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Technical Note & Surgical Technique

The Carotid Wallstent for the endovascular treatment of carotid artery stenosis☆

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ABSTRACT

Aim: To report a retrospective, 15-years single-center experience about Carotid Artery Stenting (CAS) using the Carotid Wallstent in high surgical risk patients.
Methods: Primary outcomes were procedural success, 30-day mortality and cerebrovascular complications, and long-term survival, neurological complication and restenosis. *P* values < 0.05 were considered significant.
Results: From January 2000 to June 2015, 560 patients underwent CAS using the Carotid Wallstent for either a symptomatic (22.6%) or an asymptomatic significant carotid stenosis. Primary success was achieved in 99.1% as 4 acute stent thrombosis occurred and in 1 case selective catheterization of the supra-aortic trunks was not possible due to extreme tortuosity. At 30 days, 7 TIAs and 9 strokes accounted for a 2.8% of neurological complication rate. There were 2 deaths unrelated to the procedure.
At 10 years, survival was 71.2% ± 2.5%. Freedom from cerebrovascular events (TIA/stroke) at 10 years was 91.2% ± 1.9% for asymptomatic patients and 81.7% ± 5% for symptomatic patients ($P = 0.008$). Freedom from a restenosis >30% was estimated to be of 93.9% ± 1.3% at 10 years, being significantly affected by age ($P = 0.01$).
Conclusion: In our experience the Carotid Wallstent was a safe and effective device for the treatment of both asymptomatic and symptomatic carotid stenosis in high surgical risk patients. Freedom from cerebrovascular events in the long term was worse in symptomatic patients.

1. Introduction

Since the introduction of endovascular therapy as an alternative to the gold standard carotid endarterectomy (CEA), management of critical carotid artery stenosis has been one of the most discussed topic in the literature, as lot of papers were published aiming to assess the superiority of one method over the other [1].

According to most trials up to know CEA is still the gold standard for the treatment of both symptomatic and asymptomatic carotid stenosis [2].

Thanks to the development of new devices and the improvement of the techniques, the number of endovascular procedures performed has increased over time, with a spread of the inclusion criteria. The use of the stent instead of a simple balloon dilation, in fact, has allowed the achievement of excellent immediate and long-term results with a reduction of neurological perioperative complication, as the metallic frame of the stent with the coverage of the plaque usually offers a good protection from distal embolization.

Self-expandable stents are the choice for the carotid district, because they present a lower risk of deformation or breakage than the balloon-expandable stents, in case of sudden movements or neck injury.

The most used stent is the Carotid Wallstent™ Monorail™ (Boston), which is a closed-cells stent with a woven mesh of filaments in alloy, characterized by the presence of a greater radial strength than the other types of stents and the peculiarity to provide a greater coverage of the plaque.

Aim of the study was to report a retrospective, single-center experience about Carotid Artery Stenting (CAS) using the Carotid Wallstent over 15 years in high surgical risk patients.

2. Methods

The study was approved by the Institutional Review Board.

Data of all patients who were treated for a severe carotid stenosis using the Carotid Wallstent from January 2000 to June 2015 were retrospectively reviewed.

Abbreviations: CAS, Carotid Artery Stenting; TIA, Transient Ischemic Attack; CEA, Carotid endarterectomy; MRA, Magnetic Resonance Angiography; CTA, Computed Tomographic Angiography; DUS, Duplex ultrasound scan; EPD, Embolic protection devices; IQR, Interquartile range; CCA, Common carotid artery; AUC, Are Under Curve; MAE, Major adverse events; MI, Myocardial infarction; CPD, Cerebral protection device.

☆ Each Author has contributed substantially to the research, preparation and production of the paper and approves of its submission to the Journal.

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Patients' records were reviewed for personal data (name, surname, date of birth, telephone number), medical history (the presence of cardiovascular risk factors: diabetes mellitus, hypertension, dyslipidemia, chronic renal failure, ischemic heart disease, smoking, familiar history of cardiovascular disease, obesity, any previous stroke), preoperative neurologic symptoms within the previous six months, side of the lesion, lesion location, etiology of the lesion (primary stenosis/post-surgical restenosis/in-stent restenosis), degree of carotid stenosis and any contralateral carotid occlusion. Intraoperative data included the use of any cerebral protection device, pre- and post-dilatation, operation time, the amount of contrast used, procedural success (defined as a residual stenosis < 30% [3]), the occurrence of cerebral ischemic events and intraoperative complications. The discharge date (length of in-hospital stay) was also recorded.

