

Comparison of Endovascular and Open Carotid Artery Treatment in Germany: A Retrospective Analysis from 2010 to 2015

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Received: 17 August 2018 / Accepted: 14 December 2018 / Published online: 2 January 2019

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Abstract

Introduction We analyzed trends in carotid artery stenting (CAS) and carotid endarterectomy (CEA) in hospitalized cases in Germany in the years 2010–2015.

Methods Data from national statistics (DRG statistics) published by the Federal Statistical Office in Germany describing the number of hospitalized patients treated with CEA and CAS were used. In addition, numbers of patients hospitalized with the principal diagnosis *stroke associated with precerebral lesions* (ICD code I63), transitory cerebral ischemic attacks (G45) and precerebral carotid artery stenosis (I65) treated by CEA and CAS were analyzed for the year 2015.

Results Total number of CEA decreased by 4.0% from 24.067 (2010) to 23.104 (2015) and CAS increased by 5.1% from 5.703 to 5.992. In 2015, 79.4% of all procedures coded concerning the internal carotid artery were CEA and 21.6% CAS. From 27.798 cases hospitalized with the principal diagnosis *stroke associated with precerebral lesions*, CEA was performed in 3.921 (14.1%) and in 2.132 (7.7%) CAS was documented, with CAS making up one-third of all treatments within the stroke group. In 28.273 cases hospitalized with a TIA, CEA was specified in 853 (3.0%) and CAS in 255 (0.9%) cases. In 27.553 cases with

an *occlusion and stenosis of precerebral arteries, not resulting in cerebral infarction*, 17.036 (61.8%) had a CEA and 3.156 (11.5%) a CAS procedure.

Conclusion CEA is still the primary treatment of extracranial artery stenosis. The impact of CAS becomes mainly apparent in cases presenting with acute strokes.

Keywords Carotid artery stenting · Carotid endarterectomy · Precerebral carotid artery stenosis · Stroke · Transitory cerebral ischemic attacks

Introduction

Stroke is a major cause of morbidity and mortality and the second major cause of death in Germany [1].

Ischemia and hemorrhage account for 80%, respectively, 20% of strokes, and approximately 15–20% of ischemic strokes are related to carotid artery stenosis [2].

Carotid endarterectomy (CEA) has been and remains the gold standard treatment to reduce the risk of stroke caused by extracranial carotid artery stenosis [3, 4]. Carotid artery stenting (CAS) (or carotid artery stent implantation) is another method of carotid revascularization and has developed rapidly over the last 30 years. After being initially used in patients considered too high risk of CEA, CAS has become an important and evidence-based part of interventional stroke treatment and prevention over the years [5].

Based on results of randomized trials conducted in Europe and North America, guidelines on the procedural

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management of symptomatic and asymptomatic carotid stenosis have been published throughout the last decade by the European Society for Vascular Surgery (ESVS), the European Society of Cardiology (ESC), the American College of Cardiology (ACC)/American Heart Association (AHA) and the Society for Vascular Surgery (SVS). In general, all guidelines recommend CEA as the primary interventional treatment for both symptomatic and asymptomatic patients.

This is mainly based on the higher rate of periprocedural minor strokes of CAS compared to CEA and not taking into account comparable major stroke rates of both methods in the periprocedural period and in the long-term interval [6–12].

For patients with symptomatic non-occluding carotid stenosis $\geq 70\%$, guidelines recommend CEA as the first-line interventional treatment. In vascular obliteration up to 50–69%, guidelines differ slightly while interventional treatment of stenosis under 50% of the lumen is not suggested all [13–16]. For patients with an asymptomatic carotid stenosis, the existing guidelines are not as well defined for CEA due to differences in terms of minimum carotid artery diameter reduction, inclusion of life expectancy and mandated maximum rate of perioperative stroke/death. Moreover, recommendations for CAS are different, too. While ACC and AHA do not provide clear indications for CAS in asymptomatic patients, ESVS and ESC consider CAS as an alternative to the endarterectomy when performed in high-volume centers with perioperative stroke and death rates equal to CEA ($< 3\%$) [13–17].

