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ORIGINAL ARTICLE

Carotid artery stenting performed with a flow-reversal technique: Improved technical performance

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KEYWORDS
Carotid artery stenosis;
Flow reversal;
Carotid artery stenting;
Cerebral protection devices;
Carotid stent

Summary
Objective: To report our experience in carotid artery stenting (CAS) with GORE flow reversal system®, focusing the assessment of its efficacy, security and practice procedure evolution.
Methods: Twelve patients treated for atherosclerotic carotid stenosis were prospectively evaluated. All patients were symptomatic. Carotid symptoms were embolic stroke in eight, watershed stroke in two and transient ischemic attack (TIA) in two patients. All patients underwent carotid ultrasound, brain magnetic resonance image and magnetic resonance angiography before CAS procedure. The procedure time and the flow reversal time were registered. Neurological outcome was evaluated before treatment, during the first 48 hours post-treatment and after 3 months.
Results: CAS was successful in all cases. Mean procedure time was 33.8 minutes. Mean flow reversal time was 7.3 minutes. Temporary bradycardia occurred with six patients without associated hemodynamic instability. NIHSS patients' scores ranged from 0 to 5 (average 1.1) on admission and remained unchanged during 48 hours after treatment. mRS patients' scores ranged from 0 to 3 (average 1.6) on admission and remained unchanged during the follow-up of 3 months. There were no complications concerning groin puncture, or general anesthesia, or myocardial infarct or death.
Conclusion: In our present selected subjects, the CAS procedure using the GORE flow reversal system appeared to be safe and effective, with improved technical performance of the procedure. This was observed in particular with the flow-reversal times achieved. Thus, studies comparing the GORE system and other protection devices are suggested to ascertain all of the benefits of flow reversal during CAS.

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Introduction

Ischemic stroke is the third cause of death and leading cause of long-term disability worldwide [1]. Carotid atherosclerotic disease constitutes around 15—20% [2,3] of all causes of ischemic stroke, with a prevalence rate of around 9% [4] in the general population. Since the first report of carotid artery stenting (CAS) by Théron et al. [5], using a balloon as an embolic protection device, several devices have been developed, aiming to eliminate embolic complications and to make CAS comparable to the gold-standard endarterectomy technique [6—14].

Currently, there is evidence to support the use of embolic protection devices during CAS [6,11,13]. However, embolic complications can still arise during CAS procedures, as reported by previous studies [6,10,15—17]. Therefore, an ideal model of an embolic protection device is required. As described by Parodi et al. [18] in 2000, CAS can be used during blood flow reversal in a target carotid artery as an embolic protective technique.

CAS as performed in our department is usually via femoral artery access, using a distal FilterWire EZ protection system and a carotid WALLSTENT (both by Boston Scientific, Natick, MA, USA). For patients with an aortic arch unsuitable for CAS by femoral access, a brachial access is usually chosen. However, our department frequently treats patients that, in our opinion, present with carotids that are anatomically ''unfavorable'' to CAS with filter devices. Such an unfavorable carotid profile includes critical carotid stenosis, fresh thrombus in situ and a severely tortuous distal internal carotid artery (ICA). These features most likely enhance embolic complications during CAS with filters because critical stenoses need to be dilated, using microballoons, before distal filter deployment. The presence of fresh thrombus in the target stenosis can also lead to distal embolization during first passage of the microwire through the ICA, while a tortuous distal ICA promotes inadequate filter deployment, allowing the passage of emboli during angioplasty and stenting. Thus, given the EMPiRE clinical study results [19], our department started performing CAS using the GORE flow reversal system to develop the expertise needed to treat this subgroup of ''unfavorable'' patients while aiming to achieve the best technical performance possible.

This report is of a series of 12 patients undergoing CAS with the GORE flow reversal system (W.L. Gore & Associates, Flagstaff, AZ, USA) in a tertiary hospital center to assess its technical aspects and neurological outcomes.

