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An Accumulated Deficits Model Predicts Perioperative and Long-term Adverse Events after Carotid Endarterectomy

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Abstract

Background—There is increasing recognition that decreased reserve in multiple organ systems, known as accumulated deficits (AD), may better stratify perioperative risk than traditional risk indices. We hypothesized that an AD model would predict both perioperative adverse events and long-term survival after carotid endarterectomy (CEA), particularly important in asymptomatic patients.

Methods—Consecutive patients undergoing CEA between 1st January 2000 and 31st December 2010 were retrospectively identified. Seven of the deficit items from the Canadian Study of Health and Aging–frailty index (coronary disease, renal insufficiency, pulmonary disease, peripheral vascular disease, heart failure, hypertension, and diabetes) were tabulated for each patient. Predictors of perioperative and long-term outcomes were evaluated using regression analysis.

Results—About 1,782 CEAs in 1,496 patients (mean age: 71.3 ± 9.3 years, 56.3% male, 35.4% symptomatic) were included. The risk of major adverse events (stroke, death, or myocardial infarction) at 30 days for patients with 3 deficits was 2.53% vs. 8.81% for patients with 4 deficits ($P < 0.001$). For patients with 5 deficits, the risk was 15.18%. Each additional deficit increased the odds of a 30-day major adverse event and hospital stay >2 days by 1.64 ($P < 0.001$) and 1.15 ($P < 0.001$), respectively. In multivariate analysis, the presence of 4 deficits was more predictive of perioperative major adverse events (odds ratio [OR] = 3.62, $P < 0.001$) than symptomatology within 6 months (OR = 1.57, $P = 0.08$) or octogenarian status (OR = 2.00, $P = 0.02$). Kaplan-Meier analysis showed significantly decreased survival over time with accumulating deficits ($P < 0.001$). Patients with 4 deficits have a hazards ratio for death of 2.6 compared to patients with 3 deficits ($P < 0.001$). Overall survival is estimated at 79.5% (95% confidence interval [CI]: 0.77–0.82) at 5 years in patients with 3 deficits versus 52.4% (95% CI: 0.46–0.58) in patients with 4 deficits, respectively. In subgroup analysis of asymptomatic patients, 5-year survival for octogenarian male patients with 4 deficits was only 26.8%. For asymptomatic males aged 70–79 years with 4 deficits, 5-year survival was 59.9%.

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Conclusions—An AD model is more predictive of perioperative adverse events after CEA than age or symptomatic status. This model remains predictive of long-term survival. In asymptomatic male octogenarians with 4 or more AD, 5-year survival is severely limited.

INTRODUCTION

The efficacy of carotid endarterectomy (CEA) for stroke risk reduction was established through randomized trials on both symptomatic and asymptomatic patients.¹⁻⁶ Since those landmark publications, some have hypothesized that advancements in pharmacologic management of carotid disease has again made ideal management of carotid stenosis, particularly asymptomatic disease, an issue with clinical equipoise.⁷⁻⁹ As this question is ongoing, selection of appropriate candidates for surgery and more accurate risk stratification has become a pressing issue.

Recently, there has been increasing recognition that decreased reserve in multiple organ systems, also known as accumulating deficits, may better stratify perioperative risk than traditional risk indices.^{10,11} This biologic syndrome, which results in decreased resistance to stressors and increased vulnerability to morbidity, has been termed frailty.¹²

Multiple frailty indices have been developed to scale a patient's AD and predict their operative risk.¹³ These scores have consistently been confirmed as independent risk factors for predicting adverse outcomes for surgical patients across a range of specialties including vascular surgery.^{10,11,14-16} Both the modified frailty index (mFI), an 11-point index developed in the American College of Surgeon National Surgical Quality Improvement Program (NSQIP) database, and the Risk Analysis Index (RAI), a simplified version of the Porock 6-month mortality index, have been validated in CEA patients in these national data sets demonstrating that an increasing number of AD is associated with increased 30-day adverse events after CEA including stroke, mortality, and length of stay.^{11,17,18}

The major limitation of the existing analyses using the mFI and RAI is the use of national data sets which specifically lack long-term follow-up data. For CEA patients, especially asymptomatic patients in whom the objective is long-term stroke risk reduction, information about life expectancy and long-term outcomes beyond 30 days is critically important in decision-making.^{19,20}

We hypothesized that an AD model would predict both perioperative adverse events and long-term survival after CEA. To test this, we applied an AD model to a retrospective database of patients at our institution with long-term follow-up data available.

