J Neurosurg 116:1251–1257, 2012

National trends in carotid artery revascularization surgery

Clinical article

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Object. Several randomized trials have emerged with conflicting data on the overall safety of carotid artery stenting (CAS) in comparison with carotid endarterectomy (CEA). The authors hypothesize that changes in national trends correspond to publication of randomized trials, including an increase in utilization of CAS after publication of trials favorable to CAS (for example, Carotid and Vertebral Artery Transluminal Angioplasty Study [CAVATAS] and Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy [SAPPHIRE]) and decrease in utilization of CAS after publication of trials favorable to CEA (for example, Endarterectomy versus Stenting in Patients with Symptomatic Severe Carotid Stenosis [EVA3-S] and Stent-Supported Percutaneous Angioplasty of the Carotid Artery versus Endarterectomy [SPACE]).

Methods. The Nationwide Inpatient Sample was obtained for the years 1998–2008. Individual cases were isolated for principal diagnosis of unilateral or bilateral carotid artery stenosis or occlusion undergoing CEA or CAS. The percentage of CAS for all carotid revascularization procedures was calculated for each year. Perioperative inpatient morbidity, including stroke or death, were calculated and compared.

Results. The percentage of patients undergoing CAS increased yearly from the start of the observed period to the end, with the exception of a decrease in 2007. The peak utilization of CAS for carotid artery revascularization procedures was 15% of all cases in 2006. The stroke or death rate was consistent at 5% among all patients undergoing CEA for all years, while the incidence of stroke or death decreased among patients undergoing CAS from 9% in 1998 to 5% in 2008.

Conclusions. The practice of CAS in the US is expanding, from less than 3% of all carotid artery revascularization procedures to 13% in 2008. The utilization of CAS was seen to correlate with publication of randomized trials. Utilization nearly doubled in 2005 after publication of the CAS-favorable SAPPHIRE in 2004, and decreased by 22% after publication of the CEA-favorable EVA-3S and SPACE in 2007. With the publication of Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST), the authors predict a resultant increase in the rate of CAS for carotid artery disease in the upcoming years.
(http://thejns.org/doi/abs/10.3171/2012.3.JNS111320)

Key Words • **carotid artery stenosis** • **endarterectomy** • **stent** • **Nationwide Inpatient Sample** • **vascular disorders**

Due to the relative ease of placement and generalized popularity of minimally invasive procedures, CAS has emerged as an option to CEA for revascularization of carotid artery stenosis.[1] Several randomized trials have produced conflicting data on the overall safety of CAS in comparison with CEA. Although 2 recent trials have demonstrated statistical noninferiority of CAS to CEA, no trials have displayed superiority of CAS to CEA in terms of perioperative safety.

The role of CAS is in evolution with the publication of successive randomized trials. The purpose of this study is to characterize the utilization of CAS relative to CEA in the US during the evolution of CAS technology and publication of these trials. Utilization of CAS for treatment of carotid artery stenosis on a year-to-year basis, the spectrum of perioperative complications, and the demographics of patients treated are analyzed. We hypothesize that the publication of trials favorable to CAS

Abbreviations used in this paper: ACAS = Asymptomatic Carotid Atherosclerosis Study; CAS = carotid artery stenting; CAVATAS = Carotid and Vertebral Artery Transluminal Angioplasty Study; CEA = carotid endarterectomy; CREST = Carotid Revascularization Endarterectomy Versus Stenting Trial; EVA-3S = Endarterectomy versus Stenting in Patients with Symptomatic Severe Carotid Stenosis; ICSS = International Carotid Stenting Trial; NASCET = North American Symptomatic Carotid Endarterectomy Trial; NIS = Nationwide Inpatient Sample; SAPPHIRE = Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy; SPACE = Stent-Supported Percutaneous Angioplasty of the Carotid Artery versus Endarterectomy.

(SAPPHIRE) are associated with increased use and that publication of trials favorable to CEA (EVA 3-S, SPACE) are associated with decreased use of CAS.

