

Steering Committee Charter

SVS VQI TransCarotid Revascularization Surveillance Project (VQI-TCAR)

ClinicalTrials.gov Identifier: NCT02850588

1. INTRODUCTION

The Steering Committee is the primary study and protocol advisory group for the SVS VQI TransCarotid Revascularization Surveillance Project (VQI-TCAR). This project is registered on ClinicalTrials.Gov with an identifier of NTC02850588

The Steering committee is charged with reviewing the trial protocol, especially within the context of current medical practices for the management of stents placed directly into the carotid artery while reversing blood flow within the carotid artery to reduce stroke risk. See Section 3 for a complete list of responsibilities of the Steering Committee.

The objectives of the project are to compare the efficacy of TCAR to CEA in the following areas:

Primary Objective - One-year ipsilateral stroke or death (time frame: 1 year)

- Any death or stroke in the territory of the treated carotid artery within one year of the carotid artery treatment

Secondary Objectives – 30-day stroke or death (time frame: 30 days)

- Any stroke or death within 30 days of the carotid artery treatment
- 30-day stroke, death or myocardial infarction (time frame: 30 days)
- Any stroke, death or myocardial infarction within 30 days of the carotid artery treatment

2. Detailed Objectives and Endpoints

The efficacy of TCAR will be evaluated as a non-inferiority trial to the standard of care, CEA. Based on data from SVS PSO CEA Registry, the stroke/death rate in all patients undergoing CEA is 1.5%. Using a threshold of 2% stroke/death rate for TCAR (30% increase compared to CEA), enrollment of 11,431 patients per treatment arm is needed to assess non-inferiority of TCAR compared to CEA. This sample size calculation for non-inferiority is controlled at an error rate of 0.025 and a study power of 80%. We estimate an enrollment period of 5 years, ending in December 2021, to accrue the projected TCAR sample size. This estimate is based on the steady TCAR enrollment rate seen from the initial 2 years of the TSP registry.

3. COMPOSITION OF THE STEERING COMMITTEE

The Steering Committee (SC) consists of eight physician leaders with clinical and methodological expertise. It includes the following individuals:

Steering Committee Members

Marc Schermerhorn, M.D. (Chair)	George H. A. Clowes Jr. Professor of Surgery Harvard Medical School Chief Division of Vascular and Endovascular Surgery Beth Israel Deaconess Medical Center mscherm@bidmc.harvard.edu
Mahmoud Malas, M.D.	University of California San Diego, Health System Vice Chair of Surgery for Clinical Research Professor and Chief Vascular and Endovascular Surgery mmalas@ucsd.edu
Vikram Kashyap, M.D.	University Hospitals Cleveland Medical Center Chief, Division of Vascular Surgery and Endovascular Therapy Professor of Surgery, Case Western Reserve University Phone 216 844 1631 Vikram.Kashyap@UHhospitals.org
Grace Wang, M.D.	Hospital of the University of Pennsylvania Division of Vascular and Endovascular Surgery Ph: (215) 662-2069 Grace.Wang@uphs.upenn.edu
Brian Nolan, M.D.	Maine Medical Center bwnolan@mmc.org
Raghu Motaganahalli, M.D.	Indiana University School of Medicine Division Chief of Vascular Surgery Associate Professor & Program Director Ph: (317) 962-2300 rmotagan@iupui.edu
Jack Cronenwett, M.D.	Dartmouth Hitchcock Medical Center Chief Medical Officer, M2S/Medstreaming Jack.L.Cronenwett@dartmouth.edu
Jens Eldrup-Jorgensen, M.D.	Maine Medical Center SVS PSO Medical Director Division of Vascular and Endovascular Surgery, Maine Medical Center Professor of Surgery, Tufts University School of Medicine

In the event that a member is unable to continue participation on the Steering Committee, the SVS PSO will select a replacement.

The Steering Committee will be chaired by Marc Schermerhorn, M.D.

