Comparison of the Seattle Angina Questionnaire With Daily Angina Diary in the TERISA Clinical Trial

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Background—As new techniques emerge to quantify patients’ health status, new opportunities are created to validate patient-reported outcome questionnaires. The Seattle Angina Questionnaire (SAQ), a widely used coronary artery disease–specific health status tool, has not been validated against daily records of angina frequency and sublingual nitroglycerin (SL NTG) use. Additional evidence supporting the validity of the SAQ could justify its broader use as an outcome for clinical studies designed to evaluate treatments that may improve patients’ symptoms, function, and quality of life.

Methods and Results—We used data from 917 patients with type 2 diabetes mellitus, coronary artery disease, and stable angina from the multinational Type 2 Diabetes Evaluation of Ranolazine in Subjects With Chronic Stable Angina (TERISA) trial. The number of angina episodes and SL NTG used were recorded and transmitted daily using an electronic diary. In cross-sectional analyses, there was a strong relationship between the 2 SAQ angina frequency questions (ie, frequency of angina and SL NTG use) and the corresponding diary responses, with correlation coefficients of −0.64 for angina frequency (95% confidence interval, −0.68 to −0.60) and −0.69 for SL NTG use (95% confidence interval, −0.73 to −0.66). Longitudinally, changes in SAQ angina frequency scores from day 1 to week 8 also correlated with changes in angina frequency (−0.42; 95% confidence interval, −0.48 to −0.30) and SL NTG use by diary (−0.38; 95% confidence interval, −0.43 to −0.32) over the corresponding time period. Correlations were similar when stratified by age, sex, or geography.

Conclusions—In a multinational cohort of patients with stable angina, the SAQ angina frequency domain was significantly correlated, both cross-sectionally and longitudinally, with daily diary entries of angina frequency and SL NTG use. These data further support the validity of the SAQ angina frequency domain across a broad spectrum of patients with stable angina.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT01425359.

(Circ Cardiovasc Qual Outcomes. 2014;7:844-850.)

Key Words: health status ■ chronic stable angina ■ coronary artery disease

Angina, as a manifestation of ischemic heart disease, is a highly relevant clinical condition that affects ≈20% of patients 1 year after a myocardial infarction,1 ≈25% to 30% of patients 1 year after bypass graft surgery or multivessel stenting,2 and ≈45% of patients with stable ischemic heart disease.3 Beyond the direct morbidity of the symptoms experienced by the patient, angina is associated with worse health-related quality of life and is a major driver of repeat hospitalizations and increased healthcare costs.4 As a result, there have been numerous trials of different therapies to reduce angina,5-12 with the aim of simultaneously reducing its associated morbidity and costs. In designing such trials, the accurate quantification of the frequency and severity of angina among patients with ischemic heart disease is critical for comparing treatment efficacy. Moreover, health status (symptoms, function, and quality of life) has been endorsed as an outcome-based performance measure to assess health-care quality in patients with ischemic heart disease.13 The gold standard for measuring angina frequency in clinical trials is considered to be either daily records of angina frequency and sublingual nitroglycerin (SL NTG) use. Additional evidence supporting the validity of the SAQ could justify its broader use as an outcome for clinical studies designed to evaluate treatments that may improve patients’ symptoms, function, and quality of life.

The Seattle Angina Questionnaire (SAQ) is a self-administered, disease-specific health status questionnaire that measures clinically important dimensions of health in patients with ischemic heart disease, as a manifestation of ischemic heart disease, is a highly relevant clinical condition that affects ≈20% of patients 1 year after a myocardial infarction, 1 ≈25% to 30% of patients 1 year after bypass graft surgery or multivessel stenting,2 and ≈45% of patients with stable ischemic heart disease.3 Beyond the direct morbidity of the symptoms experienced by the patient, angina is associated with worse health-related quality of life and is a major driver of repeat hospitalizations and increased healthcare costs.4 As a result, there have been numerous trials of different therapies to reduce angina,5-12 with the aim of simultaneously reducing its associated morbidity and costs. In designing such trials, the accurate quantification of the frequency and severity of angina among patients with ischemic heart disease is critical for comparing treatment efficacy. Moreover, health status (symptoms, function, and quality of life) has been endorsed as an outcome-based performance measure to assess health-care quality in patients with ischemic heart disease.13 The gold standard for measuring angina frequency in clinical trials is considered to be either daily records of angina frequency and sublingual nitroglycerin (SL NTG) use. Additional evidence supporting the validity of the SAQ could justify its broader use as an outcome for clinical studies designed to evaluate treatments that may improve patients’ symptoms, function, and quality of life.
WHAT IS KNOWN

• The Seattle Angina Questionnaire is widely used to measure disease-specific health status among patients with coronary artery disease, but it has not been validated against daily records of angina frequency and sublingual nitroglycerin, the putative gold standard for measuring angina over time.

