Lesion-Related Carotid Angioplasty and Stenting with Closed-Cell Design without Embolic Protection Devices in High-Risk Elderly Patients—Can This Concept Work Out? A Single Center Experience Focusing on Stent Design

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Abstract

To compare the performance differences of three carotid artery stents in high-risk elderly patients without embolic protection devices (EPDs) on the basis of stent design, procedure-related complications, conveniences in handling, in-stent restenosis, 30-day outcome, and long-term follow-up. A total of 101 symptomatic internal carotid stenoses of 94 patients were prospectively treated with stent-protected angioplasty to 94 patients. Three closed-cell stents, one of those being hybrid cell design, were chosen depending on vascular anatomy: curved vessel, lesion length > 1 cm: 64 Carotid Wallstent (Boston Scientific, Natick, MA); curved vessel, lesion length < 1 cm: 21 Cristallo Ideale (Invatec, Roncadelle, Italy); straight vessel, lesion length > 1 cm: 16 Xact (Vascular Abbott, Santa Clara, CA). Comparisons of demographics, procedures, and outcomes were performed. The mean age of patients was 73.1 years (standard deviation [SD], ± 7.9 ; range, 58–87 years), 71% of the patients were older than 70 years and 20% were octogenarians. Male/female ratio was 3.1:1. About 13.9% (14/101) had contralateral internal carotid artery occlusion. Overall peri-interventional complication rate was 2.9% and 30-day mortality rate was 1%. During the long-term follow-up (34 months, range 1–59) no ipsilateral stroke was documented. Ten deaths (three after MI) were recognized. Two in-stent restenosis were detected (> 70% North American Symptomatic Carotid Endarterectomy Trial) during follow-up, one patient was detected with previous carotid endarterectomy. Especially, if individual anatomical variance is considered, lesion-related stent-protected carotid angioplasty with lesion-adapted closed-cell design is an effective, reliable, safe, and comprehensible treatment option in symptomatic patients. Even without EPDs, the rate of complications is low, when compared with symptomatic carotid artery stenosis described in the literature. In-stent restenosis seems to play no significant role in follow-up.

Keywords

- carotid stent
- carotid stenosis
- closed-cell design
- lesion related
- symptomatic
- carotid endarterectomy
- CAS

Approximately 200,000 patients per year suffer from ischemic insult in Germany. Of those, approximately 30,000 originate from carotid stenosis.¹ Carotid artery stenting (CAS) has emerged as an alternative revascularization tech-

nique for extracranial carotid stenotic disease.² Nevertheless, one of the limitations of CAS is the potential for embolic stroke caused by plaque dislodgement of atheromatous material.²

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Against the increasing experience and the technical and procedural improvements in CAS stands the longstanding experience and low complication rates of the carotid endarterectomy (CEA). The expected rates of complications such as death, stroke, or myocardial infarction (MI) at 30 days after CEA range up to 3.75% in symptomatic and 1.97% in asymptomatic patients.³

Aside of the still ongoing discussion regarding protected versus unprotected carotid artery stent and the difficulties in interpreting the results of randomized studies, this study gives a review of the experience of a single center without the use of protection device in high-risk elderly patients while focusing on stent design.

Concomitantly, the aim of the present study was to match the right technical improvements up with the special anatomical characteristics of the carotid lesion.

Patients and Methods

A total of 101 internal carotid stenoses (94 patients) were treated with stent-protected angioplasty without embolic protection device (EPD). About 7.4% of the patients (7/94) were treated on both sides. Comparisons of demographics (►Table 1), procedures, and outcomes (►Table 2) were

Table 1 Demographic data of study population

	<i>n</i>	%
ACI stenosis	101	100.00
Male	77	76
Female	24	24
Age, 73.1 y (SD ± 7.9; range, 48–87)		
Carotid de novo lesion	92	91
Carotid postendarterectomy restenosis	7	6.9
Carotid post-PTA/stenting restenosis	2	2
Right carotid artery	56	55.4
Left carotid artery	45	44.6
Contralateral carotid occlusion	14	13.9
Risk factors		
Severe coronary artery disease	57	56.4
Hypertension	94	93
Diabetes mellitus	37	36.6
Renal failure	30	29.7
Myocardial infarction	42	41.6
Severe COPD	36	35.6
Two or more risk factors	82	81.2
mRS at admission	3.4 SD ± 1.0	
mRS at discharge	1.5 SD ± 1.2	

Abbreviations: COPD, chronic obstructive pulmonary disease; mRS, modified ranking scale; PTA, percutaneous transluminal angioplasty; SD, standard deviation.

