

Health-Related Quality of Life Following Carotid Stenting Versus Endarterectomy

Results From the SAPHIRE (Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy) Trial

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Objectives This study compared health-related quality of life in patients undergoing carotid artery stenting (CAS) versus surgical endarterectomy (CEA).

Background Carotid artery stenting is approved in the U.S. for treating carotid stenosis in patients at high surgical risk. Whether CAS offers advantages in terms of other patient-centered outcomes is unknown.

Methods We evaluated health-related quality of life in the SAPHIRE (Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy) trial, which randomized 334 high-risk patients with carotid stenosis to CAS versus CEA. Health status assessments were obtained at baseline; 2 weeks; and 1, 6, and 12 months after revascularization. Generic measures included the Short-Form-36 (SF-36) (0 to 100 scale), general health rating, and EuroQol (EQ-5D). In addition, we used 6 disease-specific modified Likert scales to assess difficulty with walking, eating/swallowing, driving, headaches, neck pain, and leg pain.

Results In patients treated according to protocol (n = 159 CAS; n = 151 CEA), CAS patients had better scores at 2 weeks for the SF-36 role physical scale (mean difference: 9.0; 95% confidence interval: 0.9 to 17.1; p = 0.031), but these differences had resolved by 1-month follow-up. For the disease-specific scales, CAS patients reported less difficulty eating/swallowing at 2 weeks, less difficulty driving at 2 weeks, and less neck pain at 2 weeks; each of these differences between groups was no longer present at 1 month. No other scores differed between groups at any time point.

Conclusions Among patients at high surgical risk, CAS was associated with less health status impairment during the first 2 weeks of recovery when compared with CEA. However, these differences had resolved by 1 month after the procedure, and no other differences between revascularization strategies in health-related quality of life were found. (J Am Coll Cardiol Intv 2010;3:515–23)

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For decades, carotid endarterectomy (CEA) has been considered the standard of care to prevent stroke in patients with severe atherosclerotic carotid stenosis (1–3). However, many patients are considered poor candidates for CEA due to medical comorbidities or advanced age, and these individuals experience higher rates of adverse outcomes (4). Carotid artery stenting (CAS) recently has been developed as a less invasive option for revascularization and has been evaluated as an alternative strategy for patients at high risk of adverse outcomes with surgical CEA. In the SAPPHIRE (Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy) trial, the combination of CAS with an embolic protection device was demonstrated to be noninferior to CEA for the prevention of death, stroke, or myocardial infarction among patients at high risk of surgical complications (5). As a result of this study and others, CAS with embolic protection was approved by the U.S. Food and Drug Administration in 2004 for treatment of both symptomatic and asymptomatic carotid artery stenosis in patients at high surgical risk.

Abbreviations and Acronyms

CAS = carotid artery stenting

CEA = carotid endarterectomy

EQ-5D = EuroQol

HRQOL = health-related quality of life

SF-36 = Medical Outcomes Study Short-Form 36

However, subsequent evaluations of CAS have yielded conflicting results, with some studies demonstrating acceptable rates of safety and efficacy (6–9) and others finding worse outcomes in lower-risk patients when compared with CEA (10,11). In light of this variability between studies, other outcomes may better reflect relevant strengths and weaknesses of each revascularization strategy. In particular, by virtue of its less invasive nature, CAS may lead to

more rapid functional recovery compared with CEA, as well as improved health-related quality of life (HRQOL) after the procedure. To assess these possible benefits, we performed a prospective quality of life study as part of the SAPPHIRE trial.

Methods

Trial design. Details of the SAPPHIRE trial design and primary clinical outcomes have been described previously (5). In brief, adult patients with symptomatic carotid artery stenosis >50% or asymptomatic carotid stenosis >80% were eligible for enrollment at 29 centers if they were considered to be at high risk for complications from surgical CEA. Patients were randomly assigned in a 1:1 ratio to CAS or CEA. Carotid endarterectomy was performed according to standard techniques. Carotid artery stenting used a self-expanding nitinol stent (Smart or Precise, Cordis, Bridgewater, New Jersey) and an embolic protection device (Angioguard or Angioguard XP, Cordis). Approval

was obtained from the Human Studies Committee at each enrolling site.

