Title

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Loss of follow-up after carotid revascularization is associated with worse long-term stroke and death

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Abstract

Objectives: Society for Vascular Surgery practice guidelines recommend surveillance with duplex ultrasound scanning at baseline (within 3 months from discharge), every 6 months for 2 years, and annually afterward following carotid endarterectomy or carotid artery stenting. There is a growing concern regarding the significance of postoperative follow-up after several vascular procedures. We sought to determine whether 1-year loss to follow-up (LTF) after carotid revascularization was associated with worse outcomes in the Vascular Quality Initiative (VQI) linked to Vascular Implant Surveillance and Interventional Outcomes Network (VISION) database.

Methods: All patients who underwent carotid revascularization in the VQI VISION database between 2003 and 2016 were included. LTF was defined as failure to complete 1-year follow-up in the VQI long-term follow-up dataset. Data about stroke and mortality were captured in the VISION dataset using a list of Current Procedural Terminology, International Classification of Diseases (Ninth Revision), and International Classification of Diseases (Tenth Revision) codes linked to index procedures in VQI. Kaplan-Meier life-table methods and Cox proportional hazard

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modeling were used to compare 5- and 10-year outcomes between patients with no LTF and those who were LTF.

Results: A total of 58,840 patients were available for analysis. The 1-year LTF rate was 43.8%. Patients who were LTF were older and more frequently symptomatic, with chronic obstructive pulmonary diseases, chronic kidney diseases, and congestive heart failure. Also, patients who underwent carotid artery stenting were more likely to be LTF compared with carotid endarterectomy patients (54.5% vs 42.3%; $P < .001$). The incidence of postoperative (30 days) stroke was higher in the LTF group (2.9% vs 1.7%; $P < .001$). Cox regression analysis revealed that LTF was associated with an increased risk of long-term stroke at 5 years (hazard ratio [HR]: 1.4, 95% confidence interval [CI]: 1.2–1.6; $P < .001$) and 10 years (HR: 1.3, 95% CI: 1.2–1.5; $P < .001$). It was also associated with significantly higher mortality at 5 years (HR: 2.5, 95% CI: 2.3–2.8; $P < .001$) and 10 years (HR: 2.2, 95% CI: 1.9–2.5; $P < .001$). Stroke or death was significantly worse in the LTF group at 5 years (HR: 2.3, 95% CI: 2.1–2.5; $P < .001$) and up to 10 years (HR: 2.02, 95% CI: 1.8–2.3; $P < .001$).

Conclusions: One-year follow-up after carotid revascularization procedures was found to be associated with better stroke- and mortality-free survival. Surgeons should emphasize the importance of follow-up to all patients who undergo carotid revascularization, especially those with multiple comorbidities and postoperative neurological complications.

Keywords

Loss to follow-up; Carotid revascularization

The Society for Vascular Surgery (SVS) practice guidelines recommend surveillance with duplex ultrasound scanning at baseline (within 3 months postoperatively) and every 6 months for 2 years and annually afterward. After stabilization of the clinical condition, regular surveillance (eg, every 2 years) is recommended for the life of the patient.[1] This recommendation is strong, and the quality of the evidence it is based on is moderate (grade 1B recommendation).

The adherence of the SVS surveillance guidelines has been assessed by few studies. Using the Vascular Study Group of New England database, Judelson et al[2] reported that 34% of patients who underwent carotid endarterectomy (CEA), 28% of endovascular aneurysm repair (EVAR) patients, 31% of infrainguinal bypass patients, 34% of open aneurysm repair patients, and 36% of suprainguinal bypass patients were lost to follow-up (LTF).[2] Similarly, annual imaging follow-up compliance after EVAR in the United States was found to be significantly below recommended levels.[3]