3. RESPONSIBILITIES OF THE STEERING COMMITTEE

The Committee has the overall responsibility for oversight of this quality improvement project. Specific responsibilities of the Steering Committee will include:

- Monitor the execution and conduct of the SVS VQI TransCarotid Revascularization Surveillance Project (VQI-TCAR);
- Address and resolve study related scientific issues requiring their expertise, as determined by the Steering Committee chairperson;
- Assist in development of study protocol;
- Assist in the periodic review of data submission forms;
- Assist with communications to ensure 1-year follow-up from participating sites
- Monitor the progress of the project, including the review of non-identifiable datasets;
- Address and resolve study related scientific and clinical issues/questions requiring their expertise;
- Approve or author the primary scientific publication reporting the study results;
- Approve the formation of Steering Committee writing groups, focused on the primary and secondary goals of VQI-TCAR;
- Provide oversight and review for approved RAC studies outside of the VQI-TCAR's studies primary and secondary research objectives;
- Make a final decision on submission for publication in a scientific journal

4. OPERATION OF THE STEERING COMMITTEE

Meetings

Meetings of the Steering Committee will take place approximately four times a year. Meetings will be scheduled and organized by the SVS PSO. Meetings will be conducted as face-to face, web casts, or conference calls. Meetings will be scheduled at a day and time convenient to as many of the members of the Steering Committee as is practical. Additional conference calls or meetings will be held at the discretion of the Steering Committee Chairperson.

The Steering Committee members will discuss and come to a consensus, rather than having a formal vote regarding all recommendations.

The first meeting of the Steering Committee will be an organizational meeting. This meeting is intended to formally establish the Steering Committee and to thoroughly acquaint the Steering Committee with the study device protocol, and study plans.

Non-members may attend Steering Committee meetings at the invitation of the Chairperson.

Meeting minutes will be recorded by a member of the SVS PSO, reviewed and approved by the Steering Committee Chairperson and distributed to members within 15 business days of the meeting.

5. CONFLICT OF INTEREST GUIDELINES

SVS PSO Industry Study Steering Committee members may have no direct financial relationships with the company or companies sponsoring the Committee's Industry Study during their terms of service.

- A direct financial relationship is a compensated relationship held by an individual that would generate an IRS Form W-2, 1099 or equivalent income report.
- The threshold for an individual to be considered conflict-free is zero income.
- Industry Study Steering Committee members should terminate any direct financial relationships within six months of their appointment.
- Individuals with more than \$50,000 in income in aggregate from industry, not directly related to their Industry Study, will also be precluded from serving on an Industry Study Steering Committee.
- Industry Study Steering Committee members during their terms of service may not accept direct support for research or other activities from the company or companies sponsoring the Committee's Industry Study. Uncompensated services and other permitted relationships should nevertheless be disclosed on the individual's Conflict of Interest Statement.

- Industry Study Steering Committee members shall not serve on a Board or hold a leadership position for medical device manufacturer related to their Committee's Industry Study, whether compensated or uncompensated.
- Industry Study Steering Committee members may belong to a division or institution that accepts unrestricted or educational funds and research grants as long as the grant money is paid to the division or institution (e.g., academic medical center), not to the individual.

SVS PSO Industry Study Steering Committee members may attend but may not participate in Vascular Annual Meeting satellite symposia as speakers, moderators or other significant participants, as this gives the appearance that SVS is endorsing company product(s).

SVS PSO Industry Study Steering Committee members may not participate in any promotional/marketing events held in the exhibit hall as speakers, moderators or other significant participants.

All Industry Study Steering Committee members will complete the SVS Conflict of Interest Form on an annual basis and prior to assuming their responsibilities. The Form will be reviewed by the SVS Conflict of Interest Committee.

6. CONFIDENTIALITY

All data provided to the Committee is privileged and confidential. The Committee will agree to use this information to accomplish the responsibilities of the Committee and will not use it for other purposes.