Patient population and clinical results. In SAPPHIRE, 334 patients were randomized (167 to each treatment group). Eight CAS patients and 16 CEA patients were not treated as randomized due to deterioration of their clinical condition (3 CAS, 4 CEA), inability to meet the enrollment criteria (2 CAS, 4 CEA), or withdrawal of consent prior to treatment (3 CAS, 8 CEA). Because no HRQOL data were collected for patients who withdrew from the study, the present analysis compared quality of life in patients treated according to protocol ($n = 159$ receiving CAS, $n = 151$ receiving CEA). Subjects who died during the study were included in the analyses of HRQOL outcomes up until the time of death.

The clinical results of SAPPHIRE have been presented previously (5). In the overall trial, randomization to CAS with embolic protection was demonstrated to be noninferior to CEA (intention-to-treat analysis) for reducing the primary clinical end point (composite of death, stroke, or myocardial infarction within 30 days, and death or ipsilateral stroke between 31 and 365 days). There was a strong trend toward reduction of the primary end point with CAS (12.2% vs. 20.1%, $p = 0.053$) and fewer repeat carotid revascularizations at 1 year (0.6% vs. 4.3%, $p = 0.040$).

Measures of HRQOL. The HRQOL outcomes were assessed at baseline, 2 weeks, and during additional follow-up visits at 1, 6, and 12 months. These outcomes included 3 generic HRQOL measures and several disease-specific assessments.

The generic measures of health status evaluated in SAPPHIRE included patient-reported ratings of general health (0 to 100 scale, with higher score indicating better functioning), and 2 standardized measures of general health status: the Medical Outcomes Study Short-Form 36 (SF-36) (12) and the EuroQol (EQ-5D) (13). The SF-36 is a commonly used health survey that has been well validated in patients with cardiovascular disease, stroke, and in the general population (12,14–16). Only 4 of the 8 subscales of the SF-36 (physical functioning, physical role limitations, bodily pain, and vitality) were used in this study as they were expected to be most sensitive to differences between CAS and CEA in the post-intervention period. Scores on these scales range from 0 (worst) to 100 (best). The utility score from the EQ-5D incorporates 5 domains of health status (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) into a single value that reflects an individual's preference for his or her current health state relative to perfect health (17,18). Scores range from 0 (equivalent to death) to 1 (best possible health status); the EQ-5D also has been validated in multiple clinical scenarios including stroke (19–21).

In addition to these generic HRQOL instruments, 6 disease-specific modified Likert scales designed specifically for SAPPHIRE were used to evaluate aspects of functional

status and symptoms that may be influenced by 1 or both of the treatments. The first 3 questions assessed the level of difficulty each patient experienced with walking, eating/swallowing, and driving (1 = no difficulty at all, 2 = mild difficulty, 3 = moderate difficulty, 4 = severe difficulty, 5 = unable to perform this activity). The last 3 questions evaluated how often patients were bothered by headaches, neck pain, and leg pain during the previous week (1 = not at all bothered, 2 = bothered a little bit, 3 = moderately bothered, 4 = bothered quite a bit, 5 = extremely bothered).

Statistical analysis. Bivariate analysis of baseline characteristics was performed using chi square for categorical, *t* test for continuous, and appropriate nonparametric tests for variables without normal distribution. Follow-up health status scores and changes in scores from baseline were compared between CAS and CEA groups using analysis of covariance for continuous variables and ordinal logistic regression for categorical variables, adjusting for baseline scores. Multiple imputation was used to estimate missing HRQOL scores for surviving patients. Covariates used in the multiple imputation models included all of the available HRQOL scores, treatment assignment, and baseline clinical and demographic characteristics. Any *p* values ≤0.05 were considered statistically significant, and no adjustments were performed for multiple comparisons. All analyses were performed using SAS software version 9.1 (SAS Institute, Cary, North Carolina).