The impact of LTF after several vascular surgery procedures on long-term survival was evaluated in a retrospective single-center cohort study of 440 consecutive patients.[4] LTF at 1 year was found to be associated with worse survival at 5 years ($P < .001$) after CEA, infrainguinal bypass, percutaneous lower extremity revascularization, or EVAR. The follow-up of patients after EVAR and peripheral vascular interventions (PVI) was recently addressed. LTF after these two procedures was found to be associated with worse long-term survival. The authors stressed on the importance of follow-up office visits in long-term survival for these patients.[5,6]

These studies have raised concerns about the importance of follow-up after these vascular procedures. However, there are no data available that describe the impact of follow-up on survival and long-term outcomes after carotid revascularization procedures. In this study, we aim to describe the incidence and long-term outcomes of patients who are LTF compared with those with follow-up after CEA and carotid artery stenting (CAS). We hypothesize that failure to adhere to the recommended follow-up visit will be associated with worse long-term morbidity and mortality.

METHODS

Dataset.

We performed a retrospective analysis of all patients who underwent carotid revascularization (either CEA or CAS) for the treatment of carotid artery stenosis in the Vascular Quality Initiative (VQI) Vascular Implant Surveillance and Interventional Outcomes Network (VISION) database from 2003 to 2016. The VQI is a prospectively maintained dataset including patients' demographic, procedural, and postoperative variables from over 800 hospitals in the United States and Canada.[7] MDEpiNet (The Medical Device Epidemiology Network) is a global public-private partnership that brings together leadership, expertise, and resources from several sectors to advance a national patient-centered medical device evaluation and surveillance system. VISION is a partnership between the VQI and MDEpiNet that aims to improve long-term outcomes through the linkage of VQI index procedures to Medicare claims.[8] This is accomplished through the use of a validated matching algorithm incorporating Current Procedural Terminology, International Classification of Diseases (Ninth Revision), and International Classification of Diseases (Tenth Revision) codes.[9] Therefore, only patients with Medicare coverage (with or without additional insurance) were available for the analysis. The VQI Research Advisory Committee approved data release for this study. Because of the deidentified nature of the dataset, the need for institutional review board approval and patient consent was waived for this study.

Patient population, variables definition, and comparison groups.

Patients were classified into two groups according to the availability of 1-year follow-up in the VQI dataset: those who were LTF at 1 year postoperatively and those who were not. One-year follow-up in VQI is defined as any follow-up available for the patient from 9 to 21 months postoperatively.[10] Data regarding 5- and 10-year stroke and mortality were captured in the VISION Medicare database using a list of Current Procedural Terminology, International Classification of Diseases (Ninth Revision), and International Classification of Diseases (Tenth Revision) codes linked to the VQI index procedure. Baseline patient characteristics included demographics (age, sex, race, and ethnicity), preoperative symptomatic status (amaurosis fugax, transient ischemic attack [TIA], or stroke), smoking history (none, prior, or current), degree of ipsilateral carotid artery stenosis, preoperative comorbidities (hypertension, diabetes, coronary artery disease, congestive heart failure [CHF], chronic obstructive pulmonary disease, chronic kidney disease [CKD], and hemodialysis), preoperative medications (aspirin, statins, beta-blockers, antiplatelet medications, and anticoagulants), and a history of cardiovascular procedures (major amputations, coronary artery bypass grafting or percutaneous coronary intervention, and prior CEA or CAS). Procedure factors included urgency and anesthesia type (general or local/regional). Symptomatic status included a history of ipsilateral amaurosis fugax, TIA, or stroke within the 6 months before the procedure. CKD was defined as a preoperative estimated glomerular filtration rate of less than 60 mL/min, based on the preoperative creatinine level, using the Modification of Diet in Renal Disease study equation. Only patients with atherosclerotic or restenotic lesions were included; those with dissection, trauma, and unidentified carotid lesions were excluded from the analysis.

Outcomes.

The primary outcome included a composite end point of 5- and 10-year stroke or death. Secondary outcomes included 5- and 10-year stroke and death as individual end points. Five- and ten-year stroke was defined as any ipsilateral or contralateral cortical, retinal, or vertebrobasilar ischemic or hemorrhagic stroke within 5 and 10 years after the index procedure.