To date, decision on treatment of patients with carotid artery stenosis in Germany is led by the multidisciplinary “S3-Guideline for Diagnostic, Treatment and Follow-up of extracranial Carotid Stenosis” dating back to 2012 which was supposed to be revised in 2017. Up until today, no new S3-guideline has been published. Treatment recommendations are mostly concordant with the aforementioned guidelines, though differing from those of ACC and AHA in asymptomatic patients [17].

With regard to the existing controversy and conflicting recommendations between the guidelines, the aim of this study was to analyze trends in CEA and CAS in hospitalized patients in Germany in the years 2010–2015.

Patients and Methods

Nationwide Hospitalization Data

Hospitals in Germany annually transfer their individual hospitalization data, including one primary diagnosis and up to 89 secondary diagnoses coded by ICD-10 (International Classification of Diseases, 10th edition) as well as up

to 100 medical procedures according to a national classification of operations and procedures (“Operationen- und Prozedurenschlüssel,” “OPS code”) to the Institute for the Hospital Remuneration System (InEK). After a plausibility control, the InEK forwards anonymized data to the Federal Bureau of Statistics. Principles of the analysis of this hospitalization file have been previously published several times [18, 19]. In brief, we asked the Federal Bureau of Statistics to identify all hospitalizations of the years 2010 through 2015 that include OPS codes covering CEA (5-381.02: endarterectomy of internal carotid artery) and CAS (OPS code 8-840.0 (one stent) + 8-840.1 (two stents) with k (stent placement in internal carotid artery) and m (stent placement in internal and common carotid artery) as the sixth digit). In addition, we asked for the number of patients hospitalized with the principal diagnosis *stroke associated with precerebral lesions* (ICD code I63) and transitory cerebral ischemic attacks (G45) and precerebral carotid artery stenosis (I65) independent from the OPS codes for the year 2015 and calculated the rate of cases treated with CEA or CAS.

We received a defined data set from the Federal Bureau of Statistics including information only from fully reimbursed inpatient cases with the performed procedures and the principal diagnosis separated by year, age and gender of the cases. As we did not analyze the impact of other covariables, only linear regression analysis was used for statistical evaluation of the trends over the 10-year study period. Analysis is descriptive. Calculations were done using Microsoft® Access 2003.

According to the occupational regulations for the North Rhine-Westphalian physicians, retrospective epidemiological research projects are specifically excluded from the necessity of an ethics vote.

Results

The total number of CEA and CAS procedures in Germany decreased from 29.777 in 2010 to 29.096 in 2015 (Fig. 1). Looking at each procedure separately, CEAs decreased by 4.0% from 24.067 to 23.104 in this period and CAS increased by 5.1% from 5.703 in 2010 to 5.992 in 2015.

In 2015, 79.4% of all procedures affecting the internal carotid artery were CEAs and 21.6% CAS. Looking at the median age of the patients, a slight shift from CAS to CEA can be observed, favouring CEA with increasing age, especially in the sixth to the ninth decade of life (Fig. 2). While CEA was performed in patients from 50 to 55 years in approximately 75% and CAS in 25% of all procedures, the CEA rate was above 80% in patients of both sexes in the in the seventh decade.

Fig. 1 Absolute numbers of internal carotid procedures reported as all CEA and CAS procedures separated for males and females in the years 2010–2015

