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Complications of Carotid Stenting During Live Transmissions

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Objectives We sought to examine the acute and subacute results of carotid stenting performed during live transmissions.

Background Teaching courses focusing on live demonstrations of carotid interventions have been the key educational facility for physicians interested in learning state-of-the-art interventional techniques of carotid stenosis treatment. However, starting with the very first live demonstration of interventional procedures, there has been an ongoing discussion whether patients treated during live transmissions are at higher risk.

Methods Between March 1, 2001, and June 30, 2008, 186 high-grade lesions of the internal carotid artery in 186 patients have been treated by stent implantation during live transmissions to 22 interventional conferences at 3 high-volume centers. Technical success was defined as the ability to perform carotid stent implantation. The combined end point of death, major stroke, minor stroke, or myocardial infarction was defined as primary end point.

Results The procedure was technically successful in 185 of 186 (99.5%) interventions. Seventeen patients had 1 of the following acute in-hospital complications: major stroke in 2 (1.1%), minor stroke in 3 (1.6%), transient ischemic attack in 11 (5.9%), and amaurosis of the ipsilateral eye due to an occlusion of the retinal artery in 1 (0.5%). None of the patients died, and no myocardial infarctions occurred. The composite primary end point occurred in 6 (3.2%) patients.

Conclusions In this consecutive series of carotid stent cases performed by expert operators during live demonstration courses, the procedural and 30-day clinical outcomes were similar to the results appearing in the contemporary published data. (J Am Coll Cardiol Intv 2009;2:887–91) © 2009 by the American College of Cardiology Foundation

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Transcatheter treatment of carotid stenosis was first reported by Mathias in 1977 (1). Due to the gaining expertise and experience of interventionalists, the rapid development of this endovascular method, as well as the improvement of cerebral protection devices, the periprocedural event rate has decreased over the years (2–4). Teaching courses focusing on live demonstrations of carotid interventions have been

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the key educational facility for physicians interested in learning state-of-the-art interventional techniques of carotid stenosis treatment. However, starting with the very first live demonstration of interventional procedures, there has been an ongoing discussion whether patients treated during live transmissions are at higher risk. The purpose of this study is to report the acute and subacute results of carotid stenting performed during live transmissions, to compare the outcome with the results of published carotid stenting trials.

Abbreviations and Acronyms

CEA = carotid endarterectomy

NIHSS = National Institutes of Health Stroke Scale

TIA = transient ischemic attack

Methods

Between March 1, 2001, and June 30, 2008, in-hospital results of patients with carotid artery stenosis treated during live transmissions to 22 international conferences on endovascular treatment at 3 high-volume centers. Procedure data, information on complications, and follow-up data were collected with conference programs, live case schedules, and patient hospital records and entered prospectively into each center's database system. To incorporate the original databases of these centers, a common database system was developed by the CardioVascular Center Frankfurt in May 2006. Data received from procedures before this date were entered retrospectively, thereafter in a prospective manner (123 procedures retrospectively and 63 procedures prospectively entered into database). The analyzed population consisted of all patients in whom a carotid procedure was attempted during live transmissions to endovascular courses. The number of procedures/center is listed in Table 1. No exclusions were made concerning procedures in which guest operators were the main operator.

Informed consent for live demonstrations was received from all patients before the procedure. The diameter of stenosis was determined angiographically according to the NASCET (North American Symptomatic Carotid Endarterectomy Trial) measurement criteria (5). Technical success was defined as the ability to access the carotid artery lesion and successfully stent the stenosis with a residual stenosis of <20%. Independent neurological examinations including a neurological assessment according to the National Institutes of Health Stroke Scale (NIHSS), and clinical examinations were performed before and after the procedure, before discharge, and at 30 days.