Table 2 Clinical outcome and complications

Complications	During procedure	At 30 d	Follow-up
Death	0	0	10
Major stroke	0	0	0
Minor stroke	1	1	0
Hyperperfusion syndrome	1	0	0
TIA	1	0	1
Myocardial infarction	0	0	3

Abbreviation: TIA, transient ischemic attack.

performed. The patients were examined and admitted in the neurological or vascular surgery department. An ultrasound examination and computed tomography angiography/magnetic resonance angiography scan were done. Two stents with closed-cell design and one hybrid-cell design were chosen depending on the morphology of the vessel: curved vessels with lesion length longer than 1 cm had a Carotid Wallstent (Boston Scientific, Natick, MA); implanted, curved vessels with lesion length shorter than 1 cm received a Cristallo Ideale (Invatec, Roncadelle, Italy) stent, while in straight vessels with lesions longer than 1 cm a Xact (Abbott, Santa Clara, CA) Stent was used (►Fig. 1). Patients with symptomatic stenosis greater than 70% (NASCET), as evaluated at the Duplex sonography, were included as well as patients with contraindications or high risk for CEA. If both procedures were possible, after discussion in interdisciplinary conference, the patient could decide between CAS and CEA.

Inclusion criteria:

1. Apoplex, transient ischemic attack (TIA), and retinal ischemia within the last 6 months
2. Patients with symptomatic > 70% carotid stenosis (NASCET)
3. Patients refused by surgeons as high-risk for CEA
4. No age limitations were imposed

Preconditions:

1. Dual antiplatelet therapy (DAPT)
2. Systolic blood pressure < 160 mm Hg
3. Fluid intravenous in case of elevated Creatinine levels (≥ 1.5 mg/dL)

Before treatment, patients received 100 mg oral aspirin and 75 mg clopidogrel as loading dose for 5 days, alternatively 300 mg clopidogrel once following 75 mg daily for 3 days. A femoral approach was done in all patients under local anesthesia. The carotid artery was engaged using a 4F JB3 or JB1 configuration catheter (Cordis, Miami, FL). After placing a long, 0.035-inch stiff wire (Terumo, Tokyo, Japan) in the external carotid artery, a long 6F guiding sheath was introduced in the common carotid artery (CCA). Nonfractionated 5,000 IU heparin was administrated through the sheath and an angiographic examination of the carotid lesion and

Fig. 1 Flow chart on prospective decision depending on carotid bifurcation anatomy for Carotid Wallstent, Xact Stent, and Cristallo Ideale. NASCET, North American Symptomatic Carotid Endarterectomy Trial.

intracranial circulation was performed. Using imaging-overlay technique, the stenosis was carefully passed using a 0.014-inch microwire, while avoiding touching the plaques, immediately followed by the selected stent. After deployment of the stent, postdilation was done with an angioplasty balloon, 5 × 30 mm or 5 × 20 mm, depending on the reference vessel (Sterling, Boston Scientific, Natick, MA). The control angiogram was performed to detect embolization, followed by visualization of the access vessel, before the vascular closure using Angio-Seal (St. Jude Medical, Minnetonka, MN) was performed. The patients had their vital signs constantly evaluated at the stroke or immediate care unit for 24 hours, with special attention paid to the elderly patients, to prevent a hyperperfusion syndrome. The hospital discharge succeeded after a mean hospitalization of 3 days.

Stent Design

The call to the stent design is high. Several types of stents with different designs are available as minimal invasive alternatives.