Methods

The NIS was obtained from the Agency for Healthcare Research and Quality for the years 1998–2008. This database includes roughly 8 million hospitalizations annually (serving as a stratified sample of about 20% of all admissions) and serves as a representative sample of inpatient admissions in the US. For the purposes of this study, individual cases were isolated based on ICD-9 codes for a principal diagnosis of unilateral or bilateral carotid artery stenosis or occlusion (codes 433.10, 433.11, 433.30, and 433.31) undergoing a primary procedure of CEA (code 38.12) or CAS (codes 00.63, 39.50, 39.7, and 39.90). The NIS allows for collection of up to 14 diagnoses in addition to the primary diagnosis. These ICD-9 codes were queried to create a list of premorbid conditions and periprocedural complications. For each record, a list of premorbid conditions was built based on the comorbidity score of Elixhauser et al.[4] For the purpose of this study, the Elixhauser score was modified by removing the "paralysis" and "other neurological disorders" subscores. Due to its relevance for the topic, a separate comorbidity subscore "coronary artery disease" was created based on relevant ICD-9 codes (codes 412.0–412.9, 414.0, 414.2, 414.3, 414.8, and 414.9) and individually tested but not included in calculation of the comorbidity score. Due to potential clinical relevance, the Elixhauser comorbidity subscores "diabetes—uncomplicated" and "diabetes—complicated" were summated into a single subscore (hereafter referred to as "diabetes mellitus") for individual testing.

The primary end point was inpatient stroke or death. The NIS captures information from singular inpatient hospitalizations; thus, long-term stroke or mortality risks cannot be measured. Secondary end points of interest include other periprocedural complications, length of stay, hospital charges, and discharge disposition. The ICD-9 diagnostic codes were queried to create a list of periprocedural complications. The ICD-9 codes corresponding to the primary and secondary complication end points are summarized in Table 1. Inpatient complications were identified by searching for ICD-9 codes that would be representative of acute postoperative complications and not of preexisting conditions. Length of stay is reported in days for individuals. Hospital charges are compared annually and are thus not adjusted for inflation. Discharge disposition is listed for individuals in 1 of 2 categories: home or rehabilitation/skilled nursing facility.

The percentage of CAS performed for all carotid revascularization procedures is calculated for each year. The combined incidence of inpatient stroke or death for CAS and CEA is calculated for each year and is compared using ANOVA with the Tukey test to an alpha level of 0.05. The overall inpatient stroke or death risk is compared using the chi-square test. Identical analysis was carried out for other periprocedural complications. The CAS and CEA rates are reported as a percentage of all carotid revascularization procedures. Complication rates are reported as a percentage. The Cochran-Armitage chi-square test for trend was used to analyze the utilization of CAS and incidence of inpatient stroke or death for the years included in the study. For all statistical compari-

TABLE 1: List of complications and their ICD-9 CM codes*

Complication	ICD-9 CM
stroke	
intracerebral hemorrhage	431.0
nervous system complications	997.0
cardiac complication	
acute myocardial infarction	410
cardiac arrest	427.5
acute CHF, systolic	428.21
acute on chronic CHF, systolic	428.23
acute CHF, diastolic	428.31
acute on chronic CHF, diastolic	428.33
acute CHF, systolic & diastolic	428.41
acute on chronic CHF, systolic & diastolic	428.43
cardiac complication of medical/surgical care	997.1
pulmonary complication	
acute bronchitis & bronchiolitis	466
pneumonia	480–488
pneumothorax	512
pulmonary insufficiency after op	518.5
acute respiratory failure	518.81
other pulmonary insufficiency	518.82
respiratory complication of medical/surgical care	997.3
thromboembolic complication	
acute pulmonary heart disease	415
phlebitis & thrombophlebitis	451
acute deep venous thromboembolism of LE	453.4
acute venous thromboembolism of other veins	453.8
peripheral vascular complications resulting from a procedure	997.2
renal & genitorurinary complications	
acute glomerulonephritis	580
acute kidney failure	584
acute pyelonephritis	590.1
postop urethral stricture	598.2
infection due to indwelling urinary catheter	996.64
wound complication	
hemorrhage or hematoma complicating a procedure	998.1
disruption of wound	998.3
postop infection	998.5
miscellaneous complications	
transient hypoglycemia postprocedure	251.2
transient hyperglycemia postprocedure	790.29
postop hypotension	458.29
postprocedural fever	780.62
shock due to anesthesia	995.5