Table 1. Procedures/Center

Center	Number of Procedures
CardioVascular Center Frankfurt, Frankfurt, Germany	98
Ospedale di Mirano, Mirano, Italy	34
Department of Angiology, Heart Center Leipzig, Leipzig, Germany	55

The combined end point of death, major stroke, minor stroke, or myocardial infarction at discharge was defined as primary end point. Secondary end point was defined as death, major stroke, minor stroke, or myocardial infarction at 30 days after procedure. Minor stroke was classified as a new neurological event that persisted more than 24 h and changed the NIHSS score by 2 to 3 points. Major stroke was defined as a new neurological event that persisted more than 24 h and changed the NIHSS score by at least 4 points. Embolic occlusion of the retinal artery was taken into account as a minor stroke. Diagnosis of myocardial infarction was based on the joint definition of European Society of Cardiology/American College of Cardiology for acute myocardial infarction in 2000, then adapted to the definition of European Society of Cardiology/American College of Cardiology Foundation/American Heart Association/World Heart Federation in 2007 (6,7). Rise and/or fall of cardiac biomarkers (preferably troponin) was detected with at least 1 value above the 99th percentile of the upper reference limit together with evidence of myocardial ischemia with at least 1 of the following:

Symptoms of ischemia;

Electrocardiographic changes indicative of new ischemia (new ST-T changes or new left bundle branch block;

Development of pathological Q waves in the electrocardiogram;

Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.

Platelet inhibitors (aspirin and clopidogrel) were given in preparation for the intervention in all patients. Between 0.5 and 1.0 mg atropine and 5,000 to 10,000 IU of heparin were administered routinely during the procedure. Angiography of the carotid artery was performed to identify the anatomical characteristics of the intracranial and carotid vessels and to provide information on the lesion. Intracranial circulation films were obtained immediately before and after the implantation procedure to document baseline and final results.

Table 2. Overview of the Embolic Protection Devices in the Patient Cohort

Type of Embolic Protection	Name (Company)	n	%
Distal occlusion	Percusurge GuardWire (Medtronic, Minneapolis, MN)	3	1.7
	TriActiv (Kensey Nash Exton, PA)	3	1.7
	Twin One (Minvasys Genevilliers, France)	1	0.6
Filter device	Spider (ev3, Plymouth, MN)	17	9.6
	Angioguard (Cordis, Miami Lakes, FL)	27	15.3
	Accunet (Guidant/Boston Scientific, Natick, MA)	8	4.7
	FilterWire (Boston Scientific, Natick, MA)	52	29.4
	Rubicon (Rubicon Medical/Boston Scientific, Natick, MA)	4	2.3
	Interceptor (Medtronic, Minneapolis, MN)	3	1.7
	Emboshield (Abbott Vascular, Abbott Park, IL)	14	7.9
Proximal occlusion	MoMa (Invatec, Roncadelle, Italy)	32	18.1
	NPS (W. L. Gore & Associates, Inc., Newark, DE)	8	4.5
Combined	Fibernet (Lumen Biomedical, Plymouth, MN)	5	2.8
Total		177	

Results

The ages of patients ranged from 44 to 89 years (73 ± 8 years). Forty-one (22.0%) patients were octogenarians; 130 (69.9%) were men; 13 patients (7.0%) had a contralateral occlusion; 95 (51.0%) of the patients suffered from coronary heart disease, including more than 1 main vessel; 149 (80.1%) suffered from hypertension, 62 (33.3%) from diabetes, and 104 (55.9%) from hyperlipidemia; and 39 (21.0%) were previous or current smokers. Of all patients, 123 (66.1%) had at least 1 high-surgical risk feature (age ≥80 years, coronary heart disease including more than 1 main vessel, contralateral occlusion of the internal carotid artery, or prior ipsilateral endarterectomy). Twenty-seven lesions (14.5%) were symptomatic. Mean percentage of lesion was 80 ± 13%.

Of the 186 patients treated during live transmissions, the procedure was technically successful in 185. In 46 cases (24.7%) an investigational stent or embolic protection device was chosen. In 1 patient (0.5%) the procedure was complicated due to a broken tip of a commercially available filter embolic protection device. The patient suffered a major hemorrhagic stroke during recovery of the filter tip. In 177 (95.2%) lesions the procedure was performed with use of embolic protection devices. Proximal occlusion devices were used in 40 (21.5%), distal filter systems in 125 (67.2%), and distal occlusion devices in 7 (3.8%), and the Fibernet embolic protection device—which is a combined filter and distal occlusion system—was used in 5 (2.7%) of the procedures. A detailed overview of the embolic protection devices used during the live demonstrations is listed in Table 2. In none of the procedures was a crossover to a second embolic protection device needed.