The stent design should provide vessel conformability, scaffolding, side branch preservation, visibility, and recoil control to minimize migration and foreshortening.⁴ Several studies associate the closed-cell design with a better outcome.⁵ The scaffolding benefits of a closed-cell design, which is characterized by the fact that the adjacent ring segments are connected at every possible junction, interfere with the

flexibility and conformability. For our analyses, three stents were chosen based on the experimental consideration for carotid stent design⁶: two closed-cell design, one of stainless steel (Carotid Wallstent) and one of Nitinol (nickel-titanium alloy, Xact Stent); one hybrid stent with closed-cell design in the midsection (Cristallo Ideale); and an open-cell design at the proximal and distal ends.

The Wallstent represents one of the most widely used stainless steel self-expanding stents. This stent is constructed from a single piece of cobalt alloy wire woven into a tubular structure.⁴ With cell sizes of 1.36 mm², the Wallstent has the smallest free cell area (► Fig. 2).⁶

The Xact Stent consist of a closed-cell stent used in a tapered version that is especially manufactured with full deployment. The distal diameter (internal carotid artery [ICA]) is smaller than the proximal diameter (CCA), which should provide better global vessel wall appositioning.⁷ Regarding the in vitro experimental results of Müller-Hülsbeck et al⁶ comparing six different stent designs (three closed cell and three open-cell design), the Xact Stent showed the highest scaffolding among the studied designs. The lowest flexibility with the highest bending forces at 20/30 degrees (0.890 N/0.616 N) and forces to achieve torsion at 10/15 degrees (0.905 N/1.071 N) were also observed with the Xact. These features may make the Xact Stent predestined to dealing with long, straight lesions and/or heavily calcified lesions (► Fig. 3).

Fig. 2 Angiography of a long-distant calcified lesion at the origin of the internal carotid artery before (A) and after Carotid Wallstent (Boston Scientific) (8 × 21 mm) (B) deployment and postdilatation with 5 × 30 Sterling Balloon. The Wallstent was chosen due to type 3 arch and distal elongation.

The Cristallo Ideale Stent, as a hybrid stent, consists of a two-zone design, with proximal and distal open-cell parts and closed-cell design in the midsection (►Fig. 4). According to the in vitro experiment of Müller-Hülsbeck et al, the lowest mean bending forces at 20/30 degrees were measured in the Cristallo stent (0.063 N/0.074 N), just as the lowest mean radial force (9.06 N at mid part); the Cristallo Ideale stent also resisted plastic spheres penetration, by all at the midsection⁶ (►Table 3).

Results

A total of 101 patients received CAS, with a mean age of 73.1 years (SD, ± 7.9; range, 48–87 years), where 71.3% of the patients were ≥ 70 years (►Fig. 5) and 20% were octogenarians. Male-to-female ratio was 3.9:1. About 13.9% (14/101) of the patients showed contralateral ICA occlusion at admission. One patient had an additional ipsilateral external carotid artery occlusion.

Seven stenoses were documented after CEA (7%). Two patients (2%) had already been treated from carotis stenosis with stents, 8 and 10 years respectively before the actual intervention. The modified Rankin Scale at admission was 3.4 (SD ± 1.0) and 1.5 (SD ± 1.2) at discharge. Approximately 89% of the patients fulfilled one criterion and placed them in the B category for high-risk patients, as described in the

Fig. 3 Angiography of a high-grade ulcerated straight long distant lesion involving the bifurcation and proximal segment of the internal carotid artery before (A) and after (B) stent placement (Xact Stent, Abbott Vascular, 6 × 8 × 30 mm) with additional percutaneous transluminal angioplasty.

SAPPHIRE study,⁸ with multiple comorbidities (►Table 1). Primary stent placement was successful in all patients. In two lesions predilatation was necessary (0.2%).

Peri-Interventional Complication Rate

The peri-interventional complication rate was 2.9% (3/101) including one TIA, one minor stroke, and one hyperperfusion syndrome. All peri-interventional complications were detected and treated within 3 days. All these patients could leave hospital with a similar or better modified Rankin Scale than at admission. Two of the patients who suffered a peri-interventional complication were younger than 69 years.