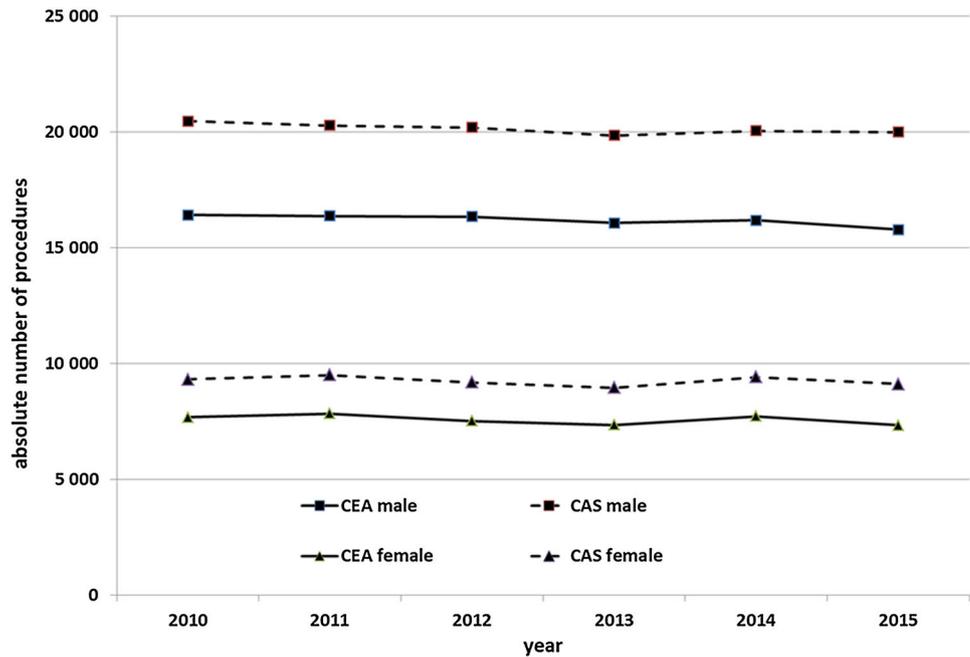
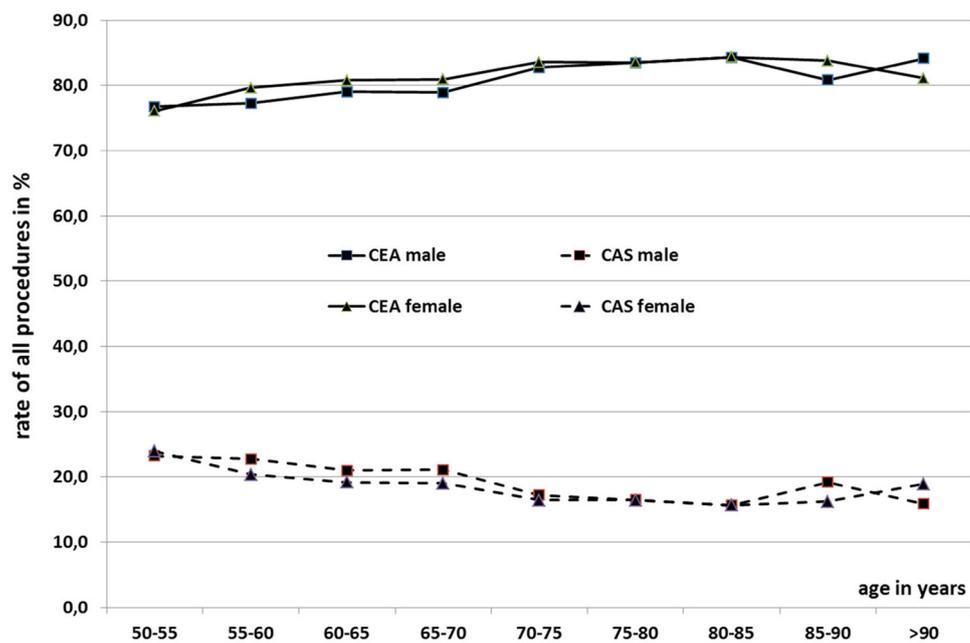


Fig. 2 Age-dependent rate of hospitalized cases with a documented procedure of carotid treatment separated for CEA and CAS and gender



In 2015, 27.798 patients were hospitalized with the principal diagnosis *stroke associated with precerebral lesions* and 28.273 with the principal diagnosis *TIA* (Table 1). Both groups of patients can be assumed to have suffered from a symptomatic carotid artery stenosis.

Another 27.553 patients can be assumed to have been hospitalized for an asymptomatic carotid artery stenosis as their documented principal diagnosis was *occlusion and stenosis of precerebral arteries, not resulting in cerebral infarction*.