Methods

Patients

To describe our experience of CAS with the GORE system, focusing on its safety, efficacy and technical development, 12 patients treated for carotid atherosclerotic stenosis at our department from August 2010 to May 2011 were analyzed. All patients gave their written informed consent to participate in the study, which had previously been approved by the institutional review boards. Patients were referred to our department by the neurovascular team, and all presented with previous neurological symptoms related to ICA stenosis. Carotid ultrasound (US) was always performed before CAS. Patients who presented with ICA stenosis more than or equal to 50% (North American Symptomatic Carotid Endarterectomy Trial [NASCET] criteria) [20] underwent 3-T magnetic resonance imaging (MRI), using a Philips Achieva Duo scanner (Philips Medical Systems, Best, The Netherlands), to assess brain ischemic injury patterns and angiographic architecture, particularly the ICA stenosis, aortic arch anatomy and intracranial collateral pattern. All patients were examined in hospital and at a 3-month follow-up by an independent vascular neurologist, who measured outcomes using the US National Institutes of Health Stroke Scale (NIHSS) and modified Rankin Scale (mRS).

Inclusion criteria

These were: age more than or equal to 18 years; life expectancy more than or equal to 1 year; presence of any grade of ICA stenosis with in situ thrombus; ICA stenosis more than 60%, or more than or equal to 50% if associated with ipsilateral neurological symptoms; favorable arterial femoral pulse; favorable aortic arch (absence of severely tortuous or mobile plaques; such cases routinely underwent CAS using a distal filter wire via brachial access, as the GORE flow reversal system is not recommended for radial or brachial access); presence of anterior or ipsilateral posterior communicating arteries; external carotid artery (ECA) diameter less than or equal to 6 mm; and absence of any arterial branch emerging below the ECA occlusion site. The percentage of stenosis was determined using magnetic resonance angiography (MRA) and, again, NASCET criteria [20]. ''Neurological symptoms'' were defined as stroke, transient ischemic attack (TIA), hypoperfusion symptoms or amaurosis fugax.

Exclusion criteria

These included: contralateral ICA occlusion; more than 50% stenosis in the contralateral ICA; any grade of stenosis in the four vessels; total occlusion of the target carotid artery; absence of posterior and anterior communicating arteries; severely tortuous or mobile plaques in the aortic arch; ECA diameter more than or equal to 6 mm; arterial branches emerging below the ECA occlusion site; contraindications to general anesthesia; ischemic stroke onset less than or equal to 14 days before CAS; myocardial infarction less than 72 h prior to the procedure; any major surgical procedure within 30 days before or planned for within 30 days after CAS; severe chronic renal insufficiency (serum creatinine more than 1.5 mg/dL); and untreatable bleeding diathesis or hypercoagulable state, or refusal of blood transfusion.

The carotid artery stenting procedure

All CAS procedures were performed by the same experienced interventional neuroradiologist (D.G.A.) using a flat-panel detector system (Innova 4100, GE, Fairfield, CT, USA). The recommended antiplatelet regimen was aspirin (300 mg/day) and clopidogrel (75 mg/day) at least 5 days before the treatment, or aspirin (300 mg/attack) and clopidogrel (300 mg/attack) at least 4 h before the procedure.

