1. Title Page:

Title: Leveraging Health IT to Avoid Unnecessary Asymptomatic Carotid Revascularization

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2. Structured Abstract (248 words)

Purpose:

For patients with asymptomatic carotid stenosis, decision-making strategies must carefully weigh the up-front risks of revascularization against the long-term risk of stroke, all within the patient's life expectancy. Trials suggest the best choice for low-risk patients expected to survive long enough to benefit from intervention is carotid revascularization. However, it is difficult to define which variables accurately identify patients at risk for poor peri-operative outcomes and long-term survival.

In this project, we developed a Health IT Tool that improves decision-making for patients with asymptomatic carotid stenosis. Our tool informs two key facets of this decision: (1) short-term surgical risk stratification, using the detailed patient and procedural variables present in our national vascular registry, the Vascular Quality Initiative (VQI), and (2) longitudinal follow-up to assess the effectiveness of carotid revascularization in preventing stroke during the patient's remaining life expectancy.

Scope:

Aim 1: To identify which patients receive unnecessary carotid revascularization using a linked registry-claims dataset, and design and implement a Health IT Tool to convey this evidence to providers.

Aim 2: To determine the potential cost savings associated with avoiding unnecessary carotid revascularization in asymptomatic patients.

Methods: Using linked clinical-claims datasets from the Vascular Quality Initiative, we developed and tested a health IT tool, called the Carotid Artery Risk Assessment Tool (CARAT).

Results: The CARAT tool accurately identified patients unlikely to benefit from carotid revascularization, as well as the patients whose procedures were likely to be expensive. The tools was feasible and effective in pilot testing in clinical practice.

Key Words: Carotid endarterectomy, stroke, carotid stenting, risk assessment, patient communication

3. Purpose

For patients with asymptomatic carotid stenosis, decision-making strategies must carefully weigh the up-front risks of revascularization against the long-term risk of stroke, all within the patient's life expectancy. Trials suggest the best choice for low-risk patients expected to survive long enough to benefit from intervention is carotid revascularization. However, it is difficult to define which variables accurately identify patients at risk for poor peri-operative outcomes and long-term survival.

In this project, we sought to develop a Health IT Tool that improves decision-making for patients with asymptomatic carotid stenosis. Our tool informs two key facets of this decision: (1) short-term surgical risk stratification, using the detailed patient and procedural variables present in our national vascular registry, the Vascular Quality Initiative (VQI), and (2) longitudinal follow-up to assess the effectiveness of carotid revascularization in preventing stroke during the patient's remaining life expectancy.

Our study had two specific aims:

Aim 1: To identify which patients receive unnecessary carotid revascularization using a linked registry-claims dataset, and design and implement a Health IT Tool to convey this evidence to providers.

Aim 2: To determine the potential cost savings associated with avoiding unnecessary carotid revascularization in asymptomatic patients.

4. Scope

Background

Cerebrovascular disease, specifically atherosclerosis of the carotid bifurcation, is a major cause of stroke. Stroke represents the second leading cause of cardiovascular death, and the third leading cause of death in the United States. This morbid event is the greatest contributor to long-term disability and results in over 45 billion dollars of direct and indirect costs annually in the Unites States.

Carotid revascularization, via carotid endarterectomy (CEA) or stenting (CAS), is commonly performed to reduce future stroke risk in patients with symptomatic**,** severe, extra-cranial carotid artery stenosis. This practice is supported by multiple randomized controlled trials. For example, in patients with recent transient ischemic attacks or stroke ipsilateral to a $\geq$70% internal carotid artery stenosis, the 2-year stroke risk under medical management is 26%. CEA reduces this 2-year stroke risk to 9%, for an annual absolute stroke risk reduction of 11%. Because of this substantial benefit, carotid revascularization is widely recommended for symptomatic patients with severe carotid stenosis. After its introduction in the mid-1990s, CAS emerged as an alternative to CEA, with similar outcomes in many patient subgroups as well as large clinical trials.

