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Carotid Artery Stenosis with Acute Ischemic Stroke: Stenting versus Angioplasty

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Abstract

Background—When a patient with carotid artery stenosis presents emergently with acute ischemic stroke, the optimum treatment plan is not clearly defined. If intervention is warranted, and open surgery is prohibitive, endovascular revascularization may be performed. The use of stents places the patient at additional risk due to their thrombogenic potential. The intent of this study was to compare outcomes following endovascular approaches (angioplasty alone vs. stent) in the setting of acute stroke.

Methods—We extracted a population from the National Inpatient Sample (2012) and the Nationwide Inpatient Sample (2003–2011) composed of patients with carotid artery stenosis with infarction that were admitted nonelectively and received endovascular revascularization. Patients treated with mechanical thrombectomy or thrombolysis were excluded. Categorical variables were compared between treatment groups with Chi-squared tests. Binary logistic regression was performed to evaluate mortality and iatrogenic stroke while controlling for age, case severity, and comorbidity burden.

Results—About 6,333 admissions met our criteria. A majority were treated via stenting (89%, $n = 5{,}608$). The angioplasty-alone group had significantly higher mortality (9.0% vs. 3.8%, $p < 0.001$) and iatrogenic stroke rate (3.9% vs. 1.9%, $p < 0.001$) than the stent group. The adjusted odds ratios of mortality and iatrogenic stroke for patients treated with angioplasty alone were 1.953 ($p < 0.001$) and 1.451 ($p = 0.105$), respectively, in comparison to patients treated with carotid stenting.

Conclusion—Multivariate analysis found the risk of mortality to be elevated following angioplasty alone. This may represent selection bias, but it also may indicate that symptomatic patients with stroke suffer from severe stenosis and unstable plaques that would benefit from stent placement. These results would caution angioplasty alone as an arm of a future randomized trial involving this severely burdened patient population requiring urgent intervention.

Keywords

acute ischemic stroke; angioplasty; carotid artery stenosis; endovascular; stent

Introduction

Carotid artery stenosis increases the risk of ischemic stroke. Treatment with revascularization has been shown to reduce the risk of recurrent stroke when symptomatic patients have stenosis that exceeds 50% (NASCET) [1]. When a patient presents emergently with acute stroke, the optimum treatment plan is not as clearly defined. If intervention is warranted, the treating team must consider the risk of open surgery. If the patient has prohibitive cardiac issues, previous carotid surgery, or prior neck radiation, then endovascular means of revascularization may be the optimal treatment [2]. Methods of endovascular recanalization include carotid angioplasty, stenting, or both.

The use of carotid stents places the patient at additional perioperative and long-term risks due to their thrombogenic potential. This potential requires patients to be placed on dual antiplatelet agents, which contributes to increased hemorrhage risk. The interventionalist may

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decide to treat the stenosis with angioplasty alone. A main drawback of this approach is the risk of restenosis [3]. However, this is generally considered a long-term risk and in the setting of acute stroke the immediate risk of stent placement may be associated with greater morbidity and mortality [4].

To address this topic, we extracted a population from a national database composed of patients with carotid artery stenosis and stroke that were admitted nonelectively and received endovascular revascularization. Our null hypothesis was that patients receiving angioplasty alone would have similar clinical disposition at discharge in comparison to patients treated with carotid stent placement.

Methods

We analyzed discharge data from the National Inpatient Sample and the Nationwide Inpatient Sample (NIS), Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality (Rockville, MD) from 2003 to 2012. This database represents approximately a 20% stratified sample of U.S. nonfederal hospitals. Detailed information on the design of the NIS is available at http://www.hcup-us.ahrq.gov.

Patients were identified in the NIS database using a combination of ICD-9-CM diagnosis and procedure codes. Only patients with a nonelective admission were included, as to eliminate nonsymptomatic cases whose condition permitted adequate time to schedule intervention [5,6]. We required a primary diagnosis of carotid artery stenosis with infarction (433.11) along with carotid artery stenting (00.63, 00.55, 39.90) or angioplasty alone (00.61, 00.62, 39.50). Patients receiving mechanical thrombectomy (ICD-9-CM 39.74) or rtPA (ICD-9-CM 99.10) were excluded to improve homogeneity of the cohorts and to minimize the impact of patients with a combined diagnosis of carotid artery stenosis and distal thromboembolic occlusions.