Thirty-Day Outcomes

The 30-day all-stroke/death rate was 1% (1/101). During this period one minor stroke was documented (Cristallo Ideale) and there was no death or MI (►Fig. 4).

Fig. 4 Angiogram of a concentric focal symptomatic stenosis before (A) and after (B) stent deployment (Cristallo Ideale, Invatec, 7/10 × 30 mm) as well as percutaneous transluminal angioplasty with a 5 × 30 mm balloon (Sterling Balloon). The fluoroscopic view of another patient shows a Carotid Wallstent on the contralateral side and the new implanted Cristallo stent on the ipsilateral side. The closed-cell design midsegment of the tapered hybrid stent is centered at the target lesion (C).

Follow-Up

Midterm follow-up has been completed in 93.1% of the patients via neurological examination or questionnaires (94/101), when they were unable to visit the hospital for the follow-up examinations due to comorbidities. Of the 10 deaths during the follow-up, six deaths were related to respiratory insufficiency following pneumonia. There were

Fig. 5 Age distribution of treated patients.

three cardiac-related deaths; two of those were 3 years after carotid stenting. An 82-year-old woman died from severe bleeding following ruptured abdominal aneurysm. One TIA was detected in a patient 59 days after treatment with a Wallstent, no ipsilateral minor or major stroke occurred. Contralateral cardioembolic stroke or ischemic event in other vessel's territory occurred in three patients.

In-Stent Restenosis/Ultrasound

During follow-up, hemodynamic significant in-stent restenosis was detected in two patients (North American Symptomatic Carotid Endarterectomy Trial [NASCET] > 70%), after receiving a Wallstent and Xact, respectively. No recurrences of symptoms related to the stent's territory were recognized. One patient had previous endarterectomy in the medical history.

Discussion

Carotid artery angioplasty and stenting still has an important role due to its potential as an alternative for patients considered at a high risk for CEA.⁹

Symptomatic Patients

If acute or subacute ischemia is confirmed by imaging exams, a stenosis could be designated as symptomatic, as long as other possible causes for the lesions are ruled out. A stenosis is to be classified as symptomatic when it has led to a not-disabling stroke attack, a TIA, or a retinal ischemia in the past 6 months.

Table 3 Stent design

	Design	Stent material	Crossing profile	Sizes (mm)/length (cm)	Working
Wallstent (Boston Scientific)	Braides wire mesh design	Cobalt alloy wire woven into a tubular structure	1.75–2.1 mm	5/30, 7/30, 9/30 7/40, 7/50, 9/40	135
Xact (Abbott Vascular)	Closed-cell design	Nickel–titanium alloy	1.83–2.08 mm	8/6/30, 9/7/40	136
Cristallo Ideale (Invatec)	Hybrid cell design open-cell ends and closed cell in the middle	Nickel–titanium alloy	1.67 mm	6/9/30, 6/9/40 7/10/30, 7/10/40	135

After further analysis of the current studies, the S3 Guidelines showed advantage regarding not-disabling strokes toward the CEA and, in counterpart, better results toward CAS, regarding lesions of the nerves and heart attacks.¹⁰

Without Protection Device

The results of CAS are compared with CEA. There are several randomized studies and analysis of subgroups comparing the two procedures (Stent-Protected Angioplasty versus Carotid Endarterectomy [SPACE 1], SAPPHIRE, Endarterectomy versus Angioplasty in Patients with Symptomatic Severe Carotid Stenosis [EVA-3S], and International Carotid Stenting Study [ICSS] trial), including discussion of protected versus unprotected stenting procedure. One of the risks associated with CAS is the periprocedural stroke resulting from embolization of debris released during treatment of the carotid stenosis. A systematic review of Kastrup et al, analyzing 26 observational studies, reported that the use of EPDs was associated with significantly less combined stroke and death rate within 30 days in both symptomatic and asymptomatic patients (1.8% in patients treated with EPD vs. 5.5% in patients treated without EPD). This effect was mainly due to a decrease in the occurrence of minor (0.5 vs. 3.7%) and major strokes (0.3 vs. 1.1%), where death rates were almost identical.¹¹ The SPACE trial represents one of the most discussed multicenter studies and it includes 1,200 patients. The primary end point was the frequency of ischemic insult and death rate, which accounted for 6.3% in the CEA group and 6.8% in the CAS group.¹² In further subgroup analyses, the complication rates for protected versus unprotected groups in SPACE 1 showed 8.3 versus 6.5%.¹³