Statistical analysis.

Categorical variables were expressed as numbers and percentages. Continuous variables were expressed as median with interquartile range or mean ± standard deviation. Baseline patients' characteristics were compared between patients with LTF and patients with no LTF using Pearson χ^2 and Fisher exact tests for categorical variables and Student's *t*-test or the rank-sum test for continuous variables, as appropriate. Five- and ten-year outcomes were evaluated using Kaplan-Meier survival analysis, and Cox proportional hazard regression analyses were used to predict the outcomes, adjusting for potential confounders. Variable selection was performed using stepwise backward regression with a *P* value of <.1. Variables with clinical relevance were forced into the final models (Supplementary Table, online only). To decrease bias from unmeasurable factors per hospital level and to account for intragroup correlation, final models were clustered by center identifier. A *P* value of ≤.05 was considered statistically significant. All analyses were accomplished using Stata version 16.1/SE software (StataCorp LP).

RESULTS

Baseline characteristics.

A total of 58,840 patients underwent carotid revascularization between 2003 and 2016. The rate of 1-year LTF was 43.8%. Patients who were LTF were slightly older, more likely to be Hispanic (3.1% vs 2.7%, $P < .001$), of non-White race (7.7% vs 6.5%, $P < .001$), symptomatic on presentation (31% vs 28.9%, $P < .001$), and with more medical comorbidities such as diabetes (37% vs 35.5%, $P < .001$), CHF (13% vs 11.02%, $P < .001$), chronic obstructive pulmonary disease (24.2% vs 23.1%, $P = .001$), CKD (42.1% vs 40.1%, $P < .001$), dialysis (1.6% vs 1.03%, $P < .001$), and contralateral occlusion (5.8% vs 5.3%, $P = .016$). They were also more likely to be on preoperative P2Y12 antagonists (35.8%

vs 33.2%, $P < .001$), current smokers (22.7% vs 21.5%, $P < .001$), with a history of prior ipsilateral CEA (4.2% vs 3.3%, $P < .001$), and prior ipsilateral CAS (5.2% vs 3.6%, $P < .001$). LTF patients were less likely to get an elective procedure (86% vs 89.3%, $P < .001$). On the other hand, patients who had follow-up were more likely to be on preoperative medications such as aspirin (83.3% vs 82.6%, $P = .018$), anticoagulants (10.9% vs 10.03%, $P = .002$), beta-blockers (61.4% vs 60.2%, $P = .002$), statins (80.5% vs 79.3%, $P < .001$), and angiotensin converting enzyme inhibitors (52.7% vs 51.3%, $P = .002$). They were also more likely to have a history of prior coronary artery bypass grafting/percutaneous coronary intervention (37.3% vs 36.5%, $P = .036$) and to undergo the procedure under general anesthesia (83.9% vs 79.5, $P < .001$). A detailed comparison of baseline characteristics between the two groups is expressed in Table I.

Five- and ten-year outcomes.

At 5 years, LTF had significantly higher risk of stroke or death (23.9% vs 11.3%, $P < .001$), any stroke (4% vs 2.9%, $P < .001$), and mortality (22.5% vs 9.7%, $P < .001$). Over 10 years, LTF had significantly higher risk of any stroke (5% vs 4.85%, $P < .001$, Fig 1), mortality (30.7% vs 22.8%, $P < .001$, Fig 2), and stroke or death (32.5% vs 26.3%, $P < .001$, Fig 3). Multi-variable Cox regression analysis revealed that LTF was associated with worse stroke or death at 5 years (adjusted hazard ratio [aHR]: 2.3, 95% confidence interval [CI]: 2.1–2.5; $P < .001$) and up to 10 years (aHR: 2.03, 95% CI: 1.8–2.3; $P < .001$) of follow-up. LTF was also associated with the increased risk of stroke at 5 years (aHR: 1.4, 95% CI: 1.2–1.6; $P < .001$) and 10 years (aHR: 1.3, 95% CI: 1.2–1.5; $P < .001$). It was also associated with significantly higher mortality at 5 years (aHR: 2.5, 95% CI: 2.3–2.8; $P < .001$) and 10 years (aHR: 2.2, 95% CI: 1.9–2.5; $P < .001$) (Table II).