However, for asymptomatic patients with severe carotid stenosis, the picture is not quite as clear. While carotid revascularization is recommended for asymptomatic patients, the benefits are admittedly modest and amortized over several years. Therefore, the up-front risks of surgery, as well as overall patient life expectancy, are more important covariates. For example, in asymptomatic patients with > 60% ICA stenosis, the 2-year stroke risk for patients under

medical management is only 5%—much less than for symptomatic patients. CEA reduces 2-year stroke risk to 2% for an annual absolute risk reduction of 1.2%, a benefit easily lost if surgical risks are high, such as in low-volume hospitals or among inexperienced surgeons. Similar benefits have been reported for carotid artery stenting (CAS). For this reason, guidelines generally suggest that to achieve benefit from prophylactic carotid revascularization, asymptomatic patients need to have low peri-operative risk, and have at least 3 to 5 years of projected life expectancy.

The majority of carotid revascularization procedures in the United States are performed for asymptomatic disease, as asymptomatic stenosis is much more prevalent than symptomatic carotid stenosis. Further, in-hospital outcomes have been the predominant focus in evaluating carotid revascularization, even though this metric is poorly suited for assessing its long-term appropriateness and effectiveness. This is especially true among patients who are being treated for asymptomatic disease.

5. Methods

As described in our Background section, current risk models that intend to inform decision-making regarding the effectiveness of carotid revascularization in patients with asymptomatic carotid stenosis are inadequate. These models fail to incorporate adequate procedural detail, or complete long-term follow-up. This gap in knowledge allows an important opportunity to improve patient selection for carotid revascularization.

Therefore, in Aim 1, we performed two specific tasks. First, we used a merged registry-claims dataset to predict which patients presenting with asymptomatic carotid disease received unnecessary carotid revascularization between 2003 and 2012. Second, we used this data to develop, implement, and integrate a Health IT Tool that clearly and efficiently conveys to providers which patients are most likely to receive an unnecessary carotid revascularization. This tool was then tested in clinical practice to determine its feasibility and pilot effectiveness. Finally, in Aim 2, we examined the cost implications of decisions guided by our Health IT tool.

6. Results

6 A. Studies and Results (by Specific Aim):

Aim 1:

In this aim, our goal was to generate a linked clinical claims dataset that combined Medicare claims with data from the Vascular Quality Initiative, our national vascular quality improvement organization (VQI). After receiving a DUA from CMS, and arranging the appropriate legal permissions, we were able to successfully link more than 20,000 patients who underwent revascularization in the VQI to their respective Medicare claims. This dataset was then used to generate a risk model that identified patients who were not likely to survive at least two years following elective revascularization for asymptomatic carotid stenosis. We have generated our risk model, and translated it into a Health IT Tool. This Health IT Tool has been fitted into an "app" for handheld computer devices, and is currently being integrated into an Epic-based EMR application.

We used our linked clinical-claims dataset to identify factors associated with poor survival following carotid revascularization, we found that age over 80, diabetes, congestive heart failure, COPD, smoking, renal failure, contralateral carotid stenosis, and absence of statin

therapy were all associated with poor survival. A risk model based on this system had excellent discrimination, and was well calibrated across a spectrum of patient risk.

In the context of identifying factors associated with survival after carotid revascularization, we used our linked clinical-claims dataset to study long-term stroke-free survival after carotid endarterectomy and carotid stenting (the two treatment choices for carotid revascularization). We found that patients selected for carotid endarterectomy has significantly better long-term survival than those selected for carotid stenting. We presented these findings on June 6th, 2014 to the national vascular society's meeting, the Society for Vascular Surgery's Vascular Annual Meeting.