WHAT THE STUDY ADDS

• Using data from 917 patients with stable angina from the multinational Type 2 Diabetes Evaluation of Ranolazine in Subjects With Chronic Stable Angina (TERISA) trial, we found that the Seattle Angina Questionnaire angina frequency scale was significantly correlated with daily diary entries on angina and sublingual nitroglycerin both cross sectionally and longitudinally (ie, comparing change in one measure versus change in the other)—correlations that were generally consistent by age, sex, and geographic region.

• Furthermore, we found that the Seattle Angina Questionnaire was most strongly correlated with diary entry using a 4-week recall, compared with shorter time periods, which provides empirical support that a 4-week recall period is reasonable for the patient-reported outcome of angina.

• These data support the validity of the Seattle Angina Questionnaire angina frequency domain, which is more practical to administer than a daily diary, and its continued use as a clinically relevant outcome for clinical trials of therapies that are designed to reduce angina and improve quality of life, as well as its use in clinical care and quality assessment.

with ischemic heart disease. The SAQ angina frequency domain (SAQ AF) is designed to quantify explicitly the frequency of angina over the prior 4 weeks and has been used in several studies as a secondary end point to quantify the long-term impact of alternative treatment strategies for ischemic heart disease. It was initially validated by comparing SAQ AF scores of stable angina patients with prescription refills for sublingual nitroglycerin (SL NTG), but it has not been validated against daily diaries of angina frequency or SL NTG use. As such, we sought to use data from the international multicenter Type 2 Diabetes Evaluation of Ranolazine in Subjects With Chronic Stable Angina (TERISA) clinical trial, which collected both SAQ and daily angina diary data, to validate further the SAQ. Notably, TERISA used an electronic diary and had high compliance with daily data entry, making it ideal for a comparison against the SAQ. Additional validation of the SAQ as an accurate assessment of angina burden in patients with ischemic heart disease could further justify its broader use as an outcome for clinical trials evaluating treatments designed to improve patients’ symptoms and quality of life.

Methods

Study Overview

The study design and population, treatment protocol, follow-up procedures, and study end points of TERISA have been described previously. TERISA was a randomized, double-blind, placebo-controlled trial in which subjects with stable angina and type 2 diabetes mellitus (T2DM) were randomized to a 1000 mg twice daily dose of ranolazine or matched placebo for 8 weeks. Subjects were required to have both a documented history of T2DM and coronary artery disease and also required at least a 3-month history of chronic stable angina.

Furthermore, subjects had to be treated with 1 or 2 antianginal therapies (β-blockers, calcium channel blockers, long-acting nitrates) at a stable dose for ≥2 weeks before study entry. Key exclusion criteria were New York Heart Association class III to IV heart failure symptoms, acute coronary syndrome in the 2 months before screening, planned coronary revascularization during the study period, and prior treatment with ranolazine.

Eligible subjects entered a 4-week, single-blind placebo run-in period to ensure compliance with diary entry and study medication (weeks −4 to day 1; Figure 1). Subjects taking >2 antianginal medications at screening were allowed to washout any additional antianginal therapies 2 weeks before the run-in period (weeks −6 to −4). After the run-in period, subjects were randomized to ranolazine (Gilead Sciences, Foster City, CA) or matching placebo for 8 weeks (day 1 to week 8). By protocol, concomitant antianginal medications were kept stable during the study. The study was conducted in 104 sites in 14 countries across Asia, Europe, and North America and was approved by the national regulatory authority in each participating country and by the institutional review board or local ethics committee for each site. All participating subjects provided written informed consent.

Outcome Assessment

Subjects were given a novel electronic diary (LogPad LV diary, PHT Corporation, Boston, MA) with built-in electronic prompts for daily entry. During both the placebo run-in period and the active treatment period, subjects were instructed to record and transmit the data to the coordinating center every evening, including the number of angina episodes and number of SL NTG doses taken in the past 24 hours.

Disease-specific health status was assessed with the SAQ at randomization (ie, after the run-in period; day 1) and at 8 weeks after study drug initiation or at study termination (in the case of patient withdrawal from the study). The SAQ is a 19-item questionnaire that measures 5 clinically important dimensions of health in patients with coronary artery disease: angina frequency, angina stability, physical limitations, treatment satisfaction, and disease-specific quality of life.

