and both stroke and ischemic heart disease, thereby adding weight to the validity of our findings. Use of categorical cutoffs with the SCID-II questionnaire is potentially problematic, given the increasing recognition that PD interviews often fail to make useful categorical distinctions between PD subtypes.[25] However, dimensional analyses using PD trait counts showed that across all 3 clusters of PD, there was a gradient of risk of cardiovascular disease associated with the degree of exposure to PD traits, i.e., a dose-response rela-

tionship. Causality cannot be inferred on the basis of these findings alone. However, we believe that this additional finding lends support to the validity of the findings obtained from our categorical analyses. Cardiovascular outcomes were derived from self-report measures, and it is possible that the associations were explained by symptom attribution rather than underlying disease.[26] Our findings therefore require further confirmation through the use of objective measures of cardiovascular disease. Finally, although the personality variables measured in this study predicted cardiovascular disease, we did not measure constructs that might be relevant to the mechanism underlying the detected associations, such as hostility or negative affectivity. (See below.)

We found little evidence of substantial mediating effects, since there was little change in either association of interest after adjustment for the factors considered in Tables 2 and 3. A deprived social background is a particularly important potential confounding or mediating factor, given its association with both personality disorder[27] and cardiovascular disease.[28] However, adjustment for socioeconomic status did not substantially weaken the associations of interest. The associations also remained relatively robust after adjustment for important potential vascular risk factors such as smoking, alcoholism, hypertension, and diabetes. These associations, however, require further confirmation, since blood pressure and glucose tolerance were not directly measured. There were also no data on diet or exercise levels and no measurements of obesity or lipid levels, which also require further investigation to clarify potential causal pathways underlying the observed associations. Depression is associated with both personality disorder[29,30] and coronary heart disease.[31] However, the role of affective symptoms in mediating associations between personality and health is potentially complex, since the 3 factors may have close interrelationships across the life course. It should also be borne in mind that, while dysfunctional personality traits may predispose to cardiovascular disease, the onset of cardiovascular disease may itself lead to changes in personality structure and function.

We hypothesized that borderline PD would be most strongly associated with cardiovascular disease. Although we detected an independent association between this disorder and cardiovascular disease, the association was nonspecific, and other PD types were also associated with cardiovascular disease (notably schizoid PD with ischemic heart disease). The nonspecificity of associations was also borne out by the dimensional analyses and suggests that people with PD traits may share an underlying psychological characteristic that renders them vulnerable to cardiovascular disease. Potential candidates for this underlying characteristic include negative affectivity,[32] affective instability,[33] and hostility.[34] Future research is required to clarify whether these factors have a role to play

in mediating the association between PD subtypes and cardiovascular disease.

CONCLUSION

Both society and individual sufferers feel the burden of personality disorders. However, in recent years, attention has focused on the risk that people with personality disorders pose to others.[35] Our findings highlight the fact that people with personality disorders are themselves at risk for experiencing serious physical health problems. Moreover, our findings suggest that they constitute a group of people who might particularly benefit from targeting with primary prevention strategies for cardiovascular disease. Clearly, our findings need to be replicated and further investigated, both through cross-sectional studies using more invasive measures of cardiovascular status and also through prospective studies of mortality and cardiovascular outcomes.

Disclosure of off-label usage: The authors have determined that, to the best of their knowledge, no investigational information about pharmaceutical agents that is outside U.S. Food and Drug Administration–approved labeling has been presented in this article.

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