Case severity was determined using the all-patient refined diagnosis-related group (APR-DRG) risk of mortality. This proprietary four-point ordinal scale (minor, moderate, major, extreme risk of mortality) developed by 3M Health Information Systems has been validated to predict mortality more reliably than other severity measures using administrative data sets and has been used as a severity indicator in prior stroke studies [7–10]. Any cases classified as minor were excluded from analysis (n = 20). Individual comorbidity burden was determined using a modified Charlson comorbidity index (CCI) based on ICD-9-CM codes [11]. This index is a weighted patient score designed to account for various comorbidities, including history of cancer, as well as cardiac, vascular, pulmonary, neurologic, endocrine, renal, hepatic, gastrointestinal, and immune disorders. Elixhauser measures, as provided in the NIS disease severity file, were used in place of similar Charlson measures and weighted accordingly, with the exception that mild liver disease was assigned three points [12]. Previous studies have demonstrated that slight modifications to the Charlson index have minimal impact on the overall score [13,14].

Hospital charges were converted to costs using the group weighted average cost-to-charge ratio (GAPICC) for years 2005 to 2011 and the cost-to-charge ratio (CCR) for 2012. The costs were adjusted to 2014 levels using the inflation calculator provided by the Bureau of Labor Statistics (http://www.bls.gov/data/inflation_calculator.htm) [15]. The primary clinical outcome was in-patient death, and the secondary clinical outcomes were iatrogenic stroke (997.02, postoperative cerebrovascular infarction or hemorrhage) and iatrogenic cardiac complication (997.1, cardiac arrest or insufficiency, cardiorespiratory failure, or heart failure during or resulting from the procedure). These iatrogenic complication codes have been utilized in prior studies on patients treated with stent placement [16–19].

Data were analyzed using SPSS Version 17 (IBM Corporation, Armonk NY, USA). To obtain national estimates, discharge weights were applied. Categorical variables were compared with Chi-squared tests and continuous variables were compared with Mann–Whitney U tests. The primary clinical outcome was assessed in binary logistic regression using the enter method and controlled for age, CCI, gender, APR-DRG risk of mortality, and revascularization procedure (stent vs. angioplasty alone). Continuous variables were transformed into categorical variables; CCI by quartiles and age by the categories defined in an analysis of the North American Symptomatic Carotid Endarterectomy Trial (NASCET) ≤65 years, 65–74 years, and >74 years [20]. Odds ratios and their 95% confidence intervals were reported. A probability value of .01 was considered statistically significant in order to nominally control for Type-I error.

Results

A total of 6,333 nonelective admissions were identified with a primary diagnosis of carotid artery stenosis/occlusion with infarction that were treated with endovascular revascularization. The majority was treated via carotid artery stenting (89%, 5,608); the remaining 725 treated

Table 1. Characteristics and outcomes of patients admitted with a primary diagnosis of carotid artery stenosis/occlusion with infarction. Comparisons are performed between endovascular approaches for revascularization.

	Stent *N* **= 5,608**	**Angioplasty alone** *N* **= 725**	***p***
Age	69 (61–77)	69 (57–76)	<0.001
Male	3610 (64.4)	373 (51.4)	<0.001
Coagulopathy	210 (3.7)	48 (6.6)	<0.001
Hypertension	4477 (79.8)	553 (76.3)	0.026
Charlson comorbidity index			
0	1480 (26.4)	236 (32.6)	
1	1727 (30.8)	171 (23.6)	<0.001
2	1178 (21.0)	128 (17.7)	
>2	1224 (21.8)	190 (26.2)	
APR-DRG risk of mortality			
Moderate	3818 (68.1)	434 (59.9)	
Major	1149 (20.5)	153 (21.1)	<0.001
Extreme	642 (11.4)	137 (18.9)	
Location/teaching status of hospital			
Rural	122 (2.2)	23 (3.2)	
Urban, nonteaching	1431 (25.7)	222 (30.8)	0.002
Urban, teaching	4024 (72.2)	475 (66.0)	
Weekend admission	1235 (22.0)	189 (26.1)	0.014
Length of stay, *d*	7 (4–11)	9 (6–13)	<0.001
Cost, $	29,223 (21,238–42,197)	28,957 (20,597–54,091)	0.035
Iatrogenic stroke	105 (1.9)	28 (3.9)	<0.001
Iatrogenic cardiac complication	99 (1.8)	NR	0.452
Mortality	211 (3.8)	65 (9.0)	<0.001
Discharge home	2512 (44.8)	273 (37.7)	<0.001

NR: not reportable as cell size ≤10

Table 2. The odds of iatrogenic stroke following carotid artery revascularization.