DISCUSSION

The SVS practice guidelines for carotid revascularization follow-up were established given the risk of restenosis after both CEA and stent placement.[11,12] However, the potential benefits of these guidelines on stroke prevention and survival remain undetermined.

In the current study, we assessed the association between completion of 1-year follow-up and long-term stroke-free survival among patients who underwent carotid revascularization. Using the VQI database linked to Medicare claims, we were able to obtain data about long-term stroke and mortality for patients who failed to complete their 1-year follow-up in the VQI database. We found that failure to complete 1-year follow-up is associated with worse stroke and mortality at 5 years and up to 10 years of follow-up after carotid revascularization procedures. Although the rates of stroke at 10 years of 4.85% vs 5% in the no LTF vs LTF groups ($P < .001$) may not indicate clinical relevance, the aHR indicated a 30% increased risk of stroke associated with LTF. Our data suggest that LTF patients were more likely stenting patients, symptomatic on presentation, and with higher medical comorbidities such as diabetes, CHF, CKD, dialysis, and contralateral occlusion. The incidence of 1-month postoperative stroke was higher in the LTF group (2.9% vs 1.7%; $P < .001$). Therefore, our data suggest that completion of 1-year follow-up after carotid revascularization is associated with better survival and stroke-free survival especially in patients with significant medical comorbidities and postoperative neurological complications.

No similar study on the impact of 1-year follow-up after carotid intervention has been reported. However, the significance of follow-up among several vascular procedures was previously established. In one study of 11,309 patients undergoing EVAR, patients with more comorbidities and a higher incidence of in-hospital complications were more likely to be LTF and ultimately have worse survival outcomes.[5] Another study showed that patients who completed 1-year follow-up after peripheral vascular intervention demonstrated improved survival compared with LTF patients.[6] The results from the previous studies are similar to the findings of this study.

The benefits associated with follow-up are most likely due to early detection of restenosis on imaging, better management of complex comorbidities, and close follow-up of different medication regimens. A large prospective study at four affiliated hospitals found 4 years after a CEA that there was a 14% incidence of either TIA or stroke in patients with restenosis, but no significant difference in patients without restenosis.[13] A retrospective review of over 150 patients found that during 1-year follow-up, 4.1% of patients had recurrent symptoms requiring reintervention and models were created to predict the development of restenosis.[14] Similarly, in the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST), 2-year follow-up was used to determine the rate of restenosis or occlusion and there was no significant difference in restenosis between CEA and CAS.[15] However, the CREST did find a higher number of ipsilateral strokes in the restenosis group, suggesting the importance of follow-up.[15] In addition, a close follow-up of optimal medical therapy after carotid artery revascularization is highlighted in the ongoing CREST-2 (Carotid Revascularization Endarterectomy versus Stent Trial 2). This study compares long-term stroke risk among asymptomatic patients with carotid artery stenosis treated with revascularization plus optimal medical therapy, vs optimal medical therapy alone.[16] Overall, the literature supports the need for surveillance after carotid revascularization due to the risk of restenosis, occlusion, or recurrent symptoms.[17]

Our results suggest that follow-up after carotid intervention is of paramount importance to identify patients at risk and potentially prevent a stroke or TIA. This is mimicked in other studies that have found similar importance of follow-up after other procedures. In patients who underwent laparoscopic adjustable gastric banding, good follow-up was associated with greater weight loss and adherence, and patients who underwent gastric bypass were found to have improvement in comorbidities if follow-up continued for 1 year.[18,19] Finally, a 16-year study of over 2000 patients with joint replacement found that those patients who were LTF were more likely to have increased pain, worse range of motion, and overall poorer outcomes than those who continued to be followed by their provider.[20] These examples serve to show the importance of follow-up in the medical community in general.