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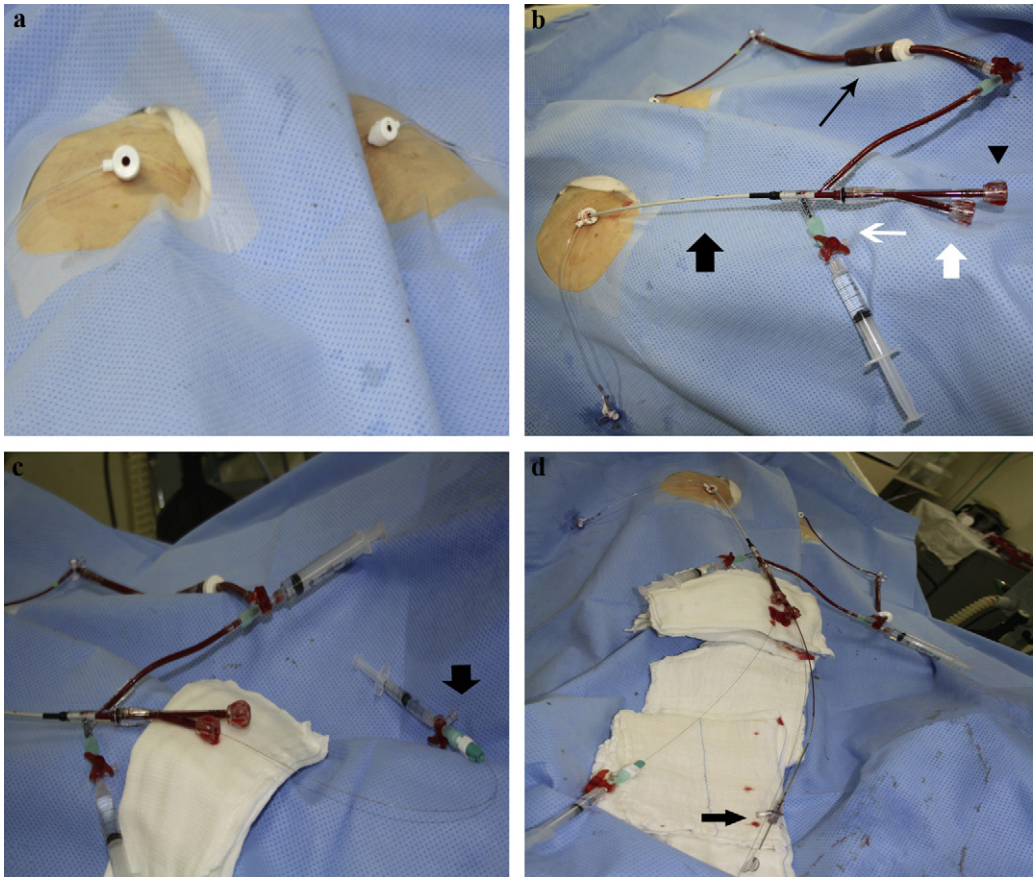

Figure 1 a: a 10-F sheath in right femoral artery and 6-F sheath in left femoral vein; b: GORE balloon sheath (thick black arrow), common carotid artery (CCA) port (arrowhead) and syringe in CCA balloon port (thick white arrow), and GORE external filter (thin black arrow) and external carotid artery (ECA) port for GORE balloon wire; c: GORE balloon wire with syringe; d: external view of the entire GORE flow reversal system: the carotid WALLSTENT and ChoICE Floppy Guide Wire (both by Boston Scientific) are in the GORE balloon sheath (black arrow) during flow reversal.

After femoral puncture, 7500 IU of heparin were administered intravenously. The first three patients were put under local anesthesia and minimally conscious sedation to better evaluate flow-reversal intolerance. The other nine patients underwent general anesthesia. All procedures were done with the GORE flow reversal system (Fig. 1).

All GORE devices were placed on the procedure table before doing the punctures, and included a balloon sheath (9.5-F outer diameter, 7.3-F inner diameter and 91-cm working length), a balloon wire for the ECA (0.015-inch outer diameter and 145-cm working length), an external filter (0.0015-inch outer diameter), a vertebral 5-F catheter or Simmons 5-F catheter (both by Merit Medical Systems, South Jordan, UT, USA), a hydrophilic guide wire (Angiotech, Gainesville, FL, USA), a 0.035-inch (260-cm) J-Tip Extra Stiff Wire Guide (Cook, Bloomington, IN, USA), a 3.0-mm × 20-mm Monorail pre-dilatation balloon, a 0.014-inch × 182-cm J-tip ChoICE Floppy Guide Wire, a 6.0-mm × 20-mm × 153-cm Monorail post-dilatation balloon and a closed-cell carotid WALLSTENT (the lattermost four by Boston Scientific).