Figure 1. Timeline of outcomes assessment in Type 2 Diabetes Evaluation of Ranolazine in Subjects With Chronic Stable Angina (TERISA) study. SAQ indicates Seattle Angina Questionnaire; and SL NTG, sublingual nitroglycerin.
life. Each domain has a score ranging from 0 to 100, with higher scores indicating less disease burden, and has a recall of 4 weeks. For this analysis, we focused on the SAQ AF scale, which is comprised of 2 questions that quantify the frequency of angina: (1) “over the past 4 weeks, on average, how many times have you had chest pain, chest tightness, or angina?” and (2) “over the past 4 weeks, on average, how many times have you had to take nitros (nitroglycerin tablets) for your chest pain, chest tightness, or angina?” Options for answers to both questions were ≥4 times per day, 1 to 3 times per day, ≥3 times per week but not every day, 1 to 2 times per week, less than once a week, and none over the past 4 weeks. Because TERISA was a multinational trial, country-specific translations were used. The SAQ has undergone a rigorous translation process into >50 languages, to be culturally and linguistically appropriate, according to the methodology and processes of the Mapi Research Institute (http://www.mapi-research.it/index.htm). This process included independent forward and backward translations, input from the instrument developer, reconciliation, and review of the SAQ translations by clinicians and patients within each country before their use. Details on the translation process for the SAQ are available at http://www.cvoutcomes.org/faqs/303043174.

Statistical Analysis
The prespecified efficacy analyses for TERISA included all randomized subjects who took ≥14 days of study drug, completed ≥1 diary entry, and met all major eligibility criteria. For this analysis, we further limited the data set to patients who had ≥4 weeks of diary entry that could be compared with SAQ AF scores (which have a 4-week recall). A total of 10 additional patients were excluded from the analytic cohort of the main TERISA study for missing SAQ scores. No patients were excluded for missing anginal diaries. For the cross-sectional analysis, we first compared categories of response to the 2 SAQ AF questions at study end to the arithmetic mean diary entry for the corresponding daily diary entry over the previous 4 weeks (SAQ AF at study end versus diary from weeks 5–8; Figure 1; ie, we compared the responses to the individual SAQ AF question about the frequency of angina with the average diary responses of the frequency of angina over a 4 week period; with a similar analysis comparing the SAQ AF question about SL NTG use with diary data on SL NTG use). We then examined the distribution of diary response by SAQ AF category of response (eg, ≥4 times per day and 1–3 times per day) using box plots and calculated a Spearman correlation statistic with 95% confidence intervals (CIs). We also examined the correlations of the SAQ AF domain score with the 2 diary responses. As the SAQ is designed to integrate angina burden over the preceding 4 weeks, there may be recall bias, where patients more heavily weight their most recent experience. To examine this issue, we also compared the SAQ responses with the average weekly angina and SL NTG used over the preceding 4 weeks, 3 weeks, 2 weeks, or 1 week. We did this both at randomization (when angina was relatively stable over the preceding 4 weeks) and at study end (when angina was changing over the preceding 4 weeks because of antianginal treatment). Finding a stronger correlation between the SAQ and the 4-week angina diaries would provide empirical support that patients can accurately integrate their experience with angina over a longer time period.

For the longitudinal analysis, we examined the correlations between the change in SAQ AF domain scores from randomization to 8 weeks with the change in average diary responses over the corresponding time period. The SAQ has a recall period of 4 weeks, thus the SAQ at day 1=diary from weeks −4 to day 1 and SAQ at week 8=diary from weeks 5 to 8. As such, we compared (1) changes in SAQ AF at week 8−diary 1 versus (2) changes in average diary from (weeks 5–8) to (weeks −4 to day 1). Finally, we examined the correlations between SAQ AF and diary responses (both cross-sectionally and longitudinally) stratified by age (<65 versus ≥65), sex (male versus female), geographic region (Russia, Ukraine, and Belarus versus Other), and randomized treatment (longitudinal analysis only).

All analyses were conducted using SAS v9.2 (SAS Institute, Inc., Cary, NC), and statistical significance was determined by a 2-sided P<0.05. TERISA was sponsored by Gilead Sciences, Foster City, CA, which did not conduct the analyses or decide on its publication.