Results

Patient population and completeness of data. Baseline demographic and clinical characteristics for the HRQOL study population are summarized in Table 1. Mean age was 72 years, 68% were male, 26% had diabetes, and 86% had hypertension. The CAS patients had higher rates of prior coronary bypass surgery (43% vs. 32%, *p* = 0.04) and prior percutaneous coronary intervention (34% vs. 23%, *p* = 0.03), but all other baseline characteristics were similar between the 2 groups. Among surviving patients, overall response rates were >80% at all time points with the exception of 1-year follow-up, where response rates were 74% and 67% for the CAS and CEA groups, respectively (Fig. 1).

HRQOL results. Results of the generic quality-of-life analyses (based on both raw and multiply imputed data) are summarized in Table 2. At baseline, each of the HRQOL subscales was well matched for the 2 groups. When compared with subjects undergoing surgical revascularization, CAS patients reported better scores at 2 weeks for the SF-36 role physical scale (mean difference: 9.0, 95% confidence interval: 0.9 to 17.1, *p* = 0.031), but these differences were no longer apparent at 1-month follow-up. There were

Table 1. Baseline Characteristics of Patients Treated With CAS Versus CEA in the SAPHIRE Trial

	CAS (n = 159)	CEA (n = 151)	<i>p</i> Value
Demographics			
Age, yrs	72 ± 8	72 ± 9	0.90
Male sex	68	68	0.94
Medical history			
Diabetes mellitus	26	27	0.86
Hypertension	86	85	0.87
Current smoker	16	17	0.92
Prior myocardial infarction	30	35	0.36
Prior coronary bypass surgery	43	32	0.04
Prior percutaneous coronary intervention	34	23	0.03
Heart failure	18	18	0.99
Chronic obstructive lung disease	18	13	0.21
Cerebrovascular history			
Symptomatic carotid disease	30	28	0.74
Prior stroke	27	24	0.54
Prior CEA	29	24	0.31

Data are presented as mean ± SD or %.
CAS = carotid artery stenting; CEA = carotid endarterectomy; SAPHIRE = Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy.

no significant differences for any of the other generic health status scales between the CAS and CEA groups at 2 weeks or at any other time points (Fig. 2). Findings were similar when multiple imputation was used to account for missing follow-up data.

Results of the disease-specific modified Likert scales are summarized in Figures 3 and 4. At 2 weeks, CAS patients reported less difficulty eating or swallowing (Fig. 3A), less difficulty driving (Fig. 3C), and less neck pain (Fig. 4B). However, all of these differences had resolved by the 1-month follow-up assessment. There were no significant differences for any of the other disease-specific scales (difficulty walking, headaches, or leg pain) at 2 weeks or any other follow-up time point.

Discussion

Although carotid stenting was developed more than 10 years ago as a less invasive form of revascularization for patients with carotid artery stenosis, to our knowledge no previous studies have directly compared HRQOL and recovery patterns between CAS and CEA. In this prospectively designed substudy of the SAPHIRE trial, patients treated with CAS experienced significant health status benefits during the early recovery period relative to those treated with surgical CEA. In particular, physical limitations in role function (i.e., the ability to carry out one's usual activities) as well as difficulty with eating or swallowing, difficulty driving, and neck pain were less frequent among