The right common femoral artery and left common femoral vein punctures were performed with the Seldinger technique, using a 10-F sheath (St Jude Medical Daig Division, Minnetonka, MN, USA) for the right access and a 6-F sheath (Arrow International, Reading, PA, USA) for the left (Fig. 1).

Diagnostic vertebral or Simmons catheters were used to navigate the common carotid artery (CCA), and carotid bifurcation and cerebral angiography were also done. The diagnostic catheter was pushed into the ECA using the hydrophilic guide wire, which was subsequently replaced by the stiff wire introduced into the ECA. The diagnostic catheter was then replaced by the balloon sheath, which was placed in the CCA and followed by removal of the stiff wire. Because of the balloon sheath size and its relatively high rigidity, the stiff wire was necessary to ensure ascension of the balloon sheath from the femoral to the CCA, especially when a Simmons catheter was needed to catheterize the CCA. The external filter was used to connect the balloon sheath to the left femoral vein sheath. The balloon wire was placed and inflated in the ECA, and followed by inflation of the balloon sheath to promote flow reversal through the ICA, thereby creating an arterial—venous shunt.

When necessary, pre-dilatation was performed to allow the stent to cross the target stenosis. The stent was then deployed, and angioplasty performed using the post-dilatation balloon. At this time, an atropine bolus (0.5—1.0 mg) was infused intravenously if cardiac arrhythmia

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Table 1 Clinical data for patients who successfully underwent carotid artery stenting with the GORE flow reversal system.

Patients	mRS score (before/3 months after treatment)	NIHSS score (before/48 h after treatment)	Procedure time	Flow reversal time	Temporary bradycardia	Pre-dilatation
1	0/0	2/2	1 h 45 min	41 min 10 s	Yes	Yes
2	3/3	1/1	51 min 6 s	6 min 7 s	No	No
3	2/2	2/2	29 min 20 s	3 min 43 s	Yes	Yes
4	0/0	1/1	28 min 5 s	2 min 55 s	No	No
5	1/1	0/0	29 min 3 s	4 min 36 s	Yes	No
6	1/1	0/0	25 min 10 s	3 min 32 s	No	No
7	3/3	5/5	26 min 50 s	6 min 37 s	Yes	Yes
8	3/3	2/2	21 min 43 s	5 min 34 s	Yes	Yes
9	3/3	0/0	24 min 1 s	3 min 46 s	No	No
10	0/0	0/0	22 min 7 s	3 min 4 s	Yes	No
11	3/3	1/1	21 min 4 s	3 min 7 s	No	No
12	1/1	0/0	22 min 10 s	3 min 55 s	No	No

occurred. Finally, the post-dilatation balloon, balloon wire and balloon sheath were deflated, thus restoring normal carotid flow.

While the 10-F sheath was maintained in place for 12 h after CAS, the 6-F sheath was removed immediately after the procedure was concluded and followed by manual compression.

Procedure times

Two duration times were recorded: the overall procedure time, and the flow-reversal time. Procedure duration was counted from the time of puncture to removal of all devices, while the flow-reversal time was counted from inflation of the balloon sheath to the instant it was deflated.

Results

Patients

The patients (five women and seven men) ranged in age from 61 to 82 years (average: 71.8 years). The vessels treated were the ICA at the bifurcation with the CCA, with seven in the left and five in the right. All patients were symptomatic, with embolic stroke in eight cases, watershed stroke in two and TIA in two others. Patients 1, 3, 7 and 8 presented with critical stenosis of the ICA, whereas the others all presented with ICA stenosis more than 60%. All patients presented with a communicating anterior artery and A1 segments of the two cerebral anterior arteries. All patients also presented with no contralateral ICA stenosis more than 50% or cervical stenosis in the four vessels. There were no complications related to groin puncture or general anesthesia, or myocardial infarction or death. Patients' NIHSS scores ranged from 0 to 5 (average: 1.1) on admission and remained unchanged for 48 h after treatment. Patients' mRS scores ranged from 0 to 3 (average: 1.6) on admission and remained unchanged throughout the 3-month follow-up (Table 1).