One hundred seventy-eight carotid stents were implanted. In 3 patients the implantation of a second stent was performed to completely cover the target lesion. A detailed overview of the carotid stents used during the live demonstrations is listed in Table 3. In none of the procedures could the initially chosen stent delivery system not be positioned or was a crossover to a different stent needed before implantation. Pre-dilation of the lesion was performed in 52 of 186 (28.0%). Post-dilation of the carotid stent was performed in 176 of 186 (94.6%) of the procedures. Residual stenosis between 20% and 50% after post-dilation was found in 41 (22.0%) of the lesions and >50% was found in 7 (3.8%) of the lesions. Seventeen patients had 1 of the following acute in-hospital complications: major stroke in 2 (1.1%), minor stroke in 3 (1.6%), transient ischemic attack (TIA) in 11 (5.9%), and amaurosis of the ipsilateral eye due to an occlusion of the retinal artery in 1 (0.5%). No deaths and no myocardial infarctions occurred. The composite primary end point occurred in 6 (3.2%) patients. The calculated risk of acute in-hospital complications is listed in Table 4. In the group of patients treated with investigational devices, the following in-hospital complications occurred: TIA in 2 of 46 (4.3%), and minor stroke in 2 of 46 (4.3%) patients. In those who were treated with commercially available devices, TIA occurred in 9 of 140 (6.4%), minor stroke including 1 occlusion of the retinal artery in 2 of 140 (1.4%), and major stroke occurred in 2 of 140 (1.4%) patients.

At 30 days after procedure, 3 of 186 patients were lost to follow-up, leaving 183 patients for complete examination. At 30-day follow-up no further deaths, major strokes, minor strokes, or myocardial infarctions occurred.

Discussion

The debate over safety and live case transmissions dates back to the first live demonstrations of interventional procedures. Subsequent obstacles of live transmissions such as distractions of the operator by panel and audience

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Table 3. Overview of the Carotid Stents in the Patient Cohort

Type of Carotid Stent	Name (Company)	n	%
Closed cell	Carotid Wallstent (Boston Scientific, Natick, MA)	34	19.1
	Xact (Abbott Vascular, Abbott Park, IL)	6	3.4
	NexStent (Endotex/Boston Scientific, Natick, MA)	14	7.9
	Zilver Stent (Cook, Bloomington, IN)	5	2.8
Open cell	Precise/Smart (Cordis, Miami Lakes, FL)	39	21.9
	Protégé (ev3, Plymouth, MN)	14	7.9
	Acculink (Guidant/Abbott Vascular, Abbott Park, IL)	30	16.9
	Conformexx/Vivexx (Bard, Covington, GA)	12	6.7
	Exponent (Medtronic, Minneapolis, MN)	4	2.2
	Sinus Carotid (Optimed, Ettlingen, Germany)	4	2.2
Combined	Cristallo Ideale (Invatec, Roncadelle, Italy)	13	7.3
Balloon expandable	Tsunami (Terumo, Somerset, NJ)	1	0.6
	FlexMaster (Abbott Vascular, Abbott Park, IL)	1	0.6
	Cypher (Cordis, Miami Lakes, FL)	1	0.6
Total		178	

discussions, timing issues such as short transmission time windows, the operator's wish to present novel investigational devices, a subliminal hesitation to stop an ongoing procedure, or hindering transmission equipment in the catheter laboratory might lead to a more stressful environment for operators and the staff.

Chatelain et al. (8) first published an article on the success of coronary angioplasty during live demonstrations in *Lancet* in 1992. The results of 104 coronary angioplasty procedures demonstrated live at 12 international angioplasty courses in 1991 were assessed by 1 of the authors' trained interventional cardiologists who participated in the conference as an unidentified observer. Merely 73% of the initially planned procedures were successful. There was a crossover to another device in 20% and a total success rate of 93%. Threatened occlusions occurred in 10%, acute occlusions in 6%, and delayed occlusions in 2% of all cases. No death or myocardial infarction was reported. Chatelain et al. (8) concluded that "real results of coronary angioplasty are inferior to those found in publications"—furthermore, "interventions done before an audience will be unusually stressful but this will be outweighed by the fact that difficult cases with a low probability of success are rarely tackled during live courses."