In patients with vascular disease, follow-up has become a key area of research interest. After EVAR, Medicare data were used to find that 43% of EVAR patients had complete surveillance, and for those with incomplete surveillance, there was an increased risk of aneurysm rupture.[21] Lifelong surveillance is currently recommended after EVAR treatment, and a single institution found a rate of 56% LTF with no identifiable pattern to predict attrition.[22] One theory based on access to health care was addressed by a single institution retrospective review in the South-west. However, in this group of patients, there was no difference in aneurysm complications or follow-up based on travel distance to a medical center, therefore suggesting that with appropriate tracking and travel assistance, patients will follow up.[23] Furthermore, 36 studies were reviewed on blunt traumatic thoracic aortic injury and found that LTF is a significant factor in the trauma population when assessing operative outcomes.[24]

Limitations.

This study has important limitations that should be noted. Given the retrospective nature of the study, we can only report an association, but not necessarily causation, between LTF and worse outcomes. Patients who were classified as LTF were those without 1-year follow-up in the VQI database. It is possible that these patients may have followed up with another physician or not entered in the follow-up forms despite follow-up, and thus could have been misclassified as being LTF. This also could have led to an underestimation of the overall follow-up rate and an overestimation of the effect of LTF on survival. Despite our thorough adjustment for potential confounders in the multivariable models, there could have been residual confounding. Another limitation of this study is the lack of data on restenosis and long-term medical management adherence, which is likely the main driver of better stroke-free survivor. Despite these limitations, this study has important strengths as it is the first study to examine the importance of follow-up after carotid revascularization. Overall, our study endorses the follow-up benefit after carotid revascularization. We have shown that through prospectively collected data, patients who are LTF have a higher risk of long-term stroke and death at both 5 years and 10 years after the procedure. Therefore, we believe that a concerted effort toward follow-up and patient engagement is warranted.

CONCLUSIONS

One-year follow-up after carotid revascularization procedures was found to be associated with a stroke- and mortality-free survival benefit for these patients. Surgeons should emphasize the importance of postoperative follow-up to all patients who undergo carotid revascularization, especially those with multiple comorbidities and postoperative neurological complications.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective review of prospectively collected data from the Vascular Quality Initiative Vascular Implant Surveillance and Interventional Outcomes Network database
- **Key Findings:** In this study of 58,840 patients, the 1-year loss to follow-up (LTF) rate was 43.8%. The incidence of postoperative stroke was higher in the LTF group (2.9% vs 1.7%; $P < .001$). LTF was associated with the increased risk of stroke or death at 5 years (hazard ratio: 2.3, 95% confidence interval: 2.1–2.5; $P < .001$) and up to 10 years (hazard ratio: 2.02, 95% confidence interval: 1.8–2.3; $P < .001$).
- **Take Home Message:** Completion of 1-year follow-up after carotid revascularization procedures was associated with better stroke-free survival. Surgeons should emphasize the importance of postoperative follow-up to all patients who undergo carotid revascularization, especially those with multiple comorbidities and postoperative neurological complications.