Carotid artery stenting procedure and recorded times

CAS was successfully accomplished in all 12 patients. Pre-dilatation was performed in patients 1, 3, 7 and 8. Patient 1 presented with the most critical ICA stenosis and needed several pre-dilatations, and represented the most difficult case, resulting in a prolonged procedure time (Fig. 2). Procedure times ranged from 21 to 105 mins (average: 33.8 mins), while flow-reversal times ranged from 2.9 to 41.1 mins (average: 7.3 mins). Excluding patients 1 and 2, the mean procedure and mean flow-reversal times were 24.9 and 4.0 mins, respectively. When pre-dilatation was not done (Fig. 3), the mean flow-reversal time was 3.5 mins, compared with 5.3 mins (excluding cases 1 and 2) when pre-dilatation was necessary. At the end of CAS, carotid bifurcation and cerebral angiography showed no embolic complications, and no signs of arterial dissection or vasospasm. Temporary bradycardia was seen in patients 1, 3, 5, 7, 8 and 10 with no associated hemodynamic instability. There were no technical complications. However, during stent deployment in patient 4, the balloon wire became dislodged and, although it was resolved by reinsertion, it caused an undesirable temporary ECA opening. Technical aspects of the procedures are presented in Table 1.

Discussion

Despite the improvement in CAS complication rates through the greater use of embolic protection devices, complications still arise [6,10,15—17]. Since the flow-reversal technique was first described, several clinical studies have demonstrated positive results and good CAS outcomes with femoral [15,18,19,21—26] and cervical approaches [27—35]. For this reason, flow reversal is a promising tool for embolic protection during CAS.

However, femoral access has received some criticism, as arch and supra-aortic trunk instrumentation could lead to brain embolic complications before reaching the CCA [27—35]. On the other hand, femoral access has the advantage of needing no CCA surgical incision, thereby avoiding the inherent risk of CCA dissection. Moreover, at present, there are no definitive or significant differences between the femoral and transcervical approaches during CAS by flow reversal [36]. When faced with challenging aortic arch anatomy or an unfavorable route between the femoral arteries and target CCA, access via radial and brachial arteries are alternative pathways for CAS [37]. In our