Based on the documented 29.096 CEA and CAS procedures performed throughout all age groups in Germany, 27.353 codes covered the ICD codes I63.0–I63.2 as well as G45.1-2 and I65.2 as demonstrated in Tables 1, 2 and Fig. 3. The missing difference of 1.743 coded OPS procedures might be due to divergent leading diagnoses specified in a different ICD code.

20.192 (73.8%) of those coded OPS procedures were performed in a clinically asymptomatic state and 7.161 (26.2%) in a symptomatic situation.

Table 1 All cases hospitalized in the year 2015 with the principal diagnosis strokes associated with precerebral lesions and Transitory cerebral ischemic attacks that are defined as symptomatic situation and all cases with the principal diagnosis of an Occlusion and stenosis of precerebral arteries, not resulting in cerebral infarction accepted as an asymptomatic situation (age groups < 50 years have been excluded)

ICD codes	All	Age groups									
		50–55	55–60	60–65	65–70	70–75	75–80	80–85	85–90	> 90	
<i>Strokes associated with precerebral lesions</i>											
I63.0 Cerebral infarction due to thrombosis of precerebral arteries	12.859	700	992	1.382	1.325	1.875	2.547	1.687	1.178	420	
I63.1 Cerebral infarction due to embolism of precerebral arteries	7.880	351	450	662	680	1.068	1.480	1.305	968	469	
I63.2 Cerebral infarction due to unspecified occlusion or stenosis of precerebral arteries	7.059	406	560	695	698	1.003	1.349	977	670	250	
Total	27.798	1.457	2.002	2.739	2.703	3.946	5.376	3.969	2.816	1.139	
<i>Transitory cerebral ischemic attacks</i>											
G45.1 Carotid artery syndrome (hemispheric)	27.462	1.397	1.672	1.904	2.185	3.482	5.256	4.510	3.338	1.370	
G45.2 Multiple and bilateral precerebral artery syndromes	811	37	46	58	64	104	161	133	114	46	
Total	28.273	1.434	1.718	1.962	2.249	3.586	5.417	4.643	3.452	1.416	
<i>Occlusion and stenosis of precerebral arteries, not resulting in cerebral infarction</i>											
I65.2 Occlusion and stenosis of carotid artery	27.553	965	2.129	3.417	4.092	5.812	6.377	3.056	1.093	169	

From those patients hospitalized with the principal diagnosis *stroke associated with precerebral lesions*, 3,921 (14.1%) underwent CEA and in 2,132 (7.7%) CAS was performed (Table 2).

Looking exclusively at the total number of procedures in the stroke group ($n = 6,053$), CAS made up approximately one-third of all treatments with 2,321 procedures.

In patients diagnosed with a TIA, CEA was documented 853 (3.0%) and CAS 255 (0.9%) times.

In the cases covering the primary diagnosis of *occlusion and stenosis of precerebral arteries, not resulting in cerebral infarction*, CEA was performed in 17,036 cases and CAS was performed in 3,156 cases. Therefore, even though the absolute numbers for coded CAS procedures in patients who are already symptomatic (TIA and stroke) are lower than in asymptomatic patients (2,132 vs. 3,156 cases), the percentage relation (33.3%) favors CAS procedures in symptomatic patients compared to patients without infarction (15.6%).

Discussion

Our analysis illustrates that the total number of cases treated for extracranial internal carotid artery disease by CEA or CAS remained relatively stable in Germany in the period from 2010 to 2015 with a decrease in CEA by 4.0% and an increase in CAS by 5.1%. CEA has been proven to be effective in both primary and secondary stroke prevention and, until recently, has been considered the