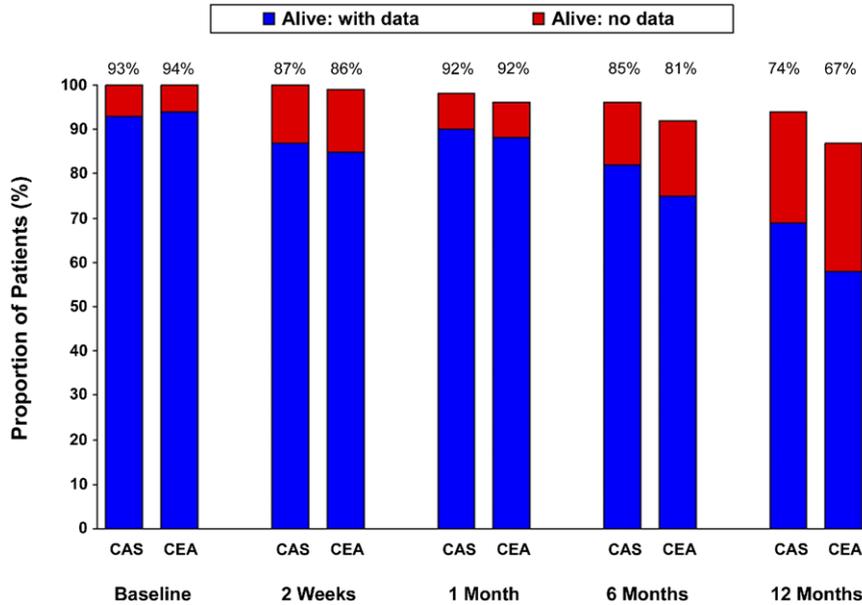


Figure 1. Completeness of Data

Available health status data in patients treated according to protocol in the SAPHIRE trial. Percentages listed **above each bar** indicate the proportion of surviving patients with health status scores available at that time point. CAS = carotid artery stenting; CEA = carotid endarterectomy.

patients undergoing CAS than among those undergoing CEA. The duration of any benefits were limited to the first 2 weeks of the post-operative period, however, and all other measures of disease-specific health status as well as general health and physical function were similar at 1, 6, and 12

months after carotid revascularization. Importantly, despite the inclusion of a complex, elderly patient population with a high degree of comorbidity, there was no evidence of a significant decline in physical function over the year of follow-up.

Table 2. Baseline Generic Health Status Scores and Differences Between CAS Versus CEA During Follow-Up

Health Status Measure	Mean Baseline Scores (± SD)		Mean Difference During Follow-Up (CAS-CEA) (95% CI)			
	CAS	CEA	2 Weeks	1 Month	6 Months	12 Months
Raw data						
Current health rating	69.2 ± 19.5	68.8 ± 19.0	1.3 (-4.1 to 6.8)	1.7 (-5.8 to 9.1)	2.6 (-5.8 to 11.0)	10.1 (-0.8 to 21.0)
SF-36 subscales						
Physical limitations	53.0 ± 29.5	51.6 ± 29.6	1.9 (-3.9 to 7.6)	7.9 (-1.7 to 17.4)	-2.1 (-13.8 to 9.6)	7.7 (-4.2 to 19.6)
Role physical	35.5 ± 39.9	33.6 ± 41.0	9.0 (0.9 to 17.1)*	3.7 (-9.8 to 17.1)	-1.3 (-20.3 to 17.7)	4.8 (-6.8 to 16.4)
Bodily pain	63.6 ± 26.8	61.9 ± 27.1	1.7 (-4.4 to 7.9)	1.6 (-7.4 to 10.5)	2.9 (-7.8 to 13.5)	-7.0 (-19.3 to 5.4)
Vitality	50.2 ± 22.5	47.9 ± 23.2	3.3 (-2.0 to 8.7)	3.3 (-4.1 to 10.6)	-4.2 (-12.6 to 4.2)	5.9 (-3.2 to 15.0)
EQ-5D utility score	0.73 ± 0.22	0.72 ± 0.20	0.01 (-0.04 to 0.06)	0.03 (-0.05 to 0.10)	0.01 (-0.07 to 0.10)	0.04 (-0.01 to 0.10)
Multiply imputed data						
Current health rating	—	—	2.0 (-3.2 to 7.2)	0.4 (-3.9 to 4.7)	1.3 (-3.2 to 5.9)	3.3 (-1.8 to 8.4)
SF-36 subscales						
Physical limitations	—	—	2.7 (-2.7 to 8.0)	1.5 (-3.7 to 6.6)	-1.4 (-7.2 to 4.4)	2.1 (-3.9 to 8.2)
Role physical	—	—	8.8 (1.5 to 16.2)*	4.0 (-8.7 to 16.7)	-0.5 (-15.9 to 14.9)	6.2 (-9.7 to 22.1)
Bodily pain	—	—	3.3 (-2.6 to 9.2)	-2.7 (-8.1 to 2.7)	1.2 (-4.8 to 7.2)	-2.6 (-9.2 to 3.9)
Vitality	—	—	3.4 (-1.5 to 8.4)	-1.2 (-5.7 to 3.3)	-4.2 (-8.9 to 0.4)	1.0 (-4.3 to 6.3)
EQ-5D utility score	—	—	0.02 (-0.04 to 0.07)	-0.03 (-0.08 to 0.02)	0.01 (-0.04 to 0.05)	0.02 (-0.03 to 0.08)

*p ≤ 0.05 for the comparison of CAS versus CEA.

