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Bypass for symptomatic in-stent carotid restenosis☆

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ABSTRACT

Background: To evaluate early and long-term outcomes of symptomatic patients treated for in-stent carotid restenosis (ISR) with carotid bypass (CB).
Methods: Data were retrospectively collected from a prospectively compiled database on patients treated with CB in two high-volume Italian centers between 2008 and 2016, for symptomatic high-grade ISR after CAS. After carotid endarterectomy and stent removal, a greater saphenous vein (GSV) was preferentially employed as the graft; when the GSV was not accessible, a 6 mm polytetrafluoroethylene (PTFE) graft was implanted. Standard follow-up protocol included clinical examinations, duplex scans (DUS) and computed tomographic angiography. Measures considered for analysis were perioperative (30-day) and long-term occurrence of new ipsilateral cerebral events, neurological deficits, death from all causes, and needs for reintervention. In addition, peripheral nerve palsy, cervical hematomas, and other local complications after surgery were noted.
Results: The population of the study comprised 13 patients (11 men and two women; median age was 66.5 years (range 56-88)). Mean times from index CAS to stent explantation were 38.9 ± 18.2 months. GSV grafts were used in seven cases (53.8%) and PTFE grafts in the remaining six (46.2%) cases. Intraoperative neurological complications rate was null. One patient presented a transient dysphagia. At 30-day, no new neurological complications, reinterventions or deaths occurred. At mean follow-up of 41.2 ± 18.2 months, three patients died in absence of further neurological events. None of the CB patients required reintervention.
Conclusions: In our experience, CB offers satisfactory results in patients treated for symptomatic ISR with an acceptable risk of cranial nerve injury.

1. Introduction

In-stent restenosis (ISR) after CAS is a relatively prevalent complication (range 5–12%) that could limit the long-term efficacy of this procedure [1–3]. Data from the two noteworthy, randomized controlled trials differentiating results from carotid endarterectomy versus CAS reported an incidence of ISR after CAS in almost 11.1% of patients in the SPACE trial [2] and 12.2% in CREST [3].

Still today, ISR remains a great controversial topic because no consensus has been reached in terms of definitions, operative indications and technical strategies [4].

Usually, an ISR requiring reintervention is treated by a cutting edge, endovascular approach [1,5,6]. If the defect significantly fills the vessel lumen, it should be first treated with in-stent balloon inflation (re-PTA) and, if necessary, with the implantation of a new stent (stent-in-stent). However, catheter based procedures for ISR seem to show unsatisfactory long-term results due to high rates of re-ISR [1].

The aim of the present study was to assess our experience with early and long-term outcomes of patients treated for in-stent (symptomatic) carotid restenosis with carotid bypass (CB).

2. Materials and methods

Thirteen cases of ISR after CAS in which stent removal plus CB were performed are reported. Data were retrospectively assembled in a prospectively compiled database for patients treated between January 2008 and December 2016, in two high-volume Italian centers: the Vascular Surgery Division at the University of "Campus Bio-Medico" of Rome and the Vascular and Endovascular Surgery Division at "Sapienza" University of Rome.

Indications for CB were high-grade (>70% defined as a peak systolic velocity [PSV] > 300 cm/s, an end-diastolic velocity (EDV) > 140 cm/s, and PSV ratio internal and common carotid artery > 3.86) restenosis after CAS (ISR), in recently symptomatic patients.

Symptoms were defined as a previous ipsilateral stroke or transient ischemic attack (TIA) in the prior three months. A TIA was defined as a focal, retinal, or hemispheric event from which the patient made a complete recovery within 24 h. A minor stroke was defined as a new neurologic deficit that either resolved completely within 30 days,

☆ As corresponding author for this manuscript, I confirm that the paper has been seen and approved by all Authors, and all the authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

In addition, all authors have contributed in a significant way, meriting authorship.

There has been no duplicate publication or submission of any part of the work, and there is no financial arrangement or other relationship that could be construed as a conflict of interest.