Finally, we have implemented our Health IT Tool in the clinic assessments of nearly 100 patients at our vascular surgery clinic. In a recent manuscript published in BMC Medical Decision Making (2015), we described the following:

1. Adherence varies by provider, but has been good overall (approximately 70% of eligible visits).

2. The Epic EMR-integrated tool allows for efficient entry of the data necessary for the Carotid Risk Assessment Tool to function. Our data flow has allowed nursing to enter the primary data, and delivers this information to the clinician seeing the patient in "real time."

This EMR-integrated tool was used to guide construction of a patient-specific tool, called the carotid Option Grid. This tool has been published on-line at www.optiongrid.org.

Aim 2:

Our initial thoughts for the project centered around identifying high-risk individuals who were unlikely to benefit from the procedures, and then calculate the potential cost savings if these patients did not undergo surgery.

Typically, for carotid revascularization, an average procedure costs Medicare between $6,000 and $8,000. However, we have found that many of the costliest patients (in addition to those who probably didn't need the procedure in the first place) are those who have complications. Often, these patients have procedural related costs that can exceed $50,000 or more. These findings, and their implications for decision-making for patients with carotid artery surgery, were reported in the Journal of Vascular Surgery in 2015.

The goal of our Health IT tool is to help surgeons and patients make the right choices for carotid revascularization, such that the patients get the best treatments at the lowest cost. Therefore, to maximize the impact of our Health IT tool, we will introduced the potential for complications into our cost models. In our original analytic plan, the cost modeling would be most dependent on long-term patient survival. However, given the potential opportunity for additional savings if we pre-operatively identify those patients at high risk for complications, we feel that this modification is a worthwhile change to make in our modeling strategy.

6. B. Significance and Future Work

Our findings are significant in two specific ways. First, we have identified clinical factors that make it possible to use electronic medical records to identify patients who are unlikely to benefit from carotid artery revascularization, and efficiently convey these findings to providers. Second,

we have been able to estimate the impact of patient risk on costs with carotid revascularization, and have found that complications play a larger role than we may have imagined previously.

Given that this is an R21 proposal, the goal of this work was to develop future projects aimed at expanding our goal of providing patients with the most effective treatments for vascular disease. The data and publications derived from this proposal helped us to continue this work in two important ways. First, the value demonstrated in our linked clinical-claims datasets led the FDA to support efforts to continue this work via a project entitled "Creating national surveillance infrastructure for priority medical devices." (U01 FD005478-01 Sedrakyan = PI, Goodney = Co-I). Further, the application of our work to patients facing critical decisions about the use of new technology such as carotid artery stenting allowed us to be funded as part of a U01 proposal entitled "Technology diffusion, health outcomes, and healthcare expenditures (U01AG046830-01, Skinner = PI, Goodney = Co-I). And lastly, the application of this work towards patient decision-making helped us to obtain a PCORI Engagement Contract #2493 (Faerber = PI, Goodney = Co-I) entitled "Connecting Patients and Researchers to Engage in Patient-Centered Vascular Disease Research". These three projects are a direct result of the work funded in this proposal, and will help us reach our goal of providing patients the best way to use Health IT to make challenging decisions about treatments for carotid artery disease.

7. Bibliography

Grant Support Derived from this R21 proposal:

PCORI Engagement Contract #2493 (Faerber = PI) 2015-2017
"Connecting Patients and Researchers to Engage in Patient-Centered Vascular Disease Research"
Co-Investigator (0.1 FTE, in-kind)
$234,043

Patient Centered Outcomes Research Institute (PCORI). Advancing Patient Centered Outcomes Research in Survival Data with Unmeasured Confounding to Improve Patient Risk Communication (O'Malley = PI).
Co-Investigator (0.1 FTE)
$1,049,937

Food and Drug Administration U01FD005478-01 (Sedrakyan = PI) 2014-2016
The Vascular Implant Surveillance and Interventional Outcomes Network (VISION)
Co-Investigator (0.2 FTE)
$250,000 per annum

National Institutes on Aging U01AG046830-01 (Skinner = PI) 2013-2018
"Technology diffusion, health outcomes, and healthcare expenditures"
Co-Investigator
$543,326

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