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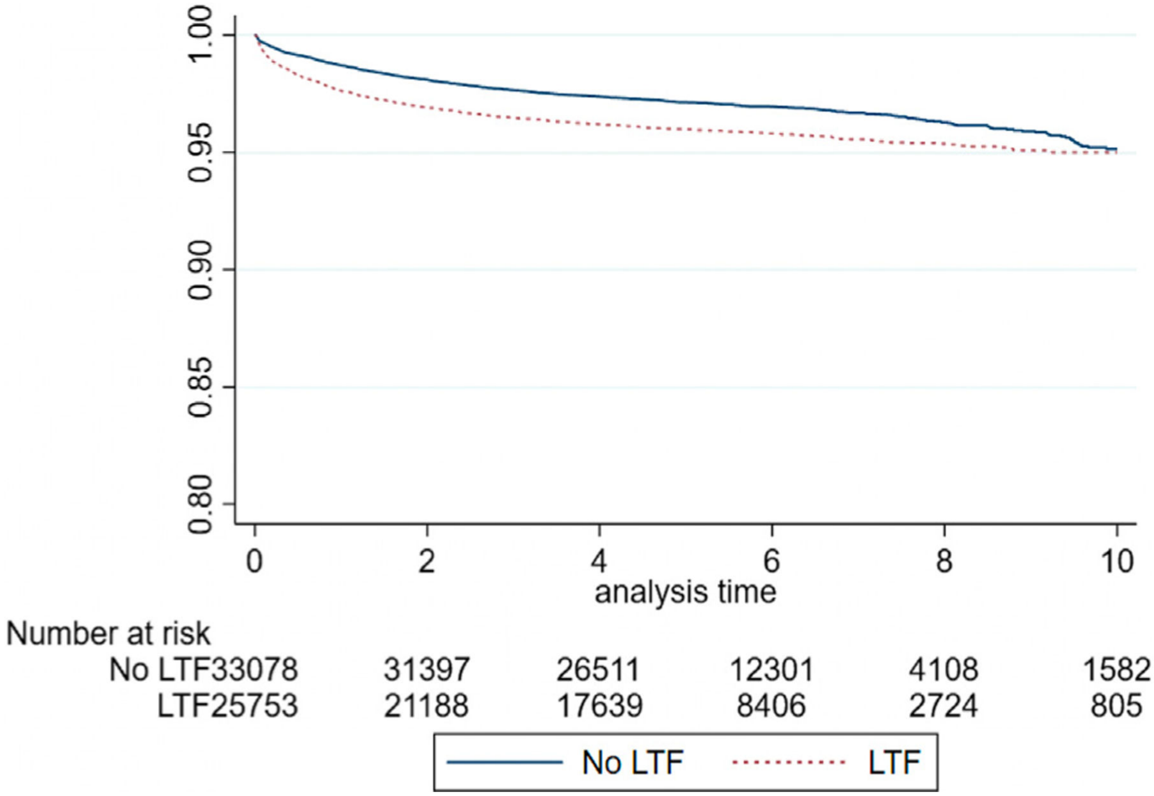

Fig 1.

Freedom from stroke. *LTF*, Loss to follow-up.