CI = confidence interval; EQ-5D = EuroQol utility score; SF-36 = Medical Outcomes Study Short-Form 36; other abbreviations as in Table 1.

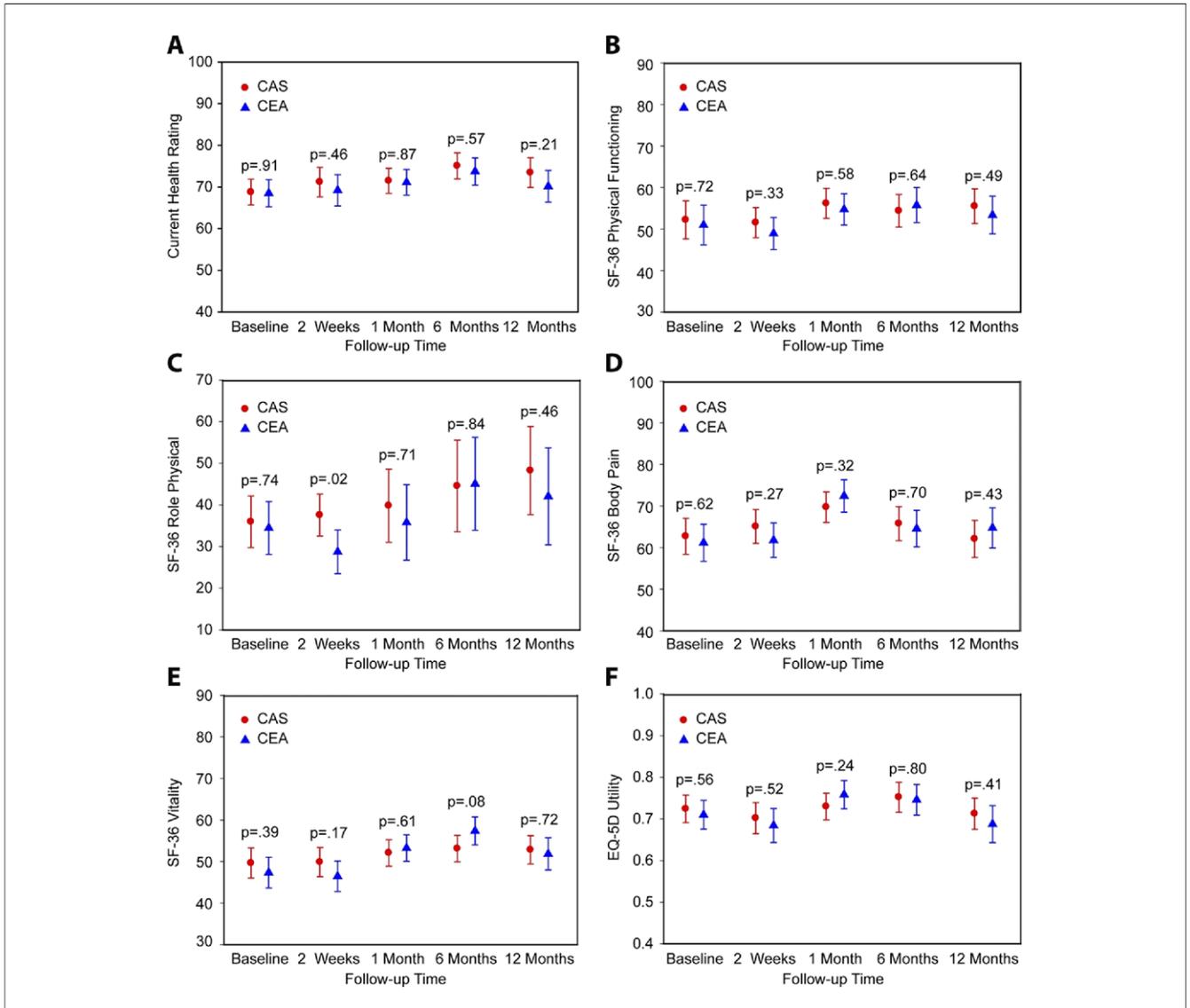


Figure 2. Generic Health Status

Trend in scores for the generic health status measures, from baseline to 1 year. Higher scores indicate better quality of life; significant differences in scores ($p \leq 0.05$) were only noted at the 2-week follow-up visit for the SF-36: Role Physical subscale. EQ-5D = EuroQol utility score; SF-36 = Short-Form 36; other abbreviations as in Figure 1.