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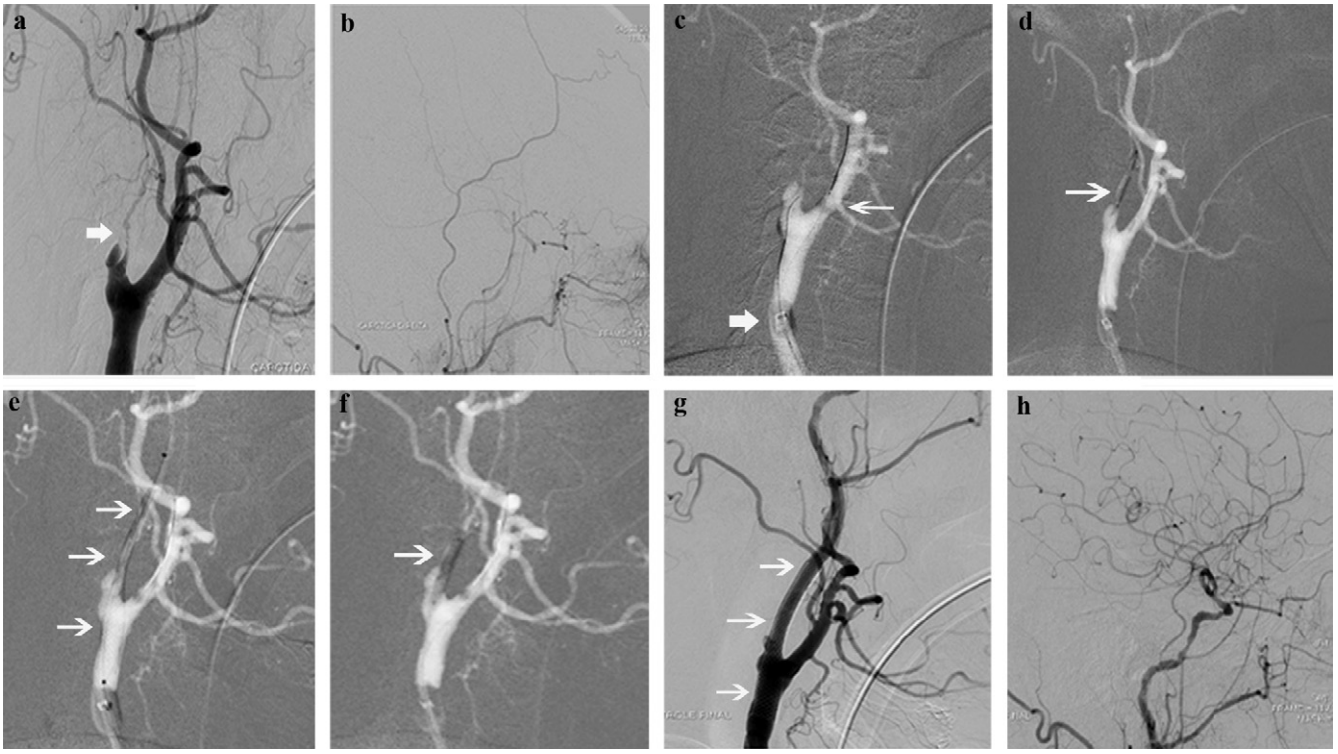

Figure 2 a: digital subtraction angiography (DSA) of right common carotid artery (RCCA), arterial phase, oblique view, shows 95% stenosis of right internal carotid artery (RICA) and ulcerated plaque at its origin (white arrow); b: DSA of RCCA, arterial phase, lateral view, shows right external carotid artery (RECA) branches and poor filling of RICA branches; c: road map of RCCA, oblique view, shows balloon sheath inflated in RCCA (thick white arrow) and balloon wire inflated in RECA (thin white arrow), promoting flow reversal in left common carotid artery (LCCA); d: road map of RCCA, oblique view, shows pre-dilatation of RICA stenosis (white arrow); e: road map of RCCA, oblique view, shows stent deployment in RICA (white arrows); f: road map of RCCA, oblique view, shows post-dilatation balloon inflated at RICA stenosis level (white arrow); g: DSA of RCCA, arterial phase, oblique view, shows final stent appearance (white arrows); and h: DSA of RCCA after Carotid artery stenting (CAS), arterial phase, lateral view, shows RECA branches and significant restoration of RICA branch filling.

department, patients with an aortic arch unfavorable for CAS by femoral access usually undergo brachial access with a distal FilterWire EZ as an embolic protection device. However, the GORE flow reversal system is not recommended for radial or brachial access because of the large balloon sheath diameter (9.5 F) and its relatively high rigidity. For this reason, patients presenting with an unfavorable aortic arch were excluded from the present series.

Another central point of CAS with flow reversal is the ability of patients to tolerate ICA flow reversal. Intolerance to ICA flow reversal has been associated with symptoms of TIA, loss of consciousness, amaurosis and/or seizures. At this time, the main factors thought to be responsible for flow-reversal intolerance are low blood pressure during the procedure, cervical vessel occlusions, little communication between the ICA and ECA, and absence of intracranial collaterals (circle of Willis, leptomeningeal collaterals) [36]. Nevertheless, for most authors, the issues described above are not formal contraindications to establishing flow reversal during CAS. Pipinos et al. [38] reported on the only study investigating the relationship between flow-reversal tolerance and the anatomical architectural patterns of the cervical and intracranial vessels. They evaluated flow-reversal intolerance during CAS under general anesthesia using electroencephalography (EEG) monitoring, and demonstrated that patients with at least one patent circle of Willis collateral, even in the presence of contralateral ICA occlusion, were able to tolerate both CCA clamping and ICA flow reversal. In addition, the team reported that 91% of the evaluated patients who needed carotid revascularization could safely undergo both CCA clamping and flow reversal [38].