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or increased on the National Institutes of Health Stroke Scale (NIHSS) by <3. A major stroke was defined as a new neurologic deficit that persisted for >30 days and increased on the NIHSS by >4.

All patients underwent cerebral magnetic resonance imaging (MRI) before surgery to assess the presence, nature, and extent of eventual brain lesions.

CB was performed under loco-regional (LA) or general anaesthesia (GA), according to surgeons, anaesthesiologists, and patients' preferences, as well as the considerations of patients' status and comorbidities.

After skin incision, an anterior sternocleidomastoid approach to the carotid bifurcation was performed in all patients. Sequential and separate cross clamping of the common, internal and external carotid arteries were obtained after systemic heparinization (70 UI/kg). Once longitudinal arteriotomy was completed, a standard endarterectomy was carried out in the usual plane and the stent was removed within the plaque (Fig. 1). Then the internal carotid was transected at its origin, and a CB was performed by a side-to-end anastomosis on the common carotid artery in both the center and by an end-to-side (Campus Bio-Medico) or end-to-end (Sapienza) anastomosis on the internal carotid artery on a healthy zone distal to the removed edge of the stent. A greater saphenous vein (GSV) was preferentially used as the graft; when the GSV were not accessible or judged unfit as a conduit (<4 mm diameter), or in patients with critical limb ischemia, a 6 mm polytetrafluoroethylene (PTFE) graft was implanted. Whenever feasible, external carotid artery patency was preserved.

When cerebral perfusion was restored, the common carotid artery clamp was positioned distally to the CB proximal anastomosis. Then, the carotid bulb was sutured in an endeavour to preserve the external carotid artery patency, whenever possible.

In cases of general anaesthesia, neurological status assessments were performed using the near-infrared spectroscopy (NIRS), obtained by INVOS™ 5100C (Medtronic Inc., Santa Rosa, CA, USA), associated with stump internal carotid artery pressure measurements.

Shunts (Pruitt-Inhara shunt; LeMaitre Vascular, Burlington, MA, USA) were selectively employed when clamping ischemic symptoms were clinically evident during LA, or when a >20% reduction of regional oxygen saturation at NIRS, associated with a stump pressure < 50 mm Hg, was detected during GA.

Patients were discharged on the third or fourth postoperative day under single antiplatelet therapy. Standard follow-up protocol in both centers included clinical examinations, duplex scan assessments and CTAs at one month after surgery. In the absence of new clinical events, routine duplex surveillances were scheduled at three, six and 12 months and yearly thereafter.

Measures considered for analysis were perioperative (30-day) and long-term occurrence of new ipsilateral cerebral events, neurological deficits, death from all causes, and needs for reintervention. In addition, peripheral nerve palsy, cervical hematomas, and other local complications after surgery were noted. Data were reported as median and range, mean and standard deviations or as absolute frequencies and percentages (%).

Both local reviewer boards approved the present study. Patients gave consents for treatment, participation in surveillance protocols, and for publication of their clinical notes.

3. Results

Eleven patients were male; median age was 66.5 years (range 56–88); demographical and clinical features of patients enrolled are reported in Table 1.

At hospital admission, two patients (15.4%) evidenced recent minor strokes, and 11 had previous TIAs (84.6%). Preoperative MRIs were positive for sub-acute ischemic lesions in both patients presenting with strokes. Mean times from index CAS to stent explantation and CB were 38.9 ± 18.2 months. CAS was performed for de novo lesions in nine patients, and in four (30.8%), to treat post carotid endarterectomy restenosis (post-CEA restenosis). Four patients received further endovascular procedures after index CAS. Data regarding previous procedures and types of implanted stents as well as intraoperative technical details are reported in Table 2.

Table 1
Demographic and clinical characteristics of study population.