* CHF = congestive heart failure; LE = lower extremity.

sons, an alpha level of 0.05 was used to determine statistical significance. Data were analyzed using SAS (version 9.2, SAS Institute, Inc.) and GraphPad Prism (version 5.0, GraphPad Software, Inc.).

Results

A total of 288,188 patients were captured in the NIS and underwent CAS or CEA for carotid artery occlusion. Patients undergoing CAS numbered 18,840, while patients undergoing CEA numbered 269,348. As this represents roughly one-fifth of patients treated, an estimate of actual CAS and CEA procedures performed in the US during the years 1998–2008 would number in excess of 90,000 and 1,350,000, respectively. Patients treated with CAS or CEA were similar with respect to mean age, sex, and preexisting comorbidities. The mean age at intervention was 71 years for patients undergoing CEA or CAS. The majority of patients (57.2% of CEA patients; 59.8% of CAS patients) were men. The majority of patients in both groups were white (86.6% of CEA patients; 90.7% of CAS patients), with a similar breakdown between minority ethnicities. The mean comorbidity score was 1.8 ± 1.0 for CEA patients and 1.9 ± 1.0 for CAS patients, with a similar breakdown of comorbidity scores between groups. Incidences of premorbid hypertension (68.8% vs 65.1%), coronary artery disease (40.3% vs 50.4%), and diabetes mellitus (26.8% vs 28.9%) were similar between the CEA and CAS groups. A CEA was more likely to be performed with an elective admission than CAS (83.2% vs 71.8%). A CAS was more likely to be performed at a teaching hospital (63.7%) than CEA (44.2%). Demographic data and premorbid conditions for patients undergoing CEA or CAS are summarized in Table 2.

There was an overall increase in the utilization of CAS from 2.8% to 12.6% of all carotid stenosis revascularization procedures from 1998 to 2008 ($p < 0.0001$, chi-square for trend). Carotid stenting procedures captured in the NIS increased from roughly 1000 to more than 3000 (Table 3). The year-by-year utilization of CAS changed at a variable rate. The mean rate of increased yearly utilization of CAS was 25.7%, with a maximum of 57.3% in 2005, and a minimum of –22.5% in 2007. Figure 1 summarizes the utilization of CAS during the study period.

The perioperative inpatient incidence of stroke or death is higher for patients undergoing CAS (6.3%) than for those undergoing CEA (4.7%, $p < 0.0001$). For elective cases, the incidence of stroke or death was decreased overall, but it remained lower in the patients undergoing CEA (4.7% vs 4.2%, $p = 0.010$). A trend toward decreased stroke or death as a complication was seen in patients undergoing CAS during the study period, from a maximum of 10.7% in 2000 to a minimum of 4.4% in 2007 ($p = 0.0472$, chi-square for trend). In 2007 the acute stroke or death risk was lower in patients undergoing CAS than in patients undergoing CEA (4.4% vs 4.5%, $p < 0.05$). In all other years, the stroke or death risk for CAS exceeded that of CEA (Fig. 2). There were significant decreases in inpatient stroke or death morbidity in the later years of the study period (2005–2008) compared with the earlier years in the study period (1998–2001) ($p < 0.05$ ANOVA, Tukey test summarized in Table 4).