		Iatrogenic stroke		
Population	**Reference category**	**Odds ratio**	**95% CI**	***p***
Angioplasty alone	Carotid stent	1.451	0.925–2.278	0.105
Female	Male	1.763	1.235–2.518	0.002
Age				
≤ 65	>74	1.141	0.716–1.820	0.579
65–74	>74	2.013	1.313–3.088	0.001
APR-DRG risk of mortality				
Major	Extreme	0.086	0.055–0.135	<0.001
Moderate	Extreme	0.479	0.316–0.724	<0.001
Charlson comorbidity index				
0	>2	3.834	2.184–6.730	<0.001
1	>2	2.352	1.310–4.226	0.004
2	>2	2.428	1.354–4.356	0.003

with angioplasty alone (Table 1). The median patient age was 69 years (IQR: 17) and there was a greater proportion of male patients (63%).

The incidence of mortality in the angioplasty-alone group was higher than the carotid stenting group (9.0% vs. 3.8%), with an unadjusted odds ratio of 2.52. Similarly, the rate of iatrogenic stroke was greater in the angioplasty-alone group in comparison with carotid stenting (3.9% vs. 1.9%), with an unadjusted odds ratio of 2.11.

These outcomes were investigated in binary logistic regression in order to adjust for confounding variables in the data set. This mitigated some of the difference between groups, as the odds of iatrogenic stroke following angioplasty alone were reduced to only 1.45 times higher than carotid stenting and lost statistical significance (p = 0.105, Table 2). Yet, the odds of death remained significantly higher (1.95 times) in the angioplasty-alone group in comparison with the carotid stenting group (p < 0.001, Table 3). As expected, APR-DRG risk of mortality had the greatest association with in-hospital mortality and with patients classified in the most serious category (extreme) experiencing the greatest odds of mortality (Table 3).

Discussion

This study is the first nationwide comparison of carotid artery stenting versus angioplasty alone in the setting of ischemic stroke. Demographics and outcomes were compared between approaches, and multivariate analysis was used to further examine mortality and iatrogenic stroke while adjusting for confounding variables.

Table 3. The odds of mortality following carotid artery revascularization.

Population	Reference category	Odds ratio	Mortality 95% CI	*p*
Angioplasty alone	Carotid stent	1.953	1.408–2.703	<0.001
Female	Male	1.178	0.898–1.545	0.237
Age				
< 65	>74	1.675	1.224–2.292	0.001
65–74	>74	1.013	0.724–1.418	0.940
APR-DRG risk of mortality				
Major	Extreme	0.032	0.023–0.046	<0.001
Moderate	Extreme	0.123	0.087–0.172	<0.001
Charlson comorbidity index				
0	>2	1.248	0.861–1.810	0.243
1	>2	1.377	0.954–1.988	0.087
2	>2	1.151	0.789–1.678	0.465

Emergency management of patients with clinically unstable carotid stenosis is not infrequent in daily practice, for which a randomized study is still lacking [21]. The underlying etiology is generally thought to be an acutely unstable plaque with overlying thrombus, posing a high risk of stroke and necessitating urgent evaluation and potential treatment [22]. While current opinion supports intervention [23], results are not widely reported in the literature and are limited to scarce case series. A systemic review in 2009 calculated the pooled absolute risk of perioperative stroke or death in patients with crescendo TIA or stroke-in-evolution treated with carotid endarterectomy as 9.0% and 20.0%, respectively [22]. Unfortunately, there are insufficient data on this patient population treated conservatively, but the assumption prevails that intervention is warranted even though an optimal treatment strategy remains to be elucidated [21].

Studies involving this population-treated endovascularly are lacking. Many studies describe their experience with carotid artery stenting using a symptomatic versus asymptomatic methodology and do not clarify outcomes for patients with acute ischemic stroke-treated nonelectively [24]. SPACE, EVA-3S, and ICSS were trials that only enrolled symptomatic patients, but revascularization was performed anytime within 120 to 365 days of the ischemic event, hence their impact on hyper-acute management is limited [25–27].