Primary outcomes were procedural success (defined as the correct delivery and placement of the stent without any immediate stent thrombosis), 30-day mortality and cerebrovascular complications, and long-term survival, neurological complication and restenosis.

Follow-up data were obtained from reports of outpatient visits and through telephonic interview (occurrence of cerebrovascular events, death and any complications). Imaging was performed every 3 months during the first year after the operation and annually thereafter using duplex scans to record the occurrence of either restenosis or stent occlusion.

2.1. Patients' selection

In our Operative Unit CEA is still the gold standard treatment for significant carotid artery stenosis in low surgical risk patients. CAS is usually proposed as an alternative to CEA if the patient is a poor surgical candidate for high risk but with a life expectancy longer than 3 years, and in absence of any contraindication to CAS such as severe tortuosity or calcification of the aortic arch or the supra-aortic vessels, hemorrhagic carotid plaques, or in case of any contraindications to platelet antiaggregants.

Almost all patients undergo an additional preoperative Magnetic Resonance Angiography (MRA) or Computed Tomographic Angiography (CTA) of the supra-aortic trunks and the intracranial vessels, in order to have a proper pre-procedural planning for either CAS or CEA, for the evaluation of the level of carotid bifurcation, the localization and extension of the stenosis, the presence of any tandem lesions, as well as for the aortic arch morphology. During the first years of our experience, however, there was a trend to perform duplex ultrasound scan (DUS) only.

All symptomatic patients usually undergo a preoperative evaluation by expert neurologists.

A careful preoperative DUS evaluation is performed in all patients on admission, to assess carotid plaque morphology, length of the lesion and diameter of both the common carotid and internal carotid arteries, in order to optimize a proper choice of the type and measures of the stent which will be used.

Usually the Carotid Wallstent is chosen in case of “soft” plaques which need to be covered as much as possible.

Femoral arteries are evaluated as well using duplex scan, to assess the presence of any iliac-femoral stenosis or plaque in order to choose the best access for the arterial puncture.

2.2. Implantation technique

All procedures are performed in the operating suite, with anesthesiological assistance. Cardiac rhythm is routinely monitored, as well as invasive radial arterial pressure.

Aspirin (100 mg daily) and Clopidogrel (75 mg daily) orally are started at least 5 days before the endovascular procedure, and continued for one month after revascularization, then aspirin alone (100 mg daily) is continued indefinitely. All patients who undergo CAS are awake during the procedure.

A percutaneous femoral access is usually preferred with a short 8 F sheath. Selective catheterization of the target common carotid artery is usually performed using two coaxial catheters (a 5.2 F Multipurpose inside a 8 F 40° guiding catheter). Supra-aortic vessels arising from a type II or a type III aortic arches, or even from bovine arches, may be selectively catheterized using a Hockey Stick catheter.

Primary stenting is performed whenever possible, using embolic protection devices (EPDs). In the first year of our experience EPDs weren't routinely used, then they were employed whenever possible.

Post-dilatation is usually achieved using 4.5–6.0 × 20 mm balloons; intravenous atropine is selectively administered if patients experience bradycardia (a decrease in heart rate < 50% or an absolute heart rate of <40 bpm) or hypotension (systolic blood pressure < 90 mmHg) before insufflation of the balloon or before delivering the stent [4]. As for the access site, manual compression on the arterial access is preferred in case of a severely diseased femoral artery, otherwise a vascular closure device (e.g. AngioSeal®) is employed.

2.3. Statistical analysis

Statistical analysis was performed using JMP® 5.1.2 (SAS Institute, Inc., Cary, NC, USA). Continuous variables are reported as median and interquartile range (IQR); categorical variables are presented as n (%). Logistic regression using the Wald statistic was performed to identify predictors of death or neurological complications. P values < 0.05 were considered statistically significant.

3. Results

Five-hundred and sixty patients underwent CAS using the Carotid Wallstent for a significant carotid artery stenosis (median stenosis degree 80% according to ECST measurement [9]). Their median age was 74 years (IQR 69–79 years) and 71.1% of them were male.