Results

Patient Population
Of the 949 randomized subjects in TERISA, 917 (97%) had complete diary and SAQ data and were included in our analyses. There were no significant differences in patient characteristics between those who were included and excluded from the analysis. Participants’ demographic and clinical characteristics are shown in Table 1. Overall, the mean age of the patients was 64±9 years, 61% were male, and 74% had experienced a prior myocardial infarction. Most of the patients were enrolled from Russia, Ukraine, or Belarus, with 29% of subjects enrolled from other counties. The mean daily compliance with diary entry was 96%.

Cross-Sectional Comparison
Over the final 4 weeks of the study (week 5–8), subjects reported having an average of 4.7±4.6 episodes of angina (range=0.0–38.4) per week and reported using an average of 3.1±4.9 SL NTG (range=0.0–50.0) per week. At the time of randomization (day 1), the mean SAQ AF score was 59.8±20.9. The distributions of diary responses for the frequency of angina and SL NTG use over the final 4 weeks of the study for the different categories of response to the corresponding SAQ AF questions are shown in Table 2 and Figure 2 (agreement of SAQ AF responses with mean diary responses is shown in Table 1).
Compared with the theoretical range of daily diary responses expected to correlate with the Likert item responses of the SAQ (eg, reporting, on average, angina 1–3 times/week would be expected to correlate with a monthly report of 7–21 episodes of angina/week on the daily diary), the means and medians were close to the anticipated ranges. Overall, the SAQ AF responses corresponded to the diary responses, with correlation coefficients \((r)\) of \(-0.64\) for angina frequency (95% CI, \(-0.67\) to \(-0.60\)) and \(-0.69\) for SL NTG use (95% CI, \(-0.73\) to \(-0.66\); Table 3). However, at both extreme ends of angina, there was less agreement. For example, among patients reporting no angina on the SAQ, a few episodes of angina were reported on the daily diaries. Specifically, patients who reported no angina (or no SL NTG taken) on the SAQ over the prior 4 weeks reported an average of 1.3 angina episodes per week (or 0.9 SL NTG taken per week), although the median responses were closer to those anticipated (1.0 episode of angina per week and 0.0 doses of SL NTG taken per week). In addition, patients who reported \(\geq 4\) angina episodes (or SL NTG taken) per day on the SAQ reported an average of 20.7 episodes of angina per week (or 26.6 SL NTG taken per week), which is somewhat less than the diary numbers anticipated.

The correlations between the SAQ AF responses and the corresponding diary entry were similar by age, sex, and geographic region (Table 3). Finally, the overall SAQ AF domain score was also significantly correlated with diary responses, with correlation coefficients of \(-0.61\) for angina frequency and \(-0.64\) for SL NTG use (\(P<0.0001\) for both). The correlations of the SAQ AF responses with the corresponding diary entry over different recall periods are shown in Table II in the Data Supplement. Both when angina was relatively stable (during placebo run-in period) and when angina was less stable (during antianginal treatment), the correlations between the SAQ AF responses and diary entries were strongest using the 4-week recall period and decreased slightly as the recall period shortened with the weakest correlation being observed with average daily angina diaries over the prior week.

### Longitudinal Comparison

Between randomization and study end (day 1 to week 8), SAQ AF scores increased by an average of 13.5±18.5 points. In the diaries, subjects reported an average of 2.2±3.7 fewer episodes of angina per week over the corresponding time. In addition, they reported using an average of 1.3±3.7 fewer SL NTG per week. The mean change in diary responses of the patients catorgized by their change in SAQ AF scores is shown in Figure 3. Changes in SAQ AF scores were significantly associated with changes in diary responses, with correlation coefficients of \(-0.42\) for angina frequency (95% CI, \(-0.48\) to \(-0.37\)) and \(-0.38\) for SL NTG use (95% CI,
Medical and interventional therapies for ischemic heart disease are designed to either improve survival, quality of life, or both. Clinical trials investigating the effectiveness of therapies that might improve survival use outcomes such as mortality or other surrogate outcomes that are expected to be along the pathway of mortality, such as myocardial infarction. Trials designed to investigate the effectiveness of therapies that improve the quality of life of patients with ischemic heart disease rely on patient-reported outcomes. Although many trials of antianginal medications have relied on treadmill testing or ambulatory ECG monitoring to measure efficacy (by reducing ECG-documented ischemia), these assessments are not necessarily clinically meaningful from the perspective of either the patient or the treating physician. In contrast, patients’ experiences of symptomatic angina are clearly meaningful to both patients and their physicians, given that symptom eradication is a primary goal of therapy.22