The early differences in health status recovery likely reflect the less invasive nature of CAS versus CEA. This is especially evident in the divergence of the modified Likert scales related to discomfort near the carotid incision (neck pain, pain with eating or swallowing). The finding that CAS patients had less difficulty with driving at 2 weeks was somewhat surprising (we had anticipated the opposite effect) but may reflect delayed healing of the incision site after CEA. Alternatively, this difference in recovery may be an artifact of post-operative instructions that often recommend avoidance of certain activities for several weeks. Regardless of the mechanism for these differences, the

extent of physical recovery was similar after either CAS or CEA beyond the first few weeks in this study.

Comparison with prior studies. Multiple studies have assessed HRQOL after CEA, with varying results. For example, several single-center studies have reported no decrement in self-reported HRQOL at 6 months after CEA (22-24), results that were sustained at 8 to 11 years in 1 series (25). Other uncontrolled studies have reported significant improvement in HRQOL after CEA (26,27), and at least 1 study described significant worsening of health status after CEA (28). To date, only 1 nonrandomized study has evaluated HRQOL after CAS versus CEA and

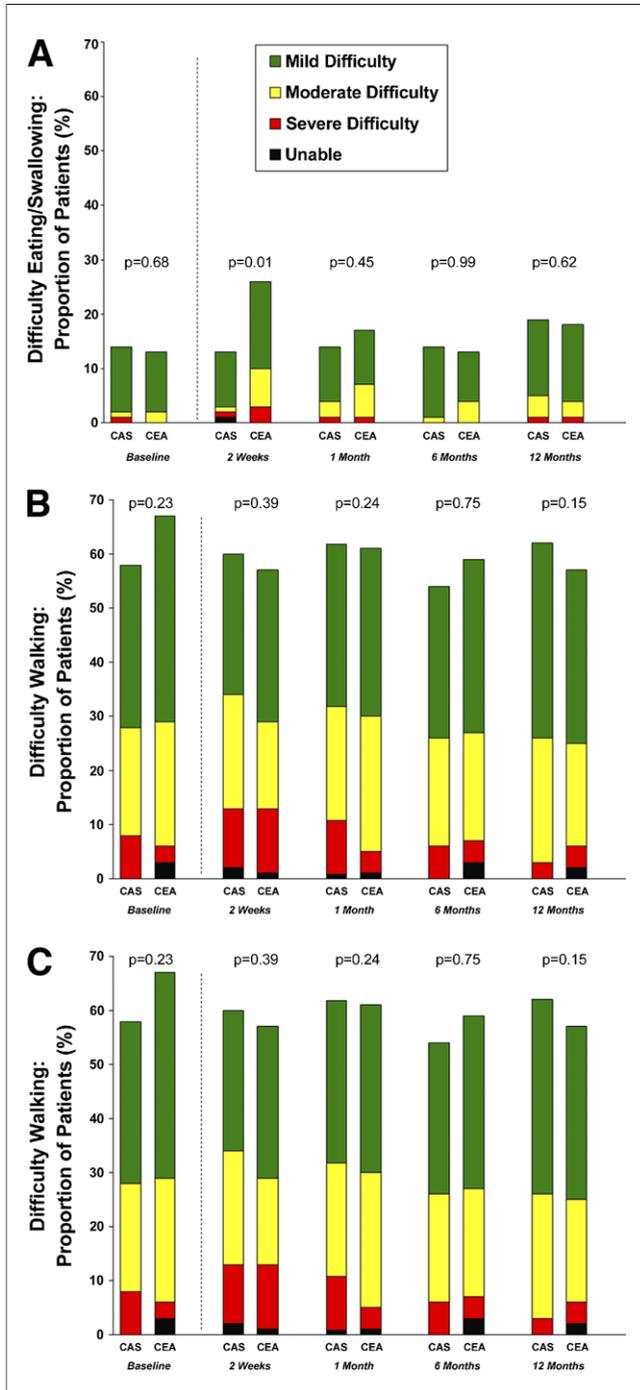


Figure 3. Disease-Specific Functional Limitations
Trend in scores from baseline to 1 year for (A) difficulty eating or swallowing, (B) difficulty walking, and (C) difficulty driving. Abbreviations as in Figure 1.