METHODS

Consecutive individuals who underwent CEA by the Division of Vascular Surgery at the University of Pittsburgh between 1st January 2000 and 31st December 2010 were identified by the Current Procedural Terminology code 35301. The records were reviewed for demographics, baseline risk factors, carotid duplex studies, operative indications, intraprocedural data, periprocedural complications, and follow-up events. The social security death index was used to record death dates. Patients who underwent concomitant

cerebrovascular procedures (e.g. carotid-to-subclavian bypass) or concomitant coronary artery bypass grafting were excluded from the study. End points were time to discharge from initial surgery and stroke, death, or myocardial infarction (MI) occurring any time after the operation.

Definitions

All baseline risk factors were recorded based on established diagnoses identified in the medical records. Preoperative parameters of interest included age, gender, and pertinent comorbidities. Elements from the 70-item FI developed from the Canadian Study of Health and Aging and from which the mFI was created and the RAI were mapped to items recorded in the database.^{17,21} Seven items from the FI and RAI were recorded in our database including a history of hypertension, diabetes mellitus, chronic renal insufficiency, coronary artery disease, peripheral vascular disease, pulmonary disease, and congestive heart failure.

These 7 comorbidities were tabulated to create an AD score for each patient (Table I). Symptomatic carotid stenosis was defined as a preprocedural ipsilateral ischemic stroke or transient ischemic attack occurring in the 6 months before operation.²³ Postoperative stroke was defined as stroke occurring within 30 days of the operation. After 30 days, only the first ipsilateral and/or contralateral stroke was recorded, and these were defined as follow-up strokes. A greater than 2-day hospital stay after surgery was considered a delayed discharge.

Carotid Endarterectomy

CEA was performed under general anesthesia in all cases. Closure technique (primary, patch, or eversion) and shunt use (selective versus routine) were variable and based on physician preference.

Statistical Analysis

An AD score was assigned to each patient on a scale of 0 to 7 based on the number of deficits from Table I in their medical history. Descriptive characteristics are reported as means $\pm$ standard deviations or as number of cases and percentages. Baseline characteristics were compared by chi-squared tests for categorical data and Student's *t*-test for continuous data. Logistic regression analysis was used to examine the effect of AD score on 30-day stroke, MI, and death as well as delayed discharge (considered greater than 2 days). Cox regression models were used to assess the effect of baseline predictors on follow-up end points. Time zero was defined as the date of the initial procedure. For stroke-free survival analyses, cases were censored on the date of the last recorded clinical follow-up that allowed accurate information collection, unless the studied event occurred at an earlier time point. For the mortality end point, events were recorded on the date of death according to the social security death index. Patients were censored on the date of the last available clinical follow-up. Survival functions were estimated by the Kaplan-Meier method and evaluated using a log-rank test. Results were considered statistically significant when *P* value was less than 0.05. Data analysis was performed using Stata Statistical Software: Release 14 (College Station, TX: StataCorp LP).

RESULTS

About 1,782 CEAs in 1,496 patients (mean age: 71.3 ± 9.3 years, 56.6% male, 35.4% symptomatic) were included. Mean clinical follow-up was 48.5 ± 38.0 months. Baseline characteristics, broken down by symptom status, are summarized in Table II. The AD score (or number of deficits) was calculated for each patient. Most patients had 1–3 deficits (Table III).