Although it is technically feasible to measure the burden of angina and the impact of treatments on this burden using either paper or electronic diaries that capture angina frequency on a daily basis, these methods have important limitations. Studies using traditional paper diaries can be limited by inappropriate input of multiple entries in a single sitting (ie, hoarding) and low subject compliance.23 Daily electronic diaries are more reliable, because they prevent hoarding, and have been shown to be feasible across many countries with observed compliance rates as high as 96% (as it was for TERISA).21 However, this can be costly because each patient must be provided with an electronic device and data must be handled by an external vendor (eg, the total cost of the electronic diaries in TERISA was $910,879) and is impractical for quality assessment purposes in routine clinical care. Moreover, forgetting to report one’s experiences for a day or more results in missing data, which can be particularly important if the reason that the entry was missed was associated with patients’ symptoms (eg, patients being more likely to complete the diaries on days that they experience angina). Although compliance with daily diary entries in TERISA was high, it is important to note that the run-in period was designed to select patients who were compliant, and the duration of monitoring was short. Furthermore, the patients knew that they were in a clinical trial that relied on these measures and had close monitoring.

Table 3. Correlations Between SAQ Angina Frequency Responses and the Corresponding Diary Entry

<table>
<thead>
<tr>
<th>Age</th>
<th>Angina</th>
<th>SL NTG</th>
<th>Longitudinal</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>−0.64 (−0.67 to −0.60)</td>
<td>−0.69 (−0.73 to −0.66)</td>
<td>−0.42 (−0.48 to −0.37)</td>
</tr>
<tr>
<td>Age ≤65 y</td>
<td>−0.64 (−0.68 to −0.58)</td>
<td>−0.69 (−0.73 to −0.64)</td>
<td>−0.42 (−0.49 to −0.35)</td>
</tr>
<tr>
<td>Male</td>
<td>−0.66 (−0.72 to −0.60)</td>
<td>−0.73 (−0.78 to −0.68)</td>
<td>−0.47 (−0.54 to −0.38)</td>
</tr>
<tr>
<td>Russia/Ukraine/Belarus</td>
<td>−0.62 (−0.67 to −0.57)</td>
<td>−0.67 (−0.71 to −0.62)</td>
<td>−0.39 (−0.46 to −0.32)</td>
</tr>
<tr>
<td>Other countries</td>
<td>−0.69 (−0.75 to −0.62)</td>
<td>−0.73 (−0.78 to −0.66)</td>
<td>−0.43 (−0.52 to −0.32)</td>
</tr>
</tbody>
</table>

−0.43 to −0.32). Although there was a consistent stepwise relationship between the change reported on the SAQ and the change reported in the diary, some minor discrepancies were observed. For example, among the patients whose SAQ scores did not change, the diary suggested a slight decrease in angina of 1.2 fewer episodes and 0.7 fewer SL NTG used per week. The correlations between change in SAQ AF scores and change in diary entries were similar by age, sex, geographic region, and treatment (Table 3).

Discussion

In a multinational cohort of patients with stable angina, SAQ AF scores were significantly correlated cross sectionally, both as individual questions and as an overall domain score, with daily diary entry of angina frequency and SL NTG use. These correlations were consistent regardless of age, sex, or geographic region. Longitudinally, changes in SAQ AF scores were also correlated with changes in diary angina frequency and SL NTG use in the overall population. These findings further support the use of the SAQ as an outcome in clinical care, in registries, and in clinical trials of treatments that are designed to assess cardiac patients’ angina symptoms.

Figure 3. Comparison of changes in Seattle Angina Questionnaire angina frequency (SAQ AF) scores from day 1 to week 8 with changes in average weekly angina and sublingual nitroglycerin (SL NTG) use by diary entry over the corresponding time period. Each bar represents the mean change in weekly angina (or NTG) reported in the diary for the patients who reported different changes in the SAQ AF over the same time frame.
and encouragement from the sites. Given their ease of use, questionnaires, such as the SAQ, can be particularly useful for evaluating the burden of angina. Given the findings of this study, we think that the SAQ is a reliable substitute for angina diaries, particularly in long-term studies, or clinical practice, where diaries are less feasible.