reported no significant differences between the 2 procedures at 1 year (earlier time points were not assessed) (29). Our analysis from SAPPHERE therefore provides unique insight into the short- and intermediate-term HRQOL benefits of CAS relative to CEA and has the advantages of being

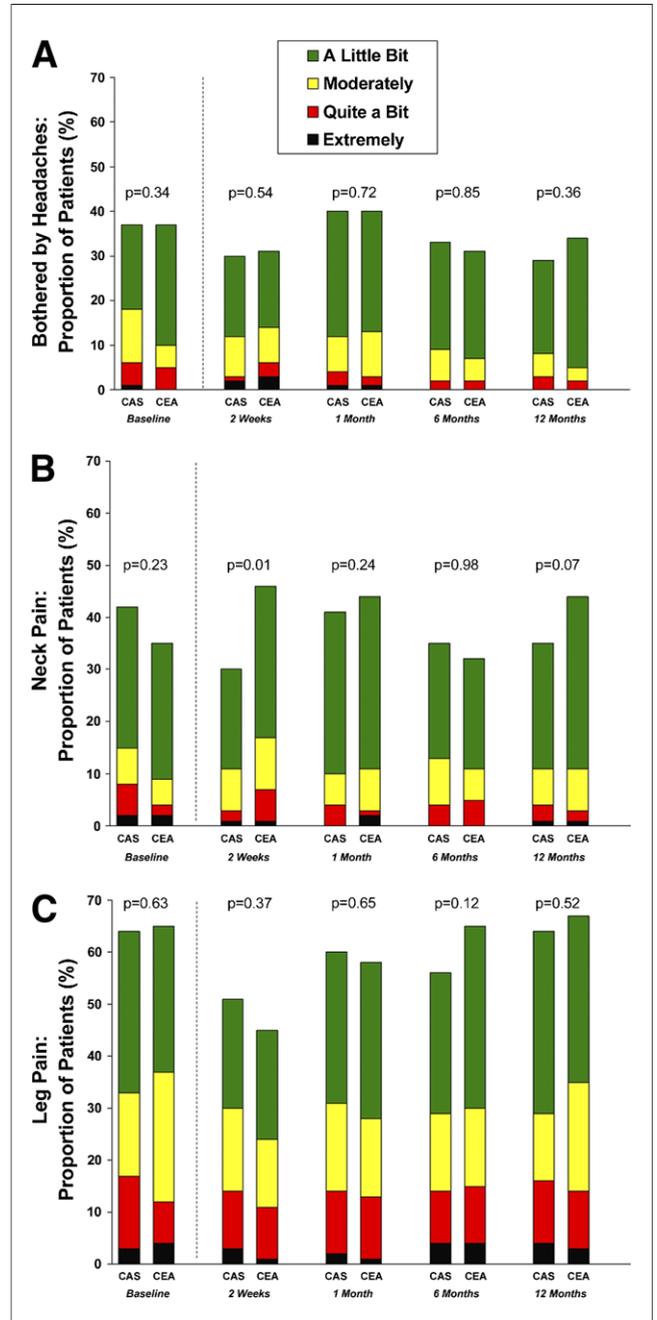


Figure 4. Disease-Specific Pain Scales
Trend in scores from baseline to 1 year for (A) headaches, (B) neck pain, and (C) leg pain. Abbreviations as in Figure 1.

derived from a head-to-head, randomized comparison. The longer-term findings of our analysis are consistent with prior studies demonstrating stabilization and convergence of health status measures over time after both procedures.