standard treatment approach for patients with severe carotid artery disease. Because of its technical limitations and some less favorable outcomes, CAS has been offered preferably to patients suffering from too many comorbidities to undergo surgical treatment. Nevertheless, CAS has evolved into a reliable method over time and is currently considered an acceptable alternative to CEA [20, 21]. A retrospective analysis of a Nationwide Inpatient Sample, constituting a 20% representative and stratified sample of non-federal US hospitals, revealed a decrease in the annual number of CEA (from 137,877 to 111,658) and an increase in CAS (from 2318 to 14,415) from 1998 to 2007 [22]. A more recent report based on the fee-for-service Medicare beneficiaries described an even more dramatic decrease in CEAs performed from 1999 to 2014 (from 81,306 to 36,325) as well as CAS from 2006 to 2014 (from 22,865 to 10,208) [23, 24]. According to the authors, advances in medical therapy as well as changes in surgical reimbursement policies over time may have contributed to this decrease within this specific population [25]. In contrast to these data from the USA, other countries reported an overall increase in these procedures. In the UK for example, a retrospective cohort study based on routinely collected Hospital Episode Statistics (HES) inpatient data reported that the number of CEA procedures per quarter increased steadily (from a minimum of 1,047 in quarter 2, 2006, to a maximum of 1,378 in quarter 3, 2009). Here, CAS made up less than 5% of carotid revascularization procedures without any trend for increasing use between 2006 and 2012 [26]. In Korea, the number of patients

Table 2 All CEA and CAS procedures performed in the year 2015 separated according to the documented principal diagnosis *stroke associated with precerebral lesions, transitory cerebral ischemic attacks and occlusion and stenosis of precerebral arteries, not resulting in cerebral infarction*. Figures in the brackets are the rate of all cases hospitalized with these principal diagnoses presented in Table 1 (age groups < 50 years have been excluded)

OPS codes	All	Age groups								
		50–55	55–60	60–65	65–70	70–75	75–80	80–85	85–90	> 90
<i>CEA</i>										
I63.* Strokes associated with precerebral lesions	3.921 (14.1)	144 (9.9)	293 (14.6)	486 (17.7)	469 (17.4)	702 (17.8)	925 (17.2)	564 (14.2)	232 (8.2)	38 (3.3)
G45.* Transitory cerebral ischemic attacks	853 (3.0)	28 (2.0)	74 (4.3)	80 (5.1)	116 (5.2)	164 (4.6)	186 (3.4)	129 (22.1)	58 (1.7)	12 (6.6)
I65.* Occlusion and stenosis of precerebral arteries, not resulting in cerebral infarction	17.036 (61.8)	544 (56.4)	1336 (62.8)	2125 (62.2)	2581 (63.1)	3748 (64.5)	4037 (63.3)	1859 (60.8)	578 (52.9)	67 (39.6)
<i>CAS</i>										
I63.* Strokes associated with precerebral lesions	2.132 (7.7)	156 (10.7)	213 (10.6)	318 (11.6)	284 (10.5)	352 (8.9)	370 (6.9)	207 (5.2)	100 (3.6)	25 (2.2)
G45.* Transitory cerebral ischemic attacks	255 (0.9)	17 (1.2)	29 (1.7)	35 (1.8)	36 (1.6)	42 (1.2)	56 (1.0)	27 (4.6)	10 (0.3)	2 (1.1)
I65.* Occlusion and stenosis of precerebral arteries, not resulting in cerebral infarction	3.156 (11.5)	118 (12.2)	275 (12.9)	411 (12.6)	533 (13.0)	680 (11.7)	707 (11.1)	289 (9.5)	80 (7.3)	14 (8.3)