As described in Table 1, the most common patient comorbidities included current or previous smoking (63.2%), hypertension (71.6%), and dyslipidemia (47.5%). No patient presented with severe renal failure.

In 22.6% of cases, the patient had been symptomatic for a cerebrovascular event within the previous six months.

Most patients were treated for a primitive carotid artery stenosis. In 6 patients, the CAS was a rescue procedure after CEA, either after a failed attempt with an important neurological suffering during the carotid clamping (2 cases) or for a residual distal dissection causing neurological impairment (4 cases).

3.1. Procedural data

Primary success was achieved in 555 out of 560 cases (99.1%). Four patients required an immediate surgical carotid exploration for an acute stent thrombosis, which was resolved by stent explantation, carotid endarterectomy and carotid patch angioplasty. In the last case, selective catheterization of the common carotid artery (CCA) was not possible for extreme vessel tortuosity in a bovine type III aortic arch and the patient eventually refused any treatment.

Embolic protection devices were used whenever possible (91.25%). As described in Table 2, a distal filter was the type of EPD most used. Primary stenting was performed whenever possible (95.3%) and pre-dilation of the lesion was reserved only for cases of failed attempt of primary stenting due to severe stenosis which precluded the delivery of the stent throughout the lesion. A pre-dilation with cutting-balloon was performed in one case only because of a severe in-stent restenosis.

In 12 patients, one more stent was required for the optimal coverage of the plaque (additional Carotid Wallstent and Cordis Precise in 2 and 9 cases respectively). Another patient required the placement of two more stents (both of them Cordis Precise).

Post-dilation was performed in 95.9% of patients, and in most cases one dilation was enough to achieve an optimal result.

Table 1
Patients' characteristics and anatomical data.

	n = 560
Male sex	398 (71.1%)
Median age, years (IQR)	74 (69–79)
Comorbidities	
Current or previous smoke	354 (63.2%)
Coronary artery disease	202 (36.1%)
Hypertension	401 (71.6%)
Dyslipidemia	266 (47.5%)
Diabetes	128 (22.8%)
Obesity	73 (13%)
Chronic Renal Failure	75 (13.4%)
Familiar history of cardiovascular disease	141 (25.2%)
Preoperative symptoms	127 (22.6%)
Any previous stroke (before 6 months)	29 (5.2%)
Anatomical data (median, IQR)	
Degree of stenosis (ECST method)	80% (75% - 85%)
Side of the lesion	
Left	278 (49.6%)
Right	282 (50.4%)
Tandem lesion	91 (16.2%)
Location	
Carotid bifurcation	546 (97.5%)
CCA	14 (2.5%)
Etiology of the stenosis	
Atherosclerotic lesion	458 (81.7%)
Post-radiation stenosis	21 (3.7%)
In-stent restenosis	7 (1.2%)
Post-CEA restenosis	74 (13.3%)
Rescue of CEA procedures	6 (1.1%)
Contralateral carotid artery	
Mild stenosis	30 (5.4%)
Severe stenosis	30 (5.4%)
Occluded	87 (15.6%)
Previous CEA/CAS	93 (16.6%)
Tortuosity of carotid vessels/aortic arch	
Severe tortuosity	39 (6.9%)
Mild tortuosity	240 (42.8%)
Absence of tortuosity	281 (50.2%)
Features of the carotid plaque	
Ulcerated	22 (3.9%)
Fibrolipidic	259 (46.3%)
Calcified	279 (49.8%)

CCA = Common Carotid Artery.
CEA = Carotid Endarterectomy.
CAS = Carotid Artery Stenting

Local complications occurred in 7 patients: four had a femoral pseudoaneurysm (0.7%) that was manually compressed with complete exclusion in all but one case, and three had a superficial groin hematoma (0.5%) which didn't require any blood transfusion nor surgical evacuation and resolved spontaneously. One patient had a pneumonia and another patient developed an allergic reaction to contrast medium which was previously unknown. The patient had intraoperative skin rash which was resolved immediately after administration of corticosteroids and antihistamines drugs.