30-day Outcomes

The risk of major adverse events (stroke, death, or MI) increased with an increasing number of AD score (Fig. 1). The risk of stroke, MI, or death at 30 days for patients with 3 deficits was 2.53% vs. 8.81% for patients with 4 deficits ($P < 0.001$). For patients with 5 deficits, the risk was 15.18%.

Each additional deficit increased the odds of a 30-day major adverse event by 1.64 ($P < 0.001$). In a multivariate logistic regression analysis, the presence of 4 deficits was more predictive of perioperative major adverse events (odds ratio [OR] = 3.62, $P < 0.001$) than symptomatology within 6 months (OR = 1.57, $P = 0.08$) or octogenarian status (OR = 2.00, $P = 0.02$). The prognostic ability of these predictors was compared by area under their receiver operator curve which was 0.56 for both age and symptom status. The area under the curve (AUC) for the AD model was 0.67, statistically significantly better than the other models ($P < 0.001$, Fig. 2). The overall model including the AD score, age, and symptom status was not a statistically better discriminator than the AD model alone ($P = 0.12$).

For asymptomatic patients, the AD model was similarly predictive of 30-day stroke, death, or MI (Fig. 3). While the risk was statistically significantly higher for symptomatic patients (OR = 1.17, $P = 0.04$), the risk of 30-day stroke, death, or MI in asymptomatic patients was notable at 8.2% for patients with 4 deficits and 15.9% for patients with 5 deficits.

Asymptomatic patients with 4 deficits had a 4.1% risk of stroke within 30 days of surgery compared to a <1% risk for patients with 3 deficits. The risk for patients with increasing number of deficits, analyzed overall and by symptom status, is summarized in Table IV.

The AD model was also highly predictive of a delayed discharge after surgery (hospital stay >2 days). Each additional deficit increased the odds of a delayed discharge by 1.15 ($P < 0.001$).

Long-term Outcomes

Kaplan-Meier analysis showed significantly decreased survival over time with accumulating deficits (Fig. 4, $P < 0.001$). Patients with 4 deficits have a hazards ratio for death of 2.6 compared to patients with 3 deficits ($P < 0.001$). Overall survival is estimated at 79.5% (95% confidence interval [CI]: 0.77–0.82) at 5 years in patients with 3 deficits versus 52.4% (95% CI: 0.46–0.58) in patients with 4 deficits, respectively.

In subgroup analysis of asymptomatic patients, 5-year survival for the highest risk group, octogenarian male patients with 4 deficits, was only 26.8%, but 67.4% if 3 deficits. For asymptomatic males aged 70–79 years with 4 deficits, 5-year survival was 59.9%.

DISCUSSION

Our analysis demonstrated that a simple 7-element AD model is highly predictive of perioperative stroke as well as the combined risk of stroke, MI, or death for both symptomatic and asymptomatic patients. This model remains predictive of long-term survival.

Increasing AD score was significantly associated with an increased stroke, MI, or death at 30 days. The number of AD predicted perioperative adverse events better than the patient's age or symptom status, traditionally considered markers of high perioperative risk.^{24,25} Age in particular added very little to the discriminative ability of the AD score model to predict perioperative adverse events, which is supportive of the idea of frailty measures as a sort of biological age.

It is noteworthy that in the asymptomatic cohort with 5 deficits, the risk of stroke and combined risk of stroke, MI, or death within 30 days of operation was unacceptably high at 8.7% and 15.9%, respectively. This far exceeds the current guidelines' recommendation that CEA should be considered for asymptomatic patients with stenosis of 60% as long as the expected combined stroke and mortality rate was not >3%.^{6,26} In patients with asymptomatic disease and more than 4 deficits, surgeons should likely pursue a frank conversation about perioperative risks and consider medical management or, at least, risk factor modification before surgery.

The number of AD a patient had at the time of surgery remained highly predictive of their long-term survival after surgery. In particular, men over 80 years old, with 4 deficits are unlikely to survive 5 years after surgery. This is the first analysis of carotid stenosis patients to show that an AD model is correlated with long-term outcomes after surgery.