	13 patients
Age (median, range)	66.5, 56–88
NIHSS for patients with stroke (median, range)	2, 1–3
Male Sex (*n*; %)	11; 84.6
Minor Stroke (*n*; %)	2; 15.4
TIA (*n*; %)	11; 84.6
Hypertension (*n*; %)	10; 76.9
Dyslipidaemia (*n*; %)	7; 53.8
Diabetes (*n*; %)	3; 23.0
CAD (*n*; %)	3; 23.0
Smoke (*n*; %)	10; 76.9
COPD (*n*; %)	3; 23.0
CRI (*n*; %)	2; 15.4

NIHSS: National Institutes of Health Stroke Scale; TIA: transient ischemic attack; CAD: coronary artery disease; COPD: chronic obstructive pulmonary disease; CRI: chronic renal insufficiency.

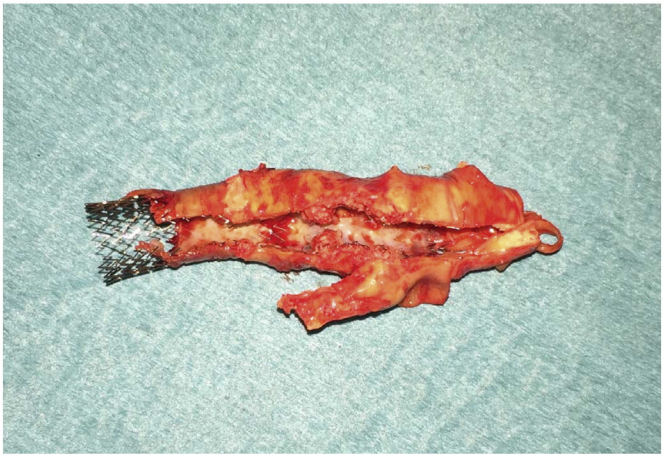

Fig. 1. Intraoperative findings during carotid endarterectomy and stent removal showing intraluminal high-grade restenosis.

GA was performed in five (38.5%) cases; all other procedures were carried out under LA (61.5%). One patient required mandibular subluxation during CB to provide better exposure of the distal ICA [7]. Selective carotid shunt was necessitated in two cases (15.4%).

After whole stent removal, GSV grafts were employed in seven cases (53.8%) and PTFE grafts in the remaining six (46.2%) cases. In one case the external carotid artery was sacrificed due to the poor quality of the residual arterial wall. Intraoperative neurological complication rates were null. No laterocervical hematomas requiring surgical management were noted.

One patient, with ISR after post-CEA restenosis, presented a transient dysphagia completely resolved after three months. No new neurological complications and deaths occurred during hospitalizations (mean in-hospital stays 3.9 ± 1.4 days).

All patients completed 30-day follow-ups and CB grafts were patent in absence of further neurological complications.

At mean follow-ups of 41.2 ± 18.2 months, three patients died (two of acute myocardial infarctions and one of lung cancer) and no further neurological events were registered. At duplex scans (DUS) examinations, none of the CB patients required reintervention. Even, if, in one patient (treated by PTFE graft), a non-hemodynamic restenosis was noted (<50%). In two cases, asymptomatic occlusions of the common-external, post-CEA segment were detected.

4. Discussion

ISR after CAS is one of the great controversial topics in modern vascular surgery. No consensus has been reached in terms of definitions, operative indications and technical strategies [4].

Even defining ISR as a serious complication that could limit the long-term efficacy of the carotid revascularization, the recently published Italian Society for Vascular and Endovascular Surgery (SICVE) guidelines failed to furnish any recommendations [8].

According to a recent Dutch review, the reported parameters for determining when an ISR should undergo re-intervention are extremely variable in different published experiences [1]. Some authors suggest performing interventions on all asymptomatic restenosis >50%; others for treating stenosis >70% (only in symptomatic patients), while others do not pose indications in cases of restenosis >90% [1]. In the present series, 70% was adopted as the threshold for treatment indications, only for symptomatic patients.

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