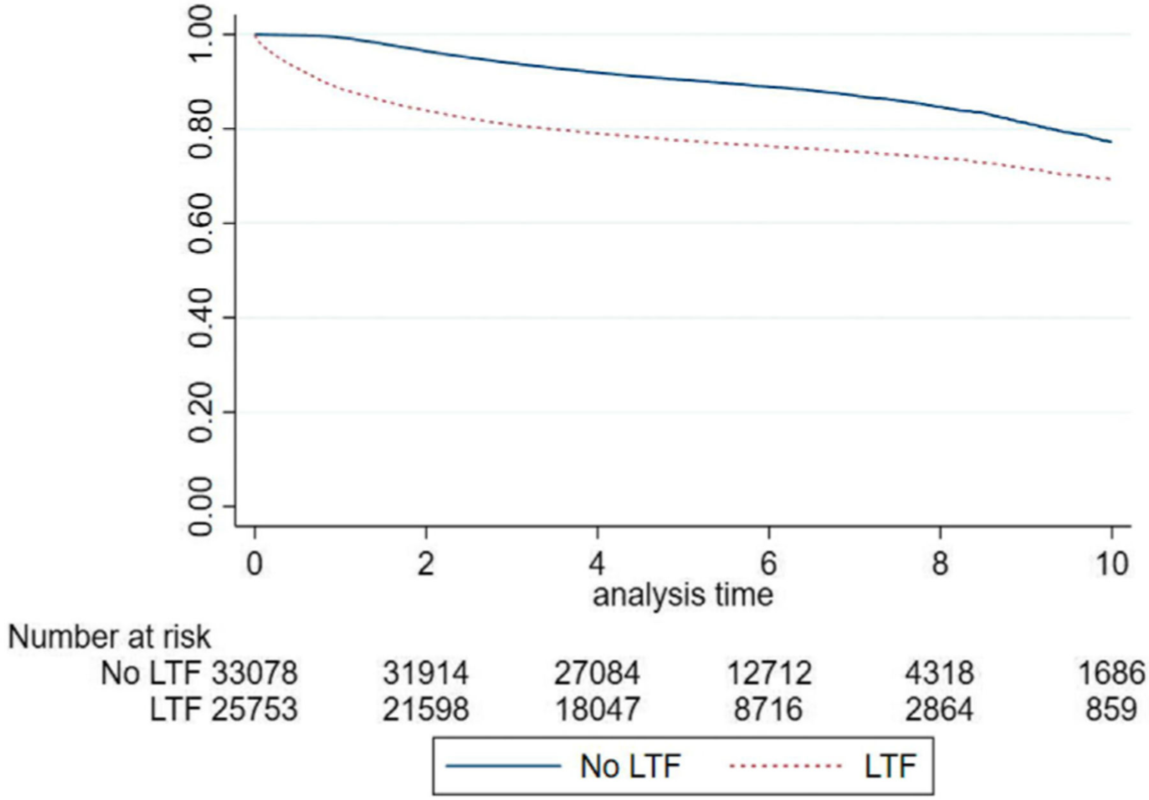

Fig 2.
Freedom from death. *LTF*, Loss to follow-up.

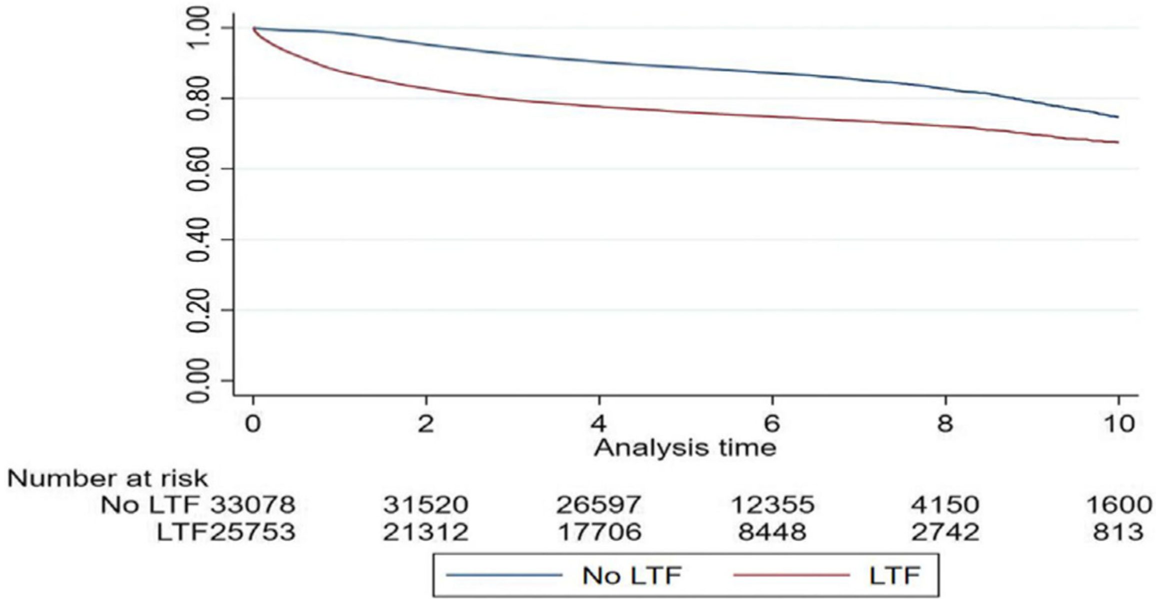

Fig 3.
Stroke-free survival. *LTF*, Loss to follow-up.