Two deaths occurred within 30 days (0.3%): 1 for traumatic causes and one for a cardiac arrhythmia (Table 3). In seven symptomatic patients an ipsilateral minor stroke occurred within 30 days, one of them during in-hospital stay (Table 3). All of these patients however gradually recovered and became clinically asymptomatic within 6 months. Two contralateral major strokes were observed in 18th and 11th postoperative day respectively, in patients who were neurologically asymptomatic before the procedure. Seven patients (1.2%) experienced a Transient Ischemic Attack (TIA) within 30 days, one of them immediately at the end of the procedure. In all of these cases, symptoms completely disappeared within 24 h and the computed tomography of the brain was negative.

Table 2
Intraprocedural and in-hospital data (Median, IQR).

	n = 560
Procedural success[a]	555 (99.1%)
Embolic Protection Device	
FilterWire EZ	473 (84.5%)
Emboshield/Neuroshield	25 (4.5%)
PAEC	6 (1%)
MoMa	2 (0.35%)
Angioguard	5 (0.9%)
Vascular Access Closure	
Manual compression	505 (90.2%)
Endovascular closure device	55 (9.8%)
Time of operation (min)	40 (30–50)
Amount of contrast (cc)	75 (70–85)
Fluoroscopy time (min)	15 (9–18)
Length of stay (days)	2 (2–3)

[a] Four acute stent thrombosis which required immediate surgical exploration and 1 failed attempt of selective catheterization of the CCA.

3.2. Long-term follow-up data

The median follow-up period was 78.2 months (IQR 37–121.5 months).

3.2.1. Survival

Survival at 1, 5 and 10 years was 96.6% ± 0.7%, 86.2% ± 1.6% and 71.2% ± 2.5% respectively (Fig. 1), without any significant difference between neurologically symptomatic and asymptomatic patients.

Age was a significant factor affecting long-term survival ($P = 0.01$), in particular for patients aged 71 and more at the time of the procedure (AUC 0.54, $R^2 = 0.0065$).

Contingency analysis of factors which significantly affected long-term survival showed that male sex, preoperative neurological symptoms and the occurrence of stroke within 30-days were independently associated with death ($P = 0.04$, 0.04 and 0.001 respectively, see Table 4).

Also procedures which lasted for >40 min were significantly related to the occurrence of death in the long-term ($P = 0.0017$, $R^2 = 0.01$; Area Under Curve = 0.61 at Receiver Operating Characteristic analysis).

Neoplasm was the main cause of death, followed by cardiologic and neurodegenerative diseases. Traumatic events also accounted for an important number of deaths in the long-term.

3.2.2. Cerebrovascular events

The occurrence of cerebrovascular events (TIA/stroke) in the long-term was significantly different between asymptomatic and symptomatic patients, being worse for the latter ($P = 0.008$).

Particularly, freedom from any cerebrovascular event at 1, 5 and 10 years was 98.6% ± 0.6%, 97.1% ± 0.8% and 91.2% ± 1.9% respectively for asymptomatic patients, and 96.8% ± 1.6%, 95.7% ± 1.9% and 81.7% ± 5% respectively for symptomatic patients (Fig. 2).

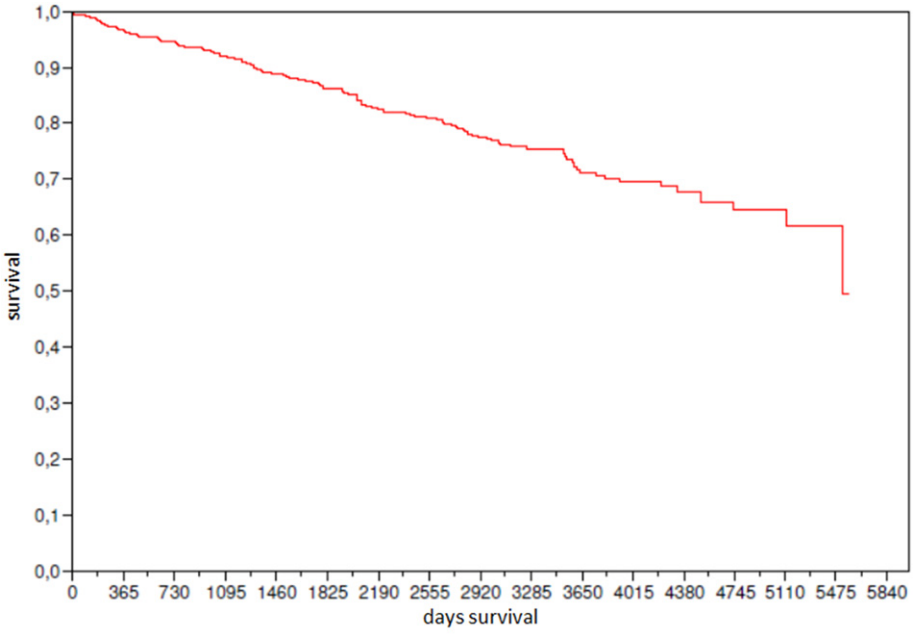
The use of any EPD was significantly related to a lower occurrence of either TIA or stroke in the long term ($P = 0.009$).