The results of this current analysis are in agreement with a growing body of literature correlating an increasing number of deficits, or frailty, with surgical outcomes across a variety of specialties, including vascular surgery. Evidence suggests that this type of model, a quantitative version of the "surgical eyeball test," may distinguish high-risk patients more accurately than previously utilized risk indices.²⁷ There is a limited body of work analyzing the AD and postoperative outcomes in carotid patients.

Ehlert et al.¹¹ compared the mFI to Lee Cardiac Risk Index and the American Society of Anesthesiologists Physical Status Classification to predict 30-day mortality in patients undergoing open carotid revascularization, abdominal aortic aneurysm repair, or lower extremity revascularization using the NSQIP database and found that the frailty score was the best discriminator of mortality. Kraiss et al. have developed and validated a frailty model in the Vascular Quality Initiative data using 7 data elements and procedure-based risk estimates to predict 9-month mortality after arterial reconstruction with an AUC of 0.76. Their initial validation included carotid patients.²⁸ Arya et al.¹⁶ similarly found that

preoperative frailty (mFI > 0.25) was associated with a 2-fold increased risk of nonhome discharge after elective vascular surgical procedures including carotid surgery.

Only one published study has looked exclusively at patients undergoing CEA. Melin et al. examined CEA patients in the NSQIP database from 2005 to 2011 using matched variables from the RAI and found that frailty was a predictor of 30-day stroke, MI, mortality, and increased length of stay. They suggested that the RAI or a similar screening tool of AD has the potential to help identify patients that may not benefit from CEA.¹⁷

While our results have reinforced the results of some these initial publications, one of the major limitations of the data gleaned from large national databases is their lack of long-term follow-up. The advantage of our carotid database is the long clinical follow-up period: a mean of more than 4 years. In addition, our data has very accurately identified true symptomatic disease (i.e. stroke or transient ischemic attack in the last 6 months). The timing of previous strokes or neurologic events is not readily available in the NSQIP data.

The importance of a deficits assessment is not only to predict risk but also to possibly reduce or modify risk. Recently, Hall et al. showed that implementation of a preoperative frailty screening initiative was actually associated with reduced mortality compared with patients treated before the initiative.²⁹ In their study, patients with high RAI scores were flagged for administrative review and possible modification of surgical plans or preoperative optimization.³⁰

For many conditions, less invasive approaches or nonsurgical management may not be feasible. However, carotid disease provides a unique pathology with multiple treatment modalities (open surgical, endovascular, and medical) where frailty screening may actually shape management.³¹ In particular, asymptomatic patients must have excellent outcomes and a reasonable life expectancy to justify a prophylactic operation.^{32,33}

There are a number of limitations to this present study. This is a retrospective study. Risk factors, postoperative and long-term events were determined from patient electronic medical record reviews and chart diagnoses. Medication use is subject to patient adherence which was not captured in this data. Moreover, it is possible that patients with limited follow-up developed neurologic events and were treated elsewhere so that symptomatic patients would be under-represented in our analysis. Transient ischemic attacks during the follow-up cannot be accurately captured so our analysis accounted for strokes only. In addition, this is a single-institution study so these results may not be generalizable to other centers. Finally, this analysis is based on existing variables in our database that matched with known items from validated frailty scores such as the RAI or the FI. Because the data does not exactly match any validated index, the AD score does not represent a true “frailty score” but simply a summation of comorbidities.³⁴

CONCLUSION

An AD model is more predictive of perioperative adverse events after CEA than age or symptomatic status. This model remains predictive of long-term survival. In asymptomatic male octogenarians with 4 or more AD, 5-year survival is severely limited.

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Fig. 1.

The risk of 30-day adverse events by accumulated deficits score (x-axis) is depicted.

Fig. 2.

The area under the receiver operator curve (ROC) for multiple predictive models for 30-day stroke, MI, and death after CEA.