Table I.

Baseline characteristics between patients with complete follow-up and patients who are lost to follow-up (*LTF*)

Patient characteristics	No LTF (N = 33,078; 56.2%)	LTF (N = 25,762; 43.8%)	*P* value
Demographics			
Age, median (IQR)	73 (68–78)	74 (68–79)	<.001
Female sex	13,121 (39.7)	10,279 (39.9)	.567
White race	30,921 (93.5)	23,749 (92.3)	<.001
Hispanic or Latino	875 (2.7)	807 (3.1)	<.001
Type			<.001
CEA	29,993 (90.7)	22,057 (85.6)	
CAS	3085 (9.3)	3705 (14.4)	
Comorbidities			
Symptomatic stenosis	9554 (28.9)	7946 (31)	<.001
Diabetes	11,735 (35.5)	9506 (37)	<.001
HTN	29,766 (90.05)	23,159 (90.2)	.6
CAD	9643 (29.2)	7654 (29.9)	.08
CHF	3644 (11.02)	3342 (13)	<.001
COPD	7629 (23.1)	6223 (24.2)	.001
CKD	13,272 (40.1)	10,826 (42.1)	<.001
Dialysis	342 (1.03)	420 (1.6)	<.001
Contralateral occlusion	1293 (5.3)	1097 (5.8)	.016
Ipsilateral stenosis ≥80%	20,320 (62.3)	15,729 (62.6)	.5
Preoperative medications			
Aspirin	27,550 (83.3)	21,222 (82.6)	.018
Anticoagulant	2694 (10.03)	2283 (10.9)	.002
Beta-blocker	20,314 (61.4)	15,448 (60.2)	.002
Statin	26,618 (80.5)	20,373 (79.3)	<.001
ACE inhibitors	14,206 (52.7)	10,762 (51.3)	.002
P2Y12 inhibitors	10,965 (33.2)	9191 (35.8)	<.001
Current smoker	7090 (21.5)	5838 (22.7)	<.001
Prior vascular procedures			

Patient characteristics	No LTF (N = 33,078; 56.2%)	LTF (N = 25,762; 43.8%)	*P* value
Prior CABG/PCI	12,160 (37.3)	9222 (36.5)	.036
Prior ipsilateral CEA	1094 (3.3)	1074 (4.2)	<.001
Prior ipsilateral CAS	980 (3.6)	1105 (5.2)	<.001
Prior contralateral CEA/CAS	2040 (8)	1549 (7.8)	.5
Elective	29,514 (89.3)	22,087 (86)	<.001
General/converted to general anesthesia	27,702 (83.9)	20,439 (79.5)	<.001

ACE, Angiotensin-converting enzyme; *CABG*, coronary artery bypass grafting; *CAD*, coronary artery disease; *CAS*, carotid stenting; *CEA*, carotid endarterectomy; *CHF*, congestive heart failure; *CKD*, chronic kidney disease; *COPD*, chronic obstructive pulmonary disease; *HTN*, hypertension; *IQR*, interquartile range; *PCI*, percutaneous coronary intervention.

Data are presented as number (%) unless otherwise specified.

Table II.

Five- and ten-year outcomes of loss to follow-up (*LTF*) vs no LTF

	No LTF	LTF	Log rank	HR (95% CI)	*P* value
Five years					
Stroke	2.9	4	<.001	1.4 (1.2–1.6)	<.001
Death	9.7	22.5	<.001	2.5 (2.3–2.8)	<.001
Stroke/death	11.3	23.9	<.001	2.3 (2.1–2.5)	<.001
Ten years					
Stroke	4.85	5	<.001	1.3 (1.2–1.5)	<.001
Death	22.8	30.7	<.001	2.2 (1.9–2.5)	<.001
Stroke/death	25.3	32.5	<.001	2.03 (1.8–2.3)	<.001

CI, Confidence interval; *HR*, hazard ratio.