On the other side, patients who had experienced a TIA within the first 30 postoperative days were more likely to be affected by either a recurrence of TIA or a major event in the long term ($P < 0.0001$, see Table 4).

Table 3
Thirty-day results.

	n = 560
Death	2 (0.3%)
Myocardial Infarction	2 (0.3%)
Any stroke	9 (1.6%)
TIA[a]	7 (1.2%)

[a] Transient Ischemic Attack.



	Survival
1 aa	96.6%±0.7% (520 at risk)
5 aa	86.2%±1.6% (338 at risk)
10 aa	71.2%±2.5% (151 at risk)

Fig. 1. Long-term survival.

Also the operator's learning curve significantly affected the occurrence of cerebrovascular events in the long term, as this complication was more likely to occur in patients in whom the procedure had been performed by an operator in the first phase of his learning curve ($P = 0.01$).

Table 4
Pearson's correlation for factors significantly associated with the occurrence of death and stroke in the long-term (*P* values).

	Death	Stroke
Male sex	**0.04**	0.83
Age	**0.01**	0.55
Preoperative symptoms	**0.04**	**0.0066**
CAD	0.23	0.62
DM	0.09	0.4
Hypertension	0.17	0.89
Dyslipidemia	0.36	1
CRF	0.09	0.86
Previous stroke	0.77	0.15
Duration of procedure	**0.0017**	0.09
First Operator	0.06	**0.01**
Contralateral carotid occlusion	0.3	0.2
EPD	0.13	**0.009**
Ulcerated plaque	0.09	0.2
Predilation	0.4	0.91
Stroke within 30 days	**0.001**	0.94
TIA within 30 days	0.62	<**0.0001**
Immediate stent thrombosis	0.17	0.44
MI within 30 days	0.31	0.59

Significant *P* value in bold.
CAD = Coronary Artery Disease.
DM = Diabetes Mellitus.
CRF = Chronic Renal Failure.
TIA = Transient Ischemic Attack.
MI = Myocardial infarction.
EPD = Embolic Protection Device.

The type of carotid plaque was not related to the occurrence of any cerebrovascular event in the long-term, neither the presence of a tortuosity of the supra-aortic vessels.

3.2.3. Restenosis

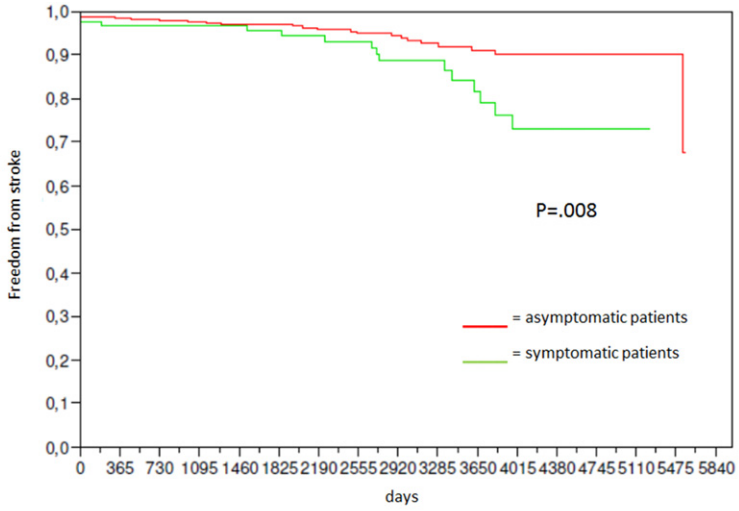
Freedom from a restenosis >30% detected at ultrasound examination was estimated to be of 99.16% ± 0.4%, 96.01% ± 0.9% and 93.9% ± 1.3% respectively at 1, 5 and 10 years (Fig. 3), however a significant in-stent restenosis >80% [5] was detected only in 7 patients, one of whom had experienced the occurrence of a TIA. In most cases, the restenosis was corrected using a simple balloon dilation (5 patients). A cutting balloon was used in one patient who had a severe in-stent restenosis due to a huge fibromuscular hyperplasia. In the remaining patient, another Carotid Wallstent was deployed inside the previous one, which presented a severe recoil in its middle third due to a highly calcified external plaque.