Our first three patients were treated under local anesthesia and minimally conscious sedation to better evaluate flow-reversal tolerance. Despite the absence of flow-reversal intolerance during the first three treatments, movement artifacts led to technical difficulties and, thus, prolonged procedure times. For this reason, and based on the studies of Pipinos et al. [38] and Criado et al. [39], who demonstrated flow-reversal tolerance in patients, our group began performing CAS under general anesthesia. In addition, precautions were taken to perform the procedures under general anesthesia only in patients presenting with at least one patent intracranial collateral, or no stenosis more than 50% in the contralateral ICA or any grade of stenosis in the four cervical vessels. Such precautions were taken because any of these features could theoretically cause flow-reversal intolerance and, possibly, even watershed brain ischemic injury during a long procedure in an unconsciousness patient.

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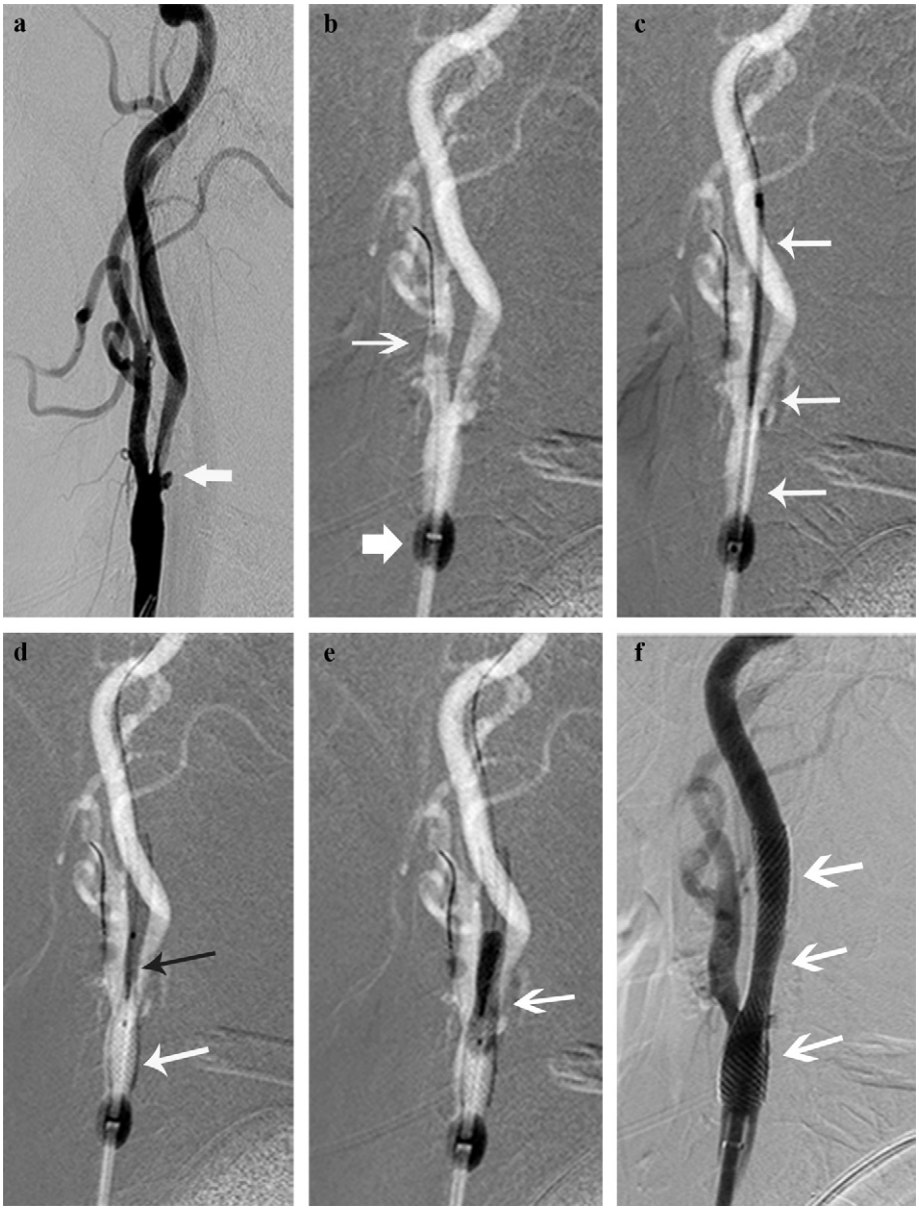