Case series involving endovascular intervention for patients with carotid stenosis and acute ischemic stroke have reported a wide range of mortality and iatrogenic stroke rates, likely attributable to inclusion of varying degrees of stroke. Several authors do not report any deaths following urgent stent placement [28–30], while others have reported a mortality following stent placement to be as high as 29% (5/17) [4]. The iatrogenic stroke rate has ranged from 4.3–35% [4,31,32]. The rate of mortality in the current study falls within the expected range, while the iatrogenic stroke rate is lower than expected [33]. The decreased stroke incidence is likely attributable to two areas. First, we could not include any strokes that occurred between discharge and the typical 30-day evaluation because these data were not available in the NIS. Secondly, there is a high likelihood that coding specialists fail to capture many postoperative strokes in their hospital discharge abstracts [34]. While this limits extrapolation of data to nationwide estimates, the subgroup comparisons may still have relevance as the deficiencies are expected to affect both treatment groups in a balanced manner.

Only one case series was found that directly compared results between carotid stenting and angioplasty alone in the setting of acute ischemic stroke [4]. The study treated 17 patients with carotid stenting and seven with angioplasty alone. There were no hemorrhagic strokes or deaths in patients treated with angioplasty alone, while carotid stenting had an incidence of hemorrhagic stroke in 6/17 (35%) and death in 5/17 (29%). These results conflict with the trend in the current study and justify further inspection, however the above-mentioned results have only been reported in abstract format and further details are currently unavailable.

Specific patient characteristics unable to be controlled for in an administrative analysis may guide the endovascular approach and bias the treatment groups [35]. A patient with a contraindication for dual-antiplatelet therapy, and therefore, stent placement, may reflect severe comorbidities, thereby biasing the angioplasty-alone group toward worse outcomes. The stenting group may have been biased by including bail-out cases in which angioplasty was not suitable due to a large dissection or significant recoiling of the lesion. Additionally, the vascular anatomy and lesion location are unknown, both of which likely impact the endovascular approach. While the anatomical variances cannot be accounted for, the use of the APR-DRG risk of mortality variable may mitigate some bias by controlling for comorbid diagnoses with particularly high risk of mortality. The angioplasty-alone group was observed to include a greater proportion of cases with an extreme risk of mortality. Multivariate analysis was performed to adjust for this variable and still found angioplasty alone to increase mortality.

The limitations of the NIS are fairly broad and manuscripts have been written critiquing the validity of NIS studies [34,36]. The circumstances surrounding each patient's nonelective admission are unknown and the timing of symptom onset is not necessarily the day of admission. The proportion of cases admitted for nonfocal symptoms such as syncope, headache, or dizziness is unknown. We are also limited by uncertainty in the manner of diagnosis, likely ranging from clinical grounds to varying degrees of high Tesla magnetic resonance imaging (MRI) or computed tomography (CT). This may affect how patients are coded and ultimately alter the study population and conclusions. No clinical information regarding stroke size, NIHSS, or degree of stenosis was available, which could present unknown bias in the group distribution. Additionally, due to the generality of certain ICD-9-CM codes, errors occur and researchers may incorrectly attribute a patient's preprocedural neurological status as a periprocedural complication, or vice versa. For this reason, we sought to focus this investigation on the "hard" end points of mortality and diagnosis codes specifically referencing postoperative origination. The accuracy of ICD-9-CM procedural codes related to endovascular angioplasty and stenting have not been established. However, as the NIS is an administrative data set based on billing information, we do not feel that stent placement would be frequently overlooked as it is a costly component of revascularization and reimbursement would be critical. The optimal timing of revascularization and the impact of hyperacute revascularization were beyond the scope of the present study and would need a larger cohort in order to stratify outcomes between temporal groups with adequate power. The limitations of the NIS also prevent us from ascertaining causal relationships and the anonymization prohibits patient follow-up. While these limitations are many and require investigation in prospective studies, they are common to large administrative database examination, and the benefits of large database inspection include the ability to study medical practice at large without selection bias.

Conclusion

Patient outcome is multifactorial and administrative database analysis limits the ability to control for critical disease-specific variables. This study found the risk of mortality to be elevated following angioplasty alone. This may represent selection bias, but it also may indicate that patients with carotid stenosis and acute stroke have increased odds of stenosis that is refractory to angioplasty alone and have a high risk of mortality without revascularization. These results would caution angioplasty alone as an arm of a future prospective randomized trial involving this severely burdened patient population requiring urgent intervention.

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This study was performed without any financial support.

Conflict of Interest

Eric M. Deshaies was a physician consultant for MicroVention, ev3/Covidien Neurovascular, and Integra LifeSciences Corporation.

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