Whereas HRQOL has been evaluated in numerous studies comparing different interventions for the treatment of symptomatic vascular disease (e.g., medical vs. surgical vs. percutaneous treatment for obstructive coronary artery dis-

ease or lower extremity claudication) (30–37), the objective of this analysis was to compare the trajectory of *recovery* after revascularization procedures for treatment of carotid artery stenosis, which is often clinically silent. This is an important distinction from studies that have compared the HRQOL benefits of alternative treatments for symptomatic conditions such as chronic stable angina and lower extremity claudication, in which patients generally experience substantial symptom relief immediately after revascularization. A more analogous clinical condition is asymptomatic abdominal aortic aneurysm, for which percutaneous versus open repair has been compared (38–41). These comparisons have generally demonstrated similar clinical outcomes but better patient-reported health status using the less invasive percutaneous options, as recovery is shorter and associated with fewer complications. Moreover, studies of endovascular versus surgical treatment of abdominal aortic aneurysm have generally demonstrated comparable health status at 1 year; these findings are similar to those for CAS versus CEA in our study.

Clinical implications. Our findings have several important implications for the choice of treatment for patients referred for carotid revascularization. In particular, given the small magnitude and limited duration of observed differences in HRQOL, these findings suggest that differences in patient recovery and overall QOL should play a relatively minor role in deciding between the less invasive CAS approach and the more invasive CEA procedure. Nonetheless, the observed differences in the early recovery period were both statistically and clinically important and may be sufficient to influence patients' decision making, as long as there is reasonable confidence that the risk of other serious adverse outcomes does not differ between the strategies. These findings are in contrast to the larger and more prolonged differences in early health status and recovery between percutaneous and surgical coronary revascularization (30–33,42,43), which may even outweigh important differences in long-term clinical outcomes in the minds of many patients and clinicians (44). The results from SAPPHIRE suggest that differences in other factors such as the risk of stroke, myocardial infarction, or restenosis should be the most important factors to consider when deciding between these 2 approaches to carotid revascularization. Consequently, ongoing efforts to more clearly define the long-term benefits of both procedures both in terms of stroke prevention as well as other complications are essential to providing the evidence base for informed patient decision making.

Study limitations. Several limitations should be acknowledged before applying our findings to health policy or clinical practice. First, the SAPPHIRE trial only included patients at high surgical risk; whether lower-risk patients experience smaller or larger differences in HRQOL (either early or late after revascularization) will require further study

in other populations. A second limitation is that our on-treatment analysis cannot account for underlying biases with respect to who underwent treatment per protocol, despite the randomized nature of the overall SAPPHIRE trial. Furthermore, the exclusion of patients who died during follow-up could have biased our results toward the null hypothesis of no difference, if deaths were more likely to occur among patients with the highest degree of comorbidity and resulting physical impairments. Differences in the availability of follow-up health status data for survivors between the CAS and CEA groups may have also tended to bias our results toward the null hypothesis, particularly at the later time points where these differences were most pronounced. In addition, the fact that SAPPHIRE patients were unblinded with respect to their assigned treatment may have introduced biases in subsequent responses to health status assessments.

Finally, given the modest sample size (SAPPHIRE was terminated early due to challenges in patient recruitment), our study may have been underpowered to detect modest treatment effects at the later time points. For example, post hoc power calculations suggest that our study only had 68% power to detect a clinically important difference of 12 points on the SF-36 role-physical scale at 1 month (45). Similarly, power to detect a 15% absolute reduction in the rate of any limitation on the modified Likert scales at 1 month ranged from 69% to 88%. As a result, future studies evaluating carotid revascularization may need substantially larger sample sizes to identify clinically meaningful differences in health status during the recovery phase after CAS versus CEA.

Conclusions

In summary, among patients at high surgical risk, CAS was associated with less health status impairment during recovery (specifically physical role limitations and localized discomfort) when compared with CEA. However, these differences were resolved by 1 month after the procedure, and no other differences between revascularization strategies in HRQOL were found. These results, in conjunction with evidence relating to the comparative risk of other key clinical outcomes (e.g., stroke, myocardial infarction, restenosis), should help to better inform patients regarding the risks and benefits of alternative approaches to carotid revascularization and lead to enhanced, patient-centered decision making.

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- Key Words:** carotid stent ■ quality of life ■ carotid endarterectomy ■ carotid artery stenosis.