Some data are available concerning the impact of new interventional devices on in-hospital complications concerning devices used in coronary interventions. The results showed that the availability of new transcatheter devices was not an independent predictor of complications (9) or, in 1 publication by Lindsay et al. (10), even proved to enhance procedural outcome.

The in-hospital and 30-day outcome of our patients treated during live transmissions is comparable to results of carotid stenting reported in major randomized trials in which carotid stenting was compared with carotid endarterectomy (CEA). An overview of the results of carotid angioplasty/stenting in major randomized trials is presented in Table 5. The CAVATAS (Carotid and Vertebral Transluminal Angioplasty Study) was the first large study in which carotid angioplasty was compared with endarterectomy (11). The incidence of major adverse neurological events at 30 days was 10% in both the carotid angioplasty and CEA groups. The SAPPHIRE (Protected Carotid Artery Stenting Versus Endarterectomy in High-risk Pa-

Table 4. 30-Day Outcome of Carotid Stenting During Live Transmissions

Complication	n	%
Minor stoke	3	1.6
Embolic occlusion of the retinal artery	1	0.5
Major stroke	2	1.1
MI	0	0
Death	0	0
All stroke/MI/death	6	3.2
All stroke/death	6	3.2
Major stroke/death	2	1.1

MI = myocardial infarction.

Table 5. 30-Day Outcome of Carotid Angioplasty/Stenting in Major Randomized Trials

Study	Inclusion Criteria	Stroke/Death Rate (%)
CAVATAS	96% Symptomatic lesions	10.0
SAPPHIRE	High surgical risk (symptomatic and asymptomatic)	4.5
EVA-3S	Symptomatic lesions	9.6
SPACE	Symptomatic lesions	6.8

CAVATAS = Carotid And Vertebral Artery Transluminal Angioplasty Study; EVA-3S = Endarterectomy Versus Angioplasty in patients with Symptomatic Severe carotid Stenosis trial; SAPPHIRE = Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy; SPACE = Stent-protected Percutaneous Angioplasty of the Carotid vs. Endarterectomy.

tients Study) compared carotid stenting with CEA in patients with high surgical risk (12). The incidence of major adverse neurological events at 30 days was 4.5% for the stented patients and 6.6% for the CEA patients. The EVA-3S (Endarterectomy versus Stenting in Patients with Symptomatic Severe Carotid Stenosis Trial) compared carotid stenting with endarterectomy in patients with a symptomatic carotid stenosis of at least 60% (13). The 30-day incidence of stroke or death was lower in the group of patients in whom the procedure was performed under embolic protection compared with those patients in whom carotid stenting was performed without embolic protection (18 of 227, 7.9%, vs. 5 of 20, 25%, respectively, $p = 0.03$). For this reason the stenting arm of the trial without the use of an embolic protection device was stopped prematurely by the safety committee. The 30-day risk of any stroke or death was significantly higher after stenting (9.6%) than after endarterectomy (3.9%), which resulted in a relative risk of 2.5. In the SPACE (Stent-protected Percutaneous Angioplasty of the Carotid versus Endarterectomy), patients with symptomatic carotid stenosis of more than 70% in duplex ultrasound or over 50% according to NASCET measurement were included (14). The use of embolic protection was optional. The rate of death or ipsilateral ischemic stroke at 30 days was 6.84% in the group of patients treated with stent implantation compared with 6.34% in the group of patients treated with endarterectomy.

Conclusions

Live transmissions of carotid stenting and other interventions are an essential component of teaching courses. The patients and lesions selected for live transmissions represent the real-world scenario in these centers. The use of investigational devices does not seem to have an impact on the percentage of device failures. It can be suggested that potential causes of difficulties such as distractions by discussions and timing issues such as short transmission time windows are outweighed by the expertise and experience of the presenting operators. Interactive discussions with an expert panel during the procedure might even influence decision making positively by suggesting alternative techniques of treatment that might not have occurred to the operator. In this consecutive series of carotid stent cases performed by expert operators during live demonstration courses, the procedural and 30-day clinical outcomes were similar to the results appearing in the contemporary published data.

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