In our study, we decided not to use EPD based on our experience and the fact that we wanted to reduce the time of the procedure and navigation through the aortic arch and supra-aortic trunks. Especially in this part, there is no protection before the deployment of the EPD, including distal balloon occlusion and distal filtration, we prefer passing the carotid plaque with minimal or less touching of the vessel's wall with a flow-assisted wire, following an immediate stenting. Intraoperative transcranial Doppler ultrasonography recognized this part of the procedure which was related to generate significant emboli.¹⁴ Studies of Whitlow et al and Cremonesi et al reported vasospasm or dissection in the vessel wall.^{15,16} Several reports pointed out that EPDs do not completely eliminate the risk of cerebral embolization.^{17,18} Especially distal vasospasm and slow flow are described with an incidence of up to 3.6 and 7.2%, respectively.¹⁹ Cardaioli et al support the statement of an increased risk of vasospasm, thrombosis, and dissection when using EPD.²⁰

In a propensity-matched analysis of the CARE Registry made by Giri et al there was no significant evidence of benefit or harm associated with the use of EPDs in 579 elective CAS patients.²¹ Wu et al also have not found differences in the incidence of ischemic lesions on magnetic resonance imaging (MRI) diffusion-weighted images when comparing protected and unprotected CAS.²²

The usage of EPDs in treating carotid stenotic lesions remains a debate, as multicenter randomized trials focusing primarily on these devices are still missing.

Closed-Cell Design Stent

In general, currently available carotid stents are divided into two categories based on the cell design: open and closed cell. The number and arrangement of bridge connectors differentiate the two design concepts. If adjacent ring segments are connected at every possible junction, the design is classified as a closed cell.⁴ Several experimental and clinical studies demonstrate the advantage and superiority of the closed-cell design regarding the complication and outcome results due to CAS.⁶

Recent studies postulated that the stent design appears to have more important impact on the resulting complications in CAS, rather than in EPDs.¹³ Jansen et al reported in a subgroup analysis of SPACE data, the outcome event of the analysis (ipsilateral stroke or ipsilateral stroke death within 30 days) rate was significantly lower in patients treated with closed-cell stent (5.6%) than in those treated with an open-cell stent (11.0%).²³ SPACE 2 trial for asymptomatic stenosis is still going on.

Tietke et al retrospectively analyzed 358 unprotected CAS procedures performed between 2003 and 2009, and demonstrated a low peri-interventional and 30-day mortality/stroke rate of 4.19%. The overall peri-interventional complication rate was 0.8%. They concluded that CAS with small cell design stents makes the use of protection device dispensable.⁵

As a most often used and proven stainless steel self-expanding stent, the Carotid Wallstent is constructed from a single piece of cobalt alloy wire and woven into a tubular structure.⁴ In our study, we could recognize one peri-interventional TIA and one minor stroke after implantation of a Wallstent. Both events occurred in symptomatic patients with a short time between ischemic event and stenting (< 3 days). In the daily work, this stent seems to be easy in handling with rapid exchange, covering multifocal stenosis, and long-standing wall ulcerations, in elongated or straight vessels. The Carotid Wallstent seems to be the ideal stent for complicated cases.

The Xact Stent design offers a good global wall appositioning, when CAS is done from ICA to CCA, due to the tapered format.⁴ These features may make the Xact Stent predestined when dealing with long, straight lesions and/or heavily calcified. Due to its hardness, the Xact Stent may considerably alter the vessel's anatomy. The deployment and the placement of the stent are, in general, easily performed. In our study, there were no complications during or after the intervention and that could be related to the Xact Stent (►Fig. 3).