One potential limitation to the SAQ is the decreased precision compared with diary reports. Because the SAQ asks about an average during the past 4 weeks, each response item is associated with a potential range of diary results. For example, if a patient responds that they have had chest pain ≥3 times a week but not every day, this would correspond to a diary range of anywhere from 3 to 6 episodes of angina per week. As such, a difference of 3 versus 4 episodes/week may not be detected in the SAQ (eg, when a treatment has a modest effect on angina) but could be detected with an angina diary. There is also a possibility of a floor effect among the few patients who have exceedingly frequent angina. For example, a patient having 20 episodes of angina/d whose angina is reduced by half to 10 episodes/d would be expected to have SAQ score of 0 at both time points, indicating ≥4 episodes/d. In these circumstances, diary data may be more useful to more accurately quantify patients’ angina frequency.

Another important observation from this study is the empirical evidence that patient can, in fact, use a 4-week recall period to assess their angina. The Food and Drug Administration Study Endpoints and Labeling Development (FDA SEALD) group has taken the position that patients are unable to recall accurately their health status over time and that daily assessments are much more accurate in assessing the impact of a new treatment than a questionnaire that has a 4-week (or even a 1-week) recall period. The issue on recall bias is particularly important with an episodic symptom, such as angina. Patients may get angina only when they exert themselves to a level where their myocardial oxygen demand exceeds their supply but may not do that level of exertion every day. It is common in clinical practice for a patient to say “I’ve had no chest pain this week, but 2 weeks ago I had it 3 times.” To address this, the SAQ was constructed with a 4-week recall period so that patients could average or integrate their symptoms over the past month to provide a more accurate assessment of their recent symptom burden. The TERISA study provided a unique opportunity to compare directly a daily angina diary with the SAQ’s 4-week recall period. Finding the strongest correlations with the daily diary averages over 4 weeks (Table II in the Data Supplement) provides empirical support that a 4-week recall period is reasonable for a patient-reported outcome of angina.

Our study should be viewed in light of the following potential limitations. First, the TERISA trial included only angina patients with T2DM. However, there is no a priori reason to expect that patients with T2DM would answer the SAQ questions or diaries in a manner different than patients without T2DM. Second, although the TERISA trial was multinational and there were minimal differences in the correlations of the SAQ with diary data across geographic regions, a minority of patients were enrolled from the United States. Third, it is possible that by having the patients record their angina in a daily diary made them more aware of their burden of angina and consequently increased the accuracy of the SAQ. Finally, we did not examine the other domains of the SAQ because we did not have diary data that corresponded to those domains of health status.

In conclusion, using a large, multinational cohort of patients with T2DM and stable angina, we found that the SAQ AF domain was significantly correlated both cross sectionally and longitudinally with daily diary entry of angina frequency and SL NTG use. These results were consistent regardless of age, sex, or geographic region. These data further support the validity of the SAQ AF domain and should support its continued use as a clinically relevant outcome for clinical trials of therapies that are designed to reduce angina and improve quality of life. Because of the ease of administration, compared with diaries, the SAQ is particularly well suited for studies with longer time frames of analysis, clinical care, and quality assessment/improvement efforts.

Sources of Funding
The Type 2 Diabetes Evaluation of Ranolazine in Subjects With Chronic Stable Angina (TERISA) trial was sponsored by Gilead Sciences (Foster City, CA). Saint Luke’s Mid America Heart Institute received funding for the independent statistical analysis of the TERISA trial from Gilead Sciences. The funding agency did not play a role in the design and conduct of the study or in the decision to submit the article for publication.

Disclosures
Dr Kosiborod has received research support from Gilead Sciences, American Heart Association, Medtronic Minimed, Genentech, Sanofi-Aventis, Glumetrics, and Maquet; and is a consultant for Gilead Sciences, Genentech, F Hoffmann-La Roche, and Medtronic Minimed; and has served on the advisory board for Gilead Sciences. Drs Yue and Belardinelli are employees of and own stock and stock options in Gilead Sciences. Dr Spertus has received research support from Gilead Sciences, National Heart, Lung, and Blood Institute, American College of Cardiology Foundation, American Heart Association, Patient-Centered Outcomes Research Institute, Amorcyte, Genentech, and Eli Lilly; is a consultant for Gilead Sciences, Genentech, Amgen, and United Healthcare (Scientific Advisory Group); is a board member for Health Outcomes Sciences; and holds the copyrights for the Seattle Angina Questionnaire, Kansas City Cardiomyopathy Questionnaire, and Peripheral Artery Questionnaire. The other authors report no conflicts.

References


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*Circ Cardiovasc Qual Outcomes*. 2014;7:844-850; originally published online September 23, 2014;
doi: 10.1161/CIRCOUTCOMES.113.000752

*Circulation: Cardiovascular Quality and Outcomes* is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 1941-7705. Online ISSN: 1941-7713

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