Contingency analysis showed that age was the only factor which significantly affected the occurrence of restenosis in the long-term ($P = 0.01$, see Table 5), in particular for patients aged 72 years and more ($R^2 = 0.02$; Area Under Curve = 0.65 at Receiver Operating Characteristic analysis).

4. Discussion

Endovascular management of critical carotid artery stenosis has been one of the most discussed topic in the literature since the last ten years, as many papers were published in the scientific literature comparing CEA to Carotid Artery Stenting (CAS) with the aim to assess the superiority of one method over the other [2].

Thanks to the use of the stent instead of a simple balloon dilation, the procedure has achieved excellent immediate and long-term results with a reduction of neurological perioperative complication, as the metallic frame of the stent with the coverage of the plaque usually offers a good protection from distal embolization. Moreover in our experience



	Asymptomatic	Symptomatic
1 aa	98.6%±0.6% (397 at risk)	96.8%±1.6% (112 at risk)
5 aa	97.1%±0.8% (252 at risk)	95.7%±1.9% (78 at risk)
10 aa	91.2%±1.9% (109 at risk)	81.7%±5% (33 at risk)

Fig. 2. Long-term estimated freedom from stroke.

the deployment of the stent is performed primarily whenever possible, from an initial strategy of predilation which could generate distal emboli.

The plaque morphology plays an important role in the occurrence of postoperative cerebral ischemic events. Particularly, Brott and Coll. demonstrated that «plaque instability» determined procedural risk in CREST [6].

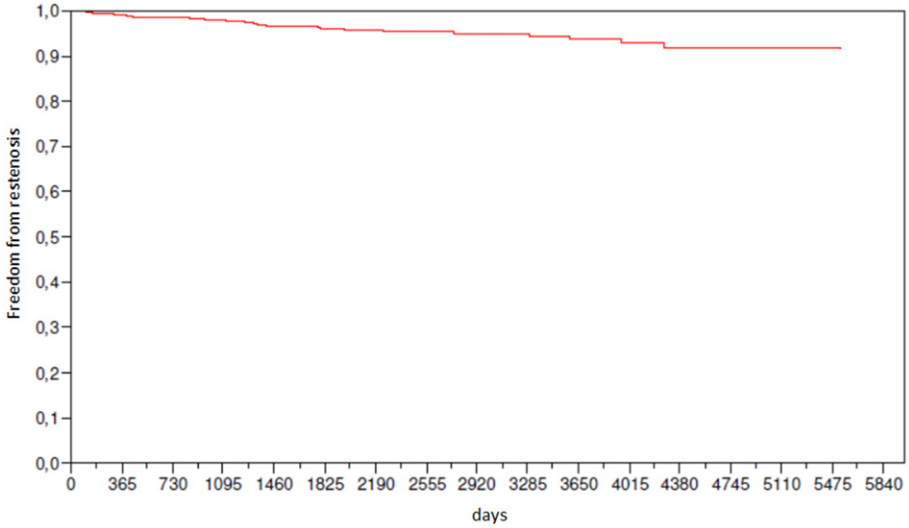
In the light of these assumptions, it is crucial to use a stent with a morphology that ensures an excellent navigability through the lesion and the smallest "maximum unprotected circular area", which is index of plaque prolapse towards the lumen.

For the treatment of carotid stenosis, self-expandable stents represent the best choice, because they carry a lower risk of deformation or breakage than the balloon-expandable stents, in case of sudden movements or neck injury. The most used stent is the Carotid Wallstent (Boston).

More recently the self-expandable nitinol stents (Precise, Cordis; ACCULINK, Guidant; X-act, MedNova; etc.) have been introduced. They are characterized by a greater radial strength and a greater adaptability to vessel tortuosity and to differences between the size of the internal and the common carotid artery.