The hybrid stent technology of the Cristallo Ideale stent demonstrates an interesting idea with the combination of open-cell design in the distal and proximal sections that provides flexibility and a closed-cell midsection for prevention of plaque dislodgment.

When comparing all three stent designs in the daily work, the Cristallo stent requires the highest precision during

Table 4 Clinical and technical data of peri-interventional complications during CAS ($n = 3$)

Patient	Lesion morphology				Technical data		Complications	Outcome	
Age/sex	mRS (pre)	t	Side	Stenosis (%) NASCET	Stent	Diameter/length (mm)	Event	mRS at admission	30 d
68/m	3	2	Right	80	Wallstent	7 × 30	Hyperperfusion syndrome	3	mRS 2
73/m	2	2	Left	90	Xact	8–6/30	TIA	0	mRS 0
66/f	1	3	Right	95	Cristallo	7–10/30	Minor stroke	2	mRS 1

Abbreviations: CAS, carotid artery stenting; f, female; m, male; mRS, modified Rankin Scale; NASCET, North American Symptomatic Carotid Endarterectomy Trial; t, time between ischemic event and stenting.

deployment, so that the closed-cell section in the middle covers the stenosis and ulcerations properly. The flexibility of the end sections allows an optimal fixation and stent conformation, so that the closed-cell section doesn't disturb the vessel's anatomy. In our study, occurred an episode of minor stroke during the implantation of a Cristallo stent and one major stroke within 30 days after stenting, following a suboptimal stent placement. The Cristallo stent shows the smallest crossing profile among the studied designs, allowing the passing even through high-grade stenosis without predilatation of the lesion. Cremonesi et al showed that the Cristallo Ideale stent used with a protection device performed safely and effectively in an unselected study population of predominantly high-risk patients.⁹

High-Risk Elderly Patients

Despite the new S3 Guidelines, we decided to also include older patients in our single-center study.

Sayed et al reported, in a retrospective study of 421 patients undergoing CAS for symptomatic and asymptomatic carotid stenosis focusing on angiographic lesion characteristics, a higher incidence of 30-day adverse events for octogenarians at 10 versus 3.8% ($p = 0.029$).²⁴ The Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) has also shown increased rates for stroke and death in octogenarians.^{25–27} A pooled data analysis from 3,433 patients with symptomatic carotid stenosis who were randomly assigned and analyzed in the EVA-3S trial, SPACE trial, and ICSS showed in the subgroup variables that age significantly modifies the treatment effect: in patients younger than 70 years, the estimated 120-day risk of stroke or death was 5.8% (50/869) in the CAS group and 5.7% (48/843) in the CEA group. In patients who are 70 years or older, the estimated risk for CAS was twice that with CEA (12%, 103/856, vs. 5.9%, 51/865).²³

In our single-center study, peri-interventional and in the 30-day follow-up, three of the four complications were detected in patients younger than 70 years (→ **Table 4**).

The objective of this prospective study was to evaluate a pragmatic concept available for daily practice, meeting requirements of individual anatomical variance, and low complication rates without changing the anatomy. Especially for the growing number of elderly patients with multiple comorbidities and high risk for CEA we tried to develop a concept, consisting of short procedure times, less material, and mini-

mal touching of the vessel wall before stent placement. Further multicenter studies focusing on closed cell and lesion adapted cell design are desired.

The great enthusiasm of CAS is gone, but the time for further rational development and improvement of this attractive method is still going on.

Study Limitations

Comparison of the results of this study is limited by non-standardized end points and the fact that it is a single center, not a randomized follow-up study. A further leak is the low number of patients included. This is largely due to the fact that after the published SPACE data the number of carotid stenting procedures decreased dramatically.

Conclusion

Improvements in design and technical skills, even careful study of the anatomy of each vessel, still make CAS an attractive therapy, especially for the growing number of elderly patients with multiple comorbidities.

The lesion-specific selection of the stent design, even without the use of EPD, demonstrates an effective and safe therapy for symptomatic stenosis of the carotid artery. Baseline is a fast, careful, and less touching passage of stenosis and a closed-cell design carotid stent with high scaffolding and wall coverage.

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