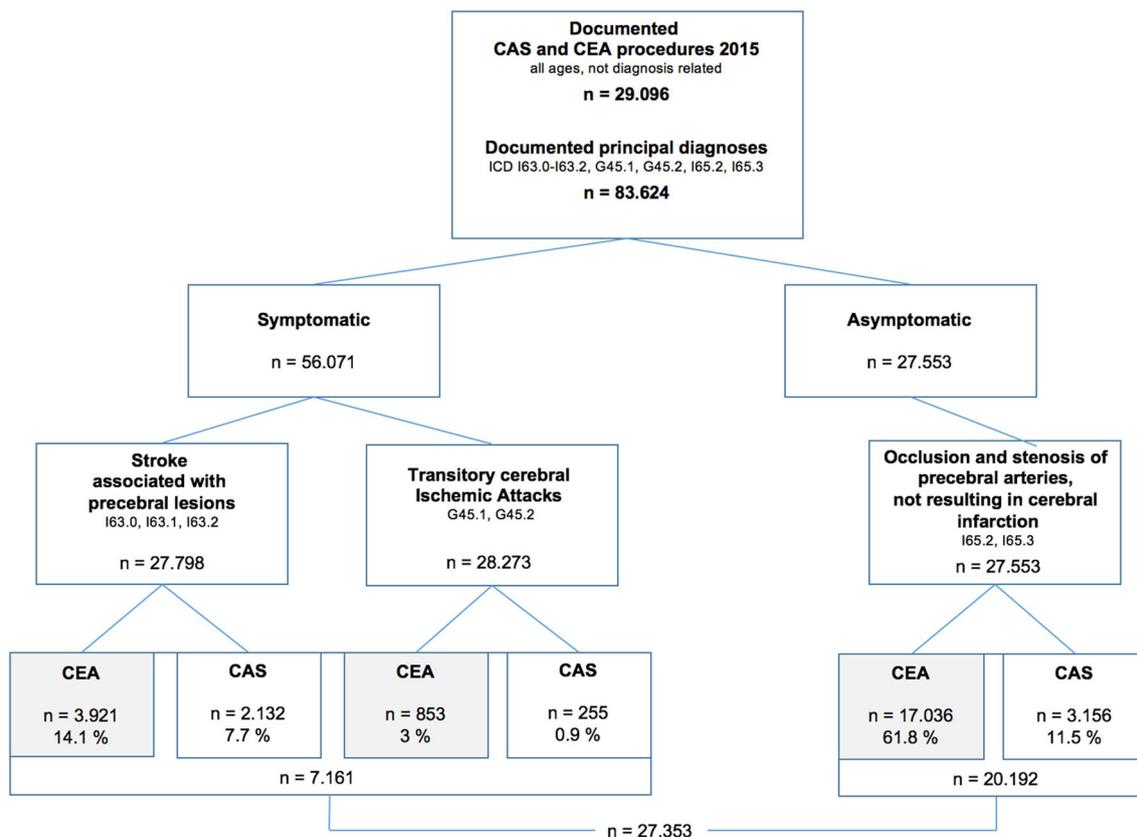


Fig. 3 Schematic overview of documented diagnoses (ICD-10) and CAS and CEA procedures (OPS codes) in 2015

receiving carotid revascularization between 2004 and 2013 almost doubled and CAS was the dominating procedure with outstanding 82.7% of all procedures [27].

Although the numbers of CEAs decreased within the assessed time span, analysis of the data from 2015 shows that CEA remains the most frequently used treatment even in older patients covering approximately 80% of all procedures in Germany—a finding that demonstrates an extensive compliance of treatment to the national S3-guideline. A VASCUNET report published in 2012 analyzed variations in carotid surgical practice in nine countries. The main indication for surgery was “symptomatic stenosis” in 60.1%. This proportion varied between 31.4% in Italy and 100% in Denmark [28]. In 2015, 66.7% of the German patients were treated by surgical intervention.

In asymptomatic patients, improvements in effective cardiovascular therapy have renewed uncertainty about the best technique for long-term prevention of vascular events. To date, asymptomatic patients represent the majority of those undergoing revascularization. With advances in medical therapy, physicians might recommend revascularization for this patient group less frequently, if their specific risk of stroke is low. Recent observational studies suggest an annual stroke risk of 1% or less for asymptomatic patients [29, 30] which is about half the risk rate

reported in clinical trials initiated in the 1980s and 1990s [31, 32].

In most countries, the number of patients considered asymptomatic outnumbers the number of patients considered symptomatic.

In the Medicare population, the rate of patients considered symptomatic [*ICD-9-CM* principal discharge diagnosis code indicating occlusion or stenosis of the precerebral or cerebral arteries with cerebral infarction (433.11, 433.31, 434.01, 434.11 or 434.91) or a secondary diagnosis code indicating prior stroke (342.xx or 438.xx), transient ischemic attack (435.x or 781.4) or amaurosis fugax (362.34 or 368.12)] made up only 15.5% in those treated by CEA and 25.9% in those treated by CAS in 2013–2014 [23].