The choice of the more appropriate stent depends on the ease of placement with the least risk of acute complications.

Bosiers and Coll. in the ELOCAS study [7] reported data about 2172 patients who underwent CAS in 4 high-volume European centers. In 1261 of them, the Carotid Wallstent was the choice, with a 3-year



	Asymptomatic
1 aa	99.16%±0.4% (515 at risk)
5 aa	96.01%±0.9% (332 at risk)
10 aa	93.9%±1.3% (147 at risk)

Fig. 3. Long-term estimated freedom from restenosis.

Table 5
Pearson's correlation for factors significantly associated with the occurrence of restenosis in the long-term (*P* values).

	Restenosis
Male sex	0.7
Age	**0.01**
Preoperative symptoms	0.77
CAD	0.09
DM	0.84
Hypertension	0.97
Dyslipidemia	0.15
CRF	0.11
Previous stroke	0.69
Duration of procedure	0.97
First Operator	0.14
Contralateral carotid occlusion	0.16
EPD	0.77
Ulcerated plaque	0.15
Predilation	0.11
Stroke within 30 days	0.51
TIA within 30 days	0.54
Immediate stent thrombosis	0.64
MI within 30 days	0.74

Significant *P* value in bold.
CAD = Coronary Artery Disease.
DM = Diabetes Mellitus.
CRF = Chronic Renal Failure.
TIA = Transient Ischemic Attack.
MI = Myocardial infarction.
EPD = Embolic Protection Device.

reported rate of stroke/death lower than 13.7% in the symptomatic cohort, which compared favourably to the 3-year outcome of CEA in symptomatic patients.

The CABANA study [8] in 2012 was designed to specifically evaluate CAS results in high-surgical-risk patients treated with the Carotid Wallstent by a broad-based group of providers. In this prospective, single-arm study, White and Coll. will analyze 30-day stroke, death, and MI rates after 1097 CAS performed at 99 study centers which meet the credential-based training requirements for participating in the study itself. In their evaluation [9], the Authors found a 30-day stroke rate of 3.3%, which was a major contributing factor in the overall major adverse events rate (MAE, 4.6%). Mortality was 1.3% and the MI rate was 0.5%. They did not found either statistically significant association between MAE rates among the center experience tiers ($P = 0.61$) nor among the operator training categories ($P = 0.26$).

Moreover, Doig and Coll. [10] recently investigated the effect of baseline patient demographic factors, processes of care, and technical factors during CAS on the risk of stroke, myocardial infarction (MI), or death within 30 days of CAS in the International Carotid Stenting Study (ICSS). Their results favored the use of closed-cell stents as the open-cell stent conferred a 1.92 time higher risk of developing perioperative stroke, MI or death. Cerebral protection device (CPD) use did not modify this risk.

Therefore, according to what is reported in the literature, the Carotid Wallstent seems to be a stent that provides good protection especially in symptomatic patients, someway regardless of the expertise of the individual operators.

In our experience the Carotid Wallstent was a safe and effective device for the treatment of both asymptomatic and symptomatic carotid stenosis in high surgical risk patients.

In particular, it showed a good navigability through almost all type of anatomies without increasing significantly the risk of neurological adverse events, as no relation was noted between the presence of a tortuosity of the supra-aortic vessels and the occurrence of any cerebrovascular event in the long-term.

As reported in the literature, also in our experience the Carotid Wallstent offered a good protection towards "soft" plaques, as evidenced also by the fact that the type of carotid plaque was not related to the occurrence of neurological impairment in the long-term.

On the other side, the expertise of the operator played an important role in the occurrence of cerebrovascular events, nevertheless it was probably due to a longer manipulation of the catheters in the aortic arch performed by inexperienced operators rather than to the learning curve of the Carotid Wallstent.

The strength of our study is represented by the high number of procedures performed over 15 years in a single Institution. Moreover, in almost half of the cases of our series, the Carotid Wallstent was chosen for the presence of a "soft" plaque, in patients who could not undergo CEA because of surgical comorbidities.

Limitations of our study are represented by the retrospective nature of the analysis. It would be interesting to compare the occurrence of 30-days and long-term cerebrovascular events between patients submitted to CAS using the Carotid Wallstent and those submitted to CEA during the same period.

Conflict of interest

The Authors have nothing to disclose.

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