Complications were generally more frequent for patients undergoing CAS than for those undergiong CEA (Table 5). The overall mortality rate was low, at 0.4%, although the risk of inpatient mortality was higher in patients undergoing CAS than in those undergoing CEA (1.0% vs 0.4%, $p < 0.001$). This relationship was noted for stroke (5.9% vs 4.5%, $p < 0.001$), cardiac complications (3.0% vs 2.2%, $p < 0.001$), pulmonary complications (both 2.0%, $p = 0.772$), and renal complications (1.5%

TABLE 2: Demographic data and premorbid conditions for patients undergoing CEA or CAS

Characteristic	CEA	CAS	p Value
no. of patients	269,321	18,840	
mean age (yrs ± SD)	71.1 ± 9.3	70.7 ± 10	<0.0001
sex			<0.0001
male	57.2%	59.8%	
female	42.8%	40.2%	
race*			<0.0001
white	86.6%	90.7%	
black	4.3%	3.2%	
Hispanic	4.4%	3.4%	
other	4.7%	2.7%	
Elixhauser comorbidity score			<0.0001
0	11.1%	10.1%	
1	28.5%	23.3%	
2	30.2%	29.6%	
3	30.2%	37.0%	
atherosclerosis risk factor			
coronary artery disease	40.3%	50.4%	<0.0001
hypertension	68.8%	65.1%	<0.0001
diabetes mellitus	26.8%	28.9%	<0.0001
teaching hospital	44.2%	63.7%	<0.0001

* Data are missing for 24%.

TABLE 3: The number of CEA and CAS procedures captured in the NIS years 1998–2008

Year	CEA	CAS
1998	22,287	647
1999	25,925	937
2000	26,511	941
2001	26,719	1249
2002	27,413	1330
2003	23,379	1341
2004	23,437	1750
2005	23,109	2825
2006	21,965	3752
2007	21,983	2797
2008	21,843	3131

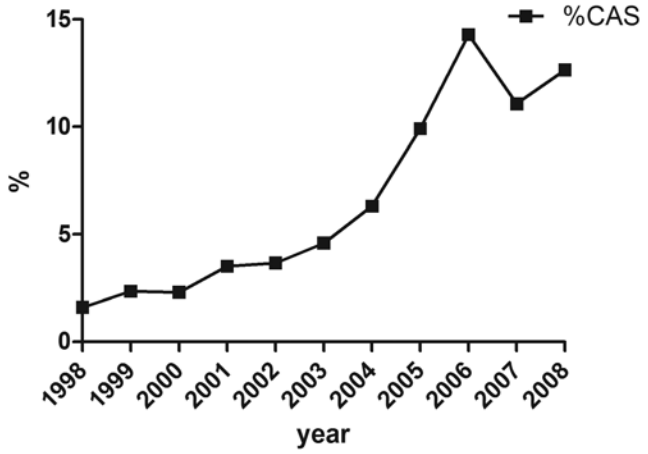

Fig. 1. Graph showing that CAS utilization increased during the study period, from 3% to 13% of all carotid revascularization procedures. A 45% increase in utilization of CAS is seen in 2005 after publication of SAPPHIRE in 2004. A 20% decrease in the number of CAS performed in 2007 coincides with the publication of EVA-3S and SPACE in 2006. Both of these studies were unfavorable to CAS procedures compared with CEA.