Fig. 3.
The risk of 30-day adverse events by accumulated deficits score (x-axis) and symptom status is depicted.

Fig. 4.

Combined Kaplan-Meier plots illustrate survival after carotid endarterectomy. The embedded tables show the respective freedom rates at 1 year, 5, and 10 years. At all times, the standard error (SE) is <0.1.

Table I

Accumulated deficits model

FI/RAI item	Matching database variable	Database variable definition
Arterial hypertension	Hypertension	Systolic blood pressure (SBP) of 140 mm Hg or more, or a diastolic blood pressure (DBP) of 90 mm Hg or more, or taking antihypertensive medication ²²
History of diabetes mellitus	Diabetes mellitus	A record of diabetes diagnosis in the medical record or prescribed oral hypoglycemic medication or insulin
Renal insufficiency	Chronic renal insufficiency	Serum creatinine consistently greater than 1.5 mg/dL or dialysis dependence
Cardiac problems	Coronary artery disease	A record of coronary disease, percutaneous coronary intervention, coronary artery bypass grafting, or myocardial infarction
Myocardial infarction		
Decreased peripheral pulses	Peripheral vascular disease	Documented history of peripheral vascular endovascular intervention, infrainguinal or suprainguinal bypass surgery, amputation, claudication, rest pain, or gangrene
Lung problems	Pulmonary disease	Documentation of chronic obstructive pulmonary disease
Respiratory problems		
Shortness of breath at rest		
Congestive heart failure	Congestive heart failure	Documentation of congestive heart failure

Table II

Baseline characteristics

Baseline characteristic	Overall	Symptomatic	Asymptomatic	P value
Gender: male	847	332	515	0.1
	56.6%	59.3%	55.0%	
Age (years)	71.3 ± 9.3	71.2 ± 10.0	71.4 ± 8.9	0.7
HTN	1,286	476	810	0.1
	88.3%	86.5%	89.3%	
DM	483	181	302	0.9
	33.1%	32.9%	33.2%	
CRI	565	92	156	0.9
	32.4%	16.5%	16.9%	
CAD	795	284	511	0.1
	54.7%	56.3%	52.0%	
PVD	327	106	221	0.03 *
	22.6%	19.5%	24.5%	
Pulmonary disease	266	117	149	0.02 *
	18.5%	21.5%	16.8%	
CHF	137	60	77	0.1
	9.5%	11.1%	8.6%	
Statin use	985	365	621	0.3
	68.4%	66.9%	69.3%	
Antiplatelet use (aspirin and/or plavix)	1,236	543	930	0.03 *
	86.6%	89.8%	84.6%	
Smoker (previous or current)	1,017	381	636	0.9
	72.0%	71.8%	72.2%	

CAD, coronary artery disease; CHF, congestive heart failure; CRI, chronic renal insufficiency; DM, diabetes mellitus; HTN, hypertension; PVD, peripheral vascular disease.

* Indicates statistically significant when *P* value was less than 0.05.

Table III

Number of patients per AD score

Number of deficits (AD score)	Number of patients
0	89 (5.95%)
1	333 (22.26%)
2	422 (28.21%)
3	373 (24.93%)
4	180 (12.03%)
5	69 (4.61%)
6	29 (1.94%)
7	1 (0.07%)

Table IV

Postoperative events by AD score

Number of deficits	All patients		Symptomatic		Asymptomatic	
	Stroke (%)	Stroke, death, or MI (%)	Stroke (%)	Stroke, death, or MI (%)	Stroke (%)	Stroke, death, or MI (%)
0	1.0	1.0	2.3	2.3	0	0
1	1.0	1.3	1.6	2.4	0.8	0.8
2	2.3	3.8	3.8	4.8	1.2	3.1
3	1.3	2.5	3.1	3.9	0.63	1.9
4	2.4	5.3	3.7	7.4	1.6	4.0
5+	6.3	15.2	2.3	14.0	8.7	15.9