In Germany, most procedures (73.8%) are performed in asymptomatic patients, a practice which is in concordance with the aforementioned S3-guideline and also found in other European countries [33].

A possible reason for the higher rate of interventions in asymptomatic patients, whether surgical or endovascular, may be the higher perioperative or periprocedural risk of stroke and death in symptomatic patients (2.9 vs. 5.2%) [34, 35]. Although the German S3-guideline suggests CEA as first-line therapy for symptomatic patients with stenosis

of the extracranial carotid artery, reality in Germany is quite different.

From our own experience, symptomatic patients with severe carotid stenosis and, i.e., a large thrombus mass are treated very reluctantly by surgeons or neuroradiologists/interventional radiologists if there is no accompanying intracerebral thrombus formation due to the risk of causing an intracerebral infarction during the procedure.

This strategy is completely different in patients with a tandem stenosis (occlusion), since periprocedural complications rates for intracranial thrombectomy with concomitant stent implantation in the extracranial internal carotid artery are not considered to be of major importance.

Furthermore, interventional treatment for severe carotid stenosis in asymptomatic patients is financially well displayed. In times of increasing economic pressure and feasibility, this aspect becomes more and more relevant.

The SPACE-2 study was set up in order to assess whether modern best medical therapy alone could replace CAS or CEA in patients with high-grade asymptomatic carotid stenosis [36]. However, SPACE-2 was stopped prematurely due to the fact that neither surgeons nor patients wanted to be randomized into the medical treatment arm. This is based on the recommendations of the S3-guideline in Germany which summarizes the results of early randomized controlled trials [31, 37, 38]. Results of ongoing trials, such as ACST-2 and CREST-2 expected by the end of 2019 and 2020 along with an individual patients data meta-analysis with ACT I and CREST-I, are supposed to clarify best interventional treatment for patients with asymptomatic carotid stenosis [39].

With increasing pressure from health insurances to improve quality, nowadays potential treatment strategies for carotid artery stenosis are being discussed in interdisciplinary meetings of vascular surgeons, interventional radiologists, neuroradiologists and neurologists deciding on optimal management.

There are two striking findings in our study:

First, there is no age-related increase in CAS performed, although guidelines of national and international societies propose CAS mainly for patients with high surgical risk and existing comorbidities such as severe coronary artery disease, heart insufficiency and COPD, all circumstances which are more likely in the elderly. This may be explained by a reluctant use of CAS due to higher periprocedural complications rates of patients being 70 years and older [40, 41].

Second, most CAS procedures were coded for cases hospitalized for an acute stroke—a trend, which possibly is attributed to the widespread introduction and establishment of interventional mechanical thrombectomy as the method of choice for intracranial occlusion throughout recent years [42]. While incidence and mortality rates are continuously

decreasing in the Western civilization over time, the absolute number of patients suffering from stroke increases due to demographic aging [43, 44]. Acute ischemic stroke related to tandem occlusions of the cervical ICA with intracranial thromboembolism to the intracranial ICA terminus or middle cerebral artery at the same time occurs in 15–20% of the patients. Since revascularization by intracranial thrombectomy combined with CAS was shown to be of significant benefit for these patients, further rise of stroke-related interventions with CAS may be anticipated [45]. Yet, this thesis has to be confirmed by further assessment of patients with OPS codes for CAS in combination with thrombectomy.

Limitations

Our ecologic study design did not allow control for confounding factors including indications for and quality of treatment as well as outcome. Moreover, our data do not allow for cross-linking of diagnosis and procedures. In addition, it has to be pointed out that the analysis is based on cases and not on individual patients. As a consequence, a patient could be included several times in the statistics if he was hospitalized because of CEA and CAS at two different times within 1 year. Although hospitalization rates are frequently used for secondary purposes, there is no systematic analysis of coding quality in Germany and the agreement of coding and the harsh “reality” has yet to be investigated in controlled trials. Therefore, we cannot assess whether and how coding errors may have impacted our analysis.

Acknowledgements We thank Referat VIII A from the Federal Statistical Office for extracting and providing the data from the DRG statistic.

Compliance with Ethical Standards

Conflict of interest All authors declare that they have no conflict of interest.

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