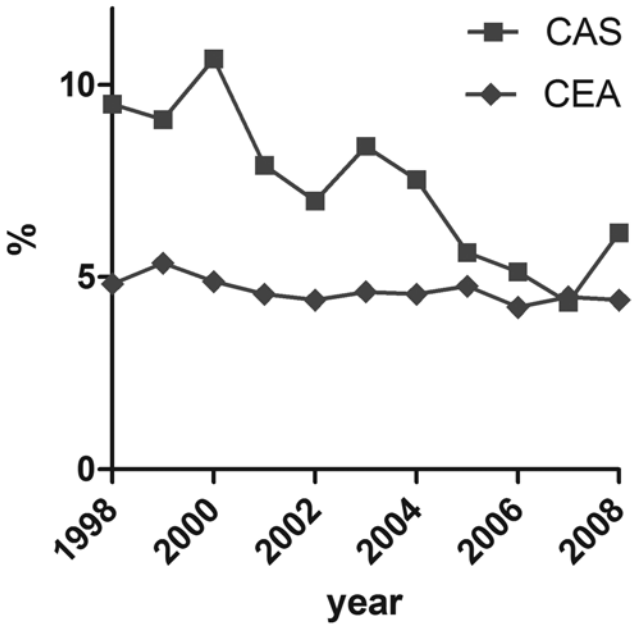

Fig. 2. The stroke or death rate after CEA was consistent at about 5% annually, while the incidence of inpatient stroke or death following CAS decreased from 9% to 5% over the study period.

vs 0.6%, $p < 0.001$). Complication rates were lower and more comparable among elective cases of CAS or CEA including mortality (both 0.3%, $p = 0.326$), stroke (4.6% vs 4.1%, $p = 0.004$), cardiac complications (2.7% vs 2.1%, $p < 0.001$), pulmonary complications (1.0% vs 1.8%, $p < 0.001$), and renal complications (1.0% vs 0.5%, $p < 0.001$). With the exception of stroke and death, complications were generally seen to decrease during the years studied for patients undergoing CAS. Renal complications increased in patients undergoing CAS or CEA. Cardiac and pulmonary complications were generally stable during the years studied for patients undergoing CAS or CEA.

Despite a shorter median length of stay for patients undergoing CAS (1 day compared with 2 days for CEA), the median hospital charge was higher for patients undergoing CAS ($29,278 vs $14,874 for CEA). Most patients were discharged home (92.5% of CAS patients and 95.3% of CEA patients, $p < 0.001$). Among elective cases, 96.1% of CAS patients and 96.7% of CEA patients were discharged home ($p = 0.006$). The median hospital charge for both treatments was the same for elective cases.

Discussion

Randomized trials represent the "gold standard" of clinical science, and NASCET and ACAS established CEA as the "gold standard" for treatment of symptomatic and asymptomatic carotid artery stenosis. The first trials of CEA published in 1970 and 1984 displayed unfavorable complication rates compared with medical treatment.[6,16] The CEA was first developed in the 1950s, and the technique was practiced and improved upon despite the negative results of these trials. When NASCET was published in 1991, well over 30 years of clinical experience led to improved outcomes and acceptable perioperative morbidity. Similarities may be drawn to the first trials of CAS.

Randomized trials for CAS began within a decade of its introduction as a technique. The first of its kind, the CAVATAS randomized 504 patients to CAS or CEA. The results published in 2001 showed no significant change in perioperative stroke or death risk, at about 10% for each group.[2] However, stents were used in the minority of patients undergoing endovascular treatment, and a higher than expected complication rate for both treatments caused variable interpretation of the role of CAS.[9,17] Although limited in practical impact, this trial in part established standards such as stenting for endovascular treatment of carotid artery stenosis.

The promise of carotid stent angioplasty displayed by CAVATAS prompted additional study. Because CEA is a robust treatment with minimal side-effect profile,[14] CAS first emerged as an alternative treatment for patients at high risk for CEA, or less suitable for CEA.[1] Subset analysis of NASCET and ACAS suggested that CEA may not be beneficial to octogenarians and patients with medical comorbidities that would increase the risk of surgery.[5] The SAPPHIRE study took into account these observations.[18] It was also designed, in part, to test the efficacy of emerging stent and promising distal protection devices.[7,10] The SAPPHIRE study randomized 334 patients at high risk for endarterectomy to CAS or CEA. Published in 2004, the SAPPHIRE study displayed noninferiority to CEA with a perioperative risk of stroke, myocardial infarction, or death of 4.4%.[18] Its publication coincided with the FDA approval of the first CAS system in August 2004.[11]

The concurrent publication of 2 European randomized trials in 2006 clouded the understanding of the risks and benefits of CAS compared with CEA.[2,4–13,15] Neither study was favorable for CAS, although the validity of

TABLE 4: A summary of the ANOVA Tukey test comparing incidence of inpatient stroke or death between each of the study years*

	p Value			
Year	2005	2006	2007	2008
1998	NS	0.05	0.05	NS
1999	0.05	0.05	0.05	NS
2000	0.05	0.05	0.05	0.05
2001	NS	NS	0.05	NS
2002	NS	NS	NS	NS
2003	NS	0.05	0.05	NS
2004	NS	0.05	0.05	NS

* NS = not significant.

these studies has been questioned due to potential selection bias and insufficient surgeon experience, among other potential problems including nonuniform stenting procedures.[8] The EVA-3S study randomized 527 symptomatic patients to either CAS or CEA. Patient randomization was stopped when interim analysis showed a perioperative risk of stroke or death of 9.6% and 3.9% for CAS and CEA, respectively.[13] The SPACE trial randomized 1200 patients with symptomatic carotid stenosis to CAS or CEA. Although the incidence of perioperative stroke or death risk was similar at 6.8% and 6.3% for CAS and CEA, respectively, the differential was insufficient to suggest noninferiority of CAS compared with CEA.[15]

The 2 largest trials to date comparing CAS with CEA were published in 2010. The CREST randomized 2502 patients over a 9-year period to undergo CAS or CEA.[12] The ICSS published preliminary perioperative results in 2010.[3] The ICSS randomized 1733 patients to undergo CAS or CEA. While CREST displayed equipoise between CAS and CEA, ICSS favored CEA with respect to perioperative risk of morbidity. Both trials featured more stringent methodological criteria than their predecessors, including a credentialing program for CAS performers and perioperative anticoagulation. In CREST, a singular stent device was used, and the use of an embolic protection device was requisite unless technically unable.[12] In ICSS, selection of stenting device and the use of embolic protection were deferred to the clinician. Although similar in design, the results were distinct. In CREST, the primary end point of perioperative stroke, myocardial infarction, or death (7.2% and 6.8%) was unchanged between CAS and CEA. The risk of stroke (4.1% and 2.3%) and death (0.7% and 0.3%) was nearly double for patients undergoing CAS than for patients undergoing CEA. Although the major measured benefit of CAS in the perioperative period was reduction of myocardial infarction, CREST is the largest study to date comparing CAS and CEA, and it displays noninferiority of CAS to CEA. In ICSS, the primary end point of perioperative stroke, myocardial infarction, or death (8.5% and 5.2%) favored CEA.

The role for CAS for patients eligible for CEA remains unclear. Like the early analysis of CEA, randomized trials commenced while the surgical technique for CAS was developing, and high morbidity rates in the first trials for both techniques reveal this truth. The practice of CAS in the US is expanding, from less than 3% of all carotid artery revascularization procedures to nearly 13% in 2008 (Fig. 1). Concurrently, perioperative stroke or deaths during admission decreased from nearly 10% from 1998 to 2000 to less than 6% from 2006 to 2008 (Fig. 2). With favorable results of the CREST trial, the performance of CAS may continue to increase. With improved training and standardization of care, perioperative morbidity from CAS could continue to decline and CAS may ultimately eclipse CEA as the new standard for treatment. However, to date the results of randomized trials and population data presented in this report support CEA as the standard for carotid revascularization procedures.

This historical review of utilization of CAS in the US serves as an example of how the publication of randomized trials affects patterns of clinical care. We hypothesized increased use of CAS compared with CEA after publication of trials displaying noninferiority to CEA. These trials include CAVATAS, SAPPHIRE, and

TABLE 5: Top 5 complications by year*

	Stroke		Cardiac		Pulmonary		Renal		Death	
Year	CAS	CEA	CAS	CEA	CAS	CEA	CAS	CEA	CAS	CEA
1998	9.1	4.9	2.7	2.2	2.7	1.9	0.8	0.3	0.6	0.4
1999	10.0	5.1	3.2	2.6	1.5	1.8	1.0	0.3	1.0	0.4
2000	9.4	4.7	2.6	2.3	1.8	1.8	0.9	0.4	1.2	0.4
2001	7.4	4.5	2.0	2.0	1.8	1.9	1.2	0.4	1.1	0.4
2002	6.7	4.2	2.1	2.2	2.0	2.0	0.8	0.5	0.2	0.4
2003	7.5	4.5	4.3	2.3	2.3	1.8	1.7	0.4	0.5	0.3
2004	7.8	4.5	2.5	2.2	1.9	2.1	0.7	0.6	0.6	0.3
2005	5.5	4.6	2.3	2.1	0.8	2.2	2.4	0.7	0.2	0.2
2006	4.9	4.1	3.0	1.9	1.1	1.8	1.5	0.7	0.4	0.3
2007	4.2	4.3	2.3	2.1	1.3	1.9	1.3	1.0	0.3	0.3
2008	4.9	4.3	4.1	2.3	1.5	2.2	1.7	1.1	0.4	0.2

* All values are percentages.

CREST. While the percentage of CAS performed after CAVATAS was minimal, an exponential increase in the use of CAS was noted in 2005 after publication of SAPPHIRE. This would be expected, as the results of CAVATAS were met with mixed response from experts,[9,17] whereas SAPPHIRE was interpreted more favorably by experts. We additionally hypothesized that there is a decreased use of CAS compared with CEA after publication of trials displaying superior results for patients undergoing CEA (EVA-3S and SPACE). A decrease of utilization of CAS by 22% in 2007 (the year following publication of EVA-3S and SPACE) supports this hypothesis. That year, 2007, was the only year with decreased utilization of CAS compared with the previous year in the interval between 1998 and 2008.

Concurrent with increased utilization of CAS for patients with carotid stenosis, the perioperative complication rates for CAS are seen to decrease from a peak in excess of 10% in 2000 to a nadir of 4.4% in 2007. This was seen to then worsen in 2008, with a stroke or death complication rate of 6.2% in 2008. Both evolution in technology and improved surgeon experience are likely causes of diminishing complication rates in CAS in the last 10 years. The uniformity of usage of distal protection devices and antiplatelet medication may also contribute to the reduction in stroke and deaths in the perioperative setting. In comparison, CEA represents a procedure with matured technique and technologies, and consequently little change in complication rates in the last 10 years.

Understanding trends in utilization of new technology such as CAS in reference to major trials establishes the link between science and practice. Despite questionable design, the EVA-3S and SPACE trials appear to have a major impact in utilization of CAS. The decline in utilization coincides with publication of these trials, but may neglect the observed decline in inpatient perioperative mortality seen in patients undergoing CAS.

It is not particularly surprising that population data reflect the publication of trials; however, a word on utilization of the NIS for research purposes is in order. The NIS represents the largest multipayer database in the US and captures roughly 20% of inpatient hospitalizations. Its limitations include potential inaccuracies in coding, including regional and hospital variability that may create sampling error. In a study comparing time epochs, this is particularly relevant as efforts to code complications and comorbid conditions may change over time. Despite its shortcomings, the NIS allows for comparison of treatments such as displayed in the present study.

Conclusions

Understanding trends in utilization of new technology such as CAS in reference to major trials establishes the link between science and practice. Despite questionable design, the EVA-3S and the SPACE trials appear to have had a major impact in utilization of CAS. The decline in utilization coincides with publication of these trials, but ignores a clinically relevant decline in inpatient perioperative mortality seen in patients undergoing CAS.

Disclosure

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author contributions to the study and manuscript preparation include the following. Conception and design: both authors. Acquisition of data: both authors. Analysis and interpretation of data: both authors. Drafting the article: both authors. Critically revising the article: both authors. Reviewed submitted version of manuscript: both authors. Approved the final version of the manuscript on behalf of both authors: Dumont. Statistical analysis: both authors.

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Manuscript submitted August 1, 2011.
Accepted March 5, 2012.
Please include this information when citing this paper: published online April 6, 2012; DOI: 10.3171/2012.3.JNS111320.

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