Figure 3 a: digital subtraction angiography (DSA) of left common carotid artery (LCCA), arterial phase, oblique view, shows 90% stenosis of LICA origin and ulcerated plaque (white arrow); b: road map of LCCA, oblique view, shows balloon sheath inflated in LCCA (thick white arrow) and balloon wire inflated in left external carotid artery (LECA; thin white arrow), promoting flow reversal in LICA; c: road map of LCCA, oblique view, shows stent crossing LICA stenosis (white arrows); d: road map of LCCA, oblique view, shows stent deployment (white arrow) and post-dilatation balloon positioned at LICA stenosis level (black arrow); e: road map of LCCA, oblique view, shows post-dilatation balloon inflated at LICA stenosis level (white arrow); and f: DSA of LICA, arterial phase, oblique view, shows final stent appearance (white arrows).

The EMPiRE study was the first to assess the GORE flow reversal system and showed, in 245 patients, a 30-day rate of stroke or death of 2.9% and a low incidence of major clinical complications compared with previous trials [19]. However, because of our small sample size, the present results cannot be compared with EMPiRE results. Nevertheless, our present study achieved relatively short mean CAS procedure and flow-reversal times. Thus, a review of the literature in PubMed up to November 27, 2011, was carried out, using electronic search strategies for CAS and flow reversal (keywords carotid AND flow reversal), with the intention of comparing procedure durations, if described, with our results.

Of the 29 studies reviewed, we selected those that included procedure times [19,21,22,25,27—31,33—35,38]. In total, 821 CAS procedures using flow reversal were reported, 713 of which were performed under local anesthesia and 108 under general anesthesia. A total of 28 patients presented with clinical flow-reversal intolerance (average: 3.8%, range: 0.0—9.7%). Contralateral ICA occlusion was reported in 66 patients (average: 8.0%), eight of whom presented with flow-reversal intolerance. The mean

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Table 2 Studies of carotid artery stenting involving flow reversal that included duration times.

Author	Year	Procedures/local anesthesia (*n*/*n*)	Procedure time/flow-reversal time	Contralateral ICA occlusion (*n* [%])	Flow-reversal intolerance (*n* [%])	Flow-reversal intolerance and contralateral ICA occlusion (*n*)
Criado et al. [39]	2004	50/27	66 min/21.4 min	7 (14)	2 (7.4)	2
Parodi et al. [18]	2005	100/100	NR/200 s[a]	5 (5.0)	3 (3.0)	NR
Pipinos et al. [38]	2005	17/4	146 min/34 min	0 (0.0)[b]	0 (0.0)	0[b]
Rabe et al. [25]	2006	56/56	NR/14 min	1 (1.7)	5 (8.9)	1[c]
Ribo et al. [29]	2006	23/23	NR/15.4 min	NR	0 (0.0)	NR
Criado et al. [30]	2007	100/72	69 min/21 min	10 (10)	3 (4.1)	2
Matas et al. [31]	2007	62/62	50 min/15.1 min	7 (9.6)	1 (1.6)	NR
Faraglia et al. [33]	2009	52/52	68 min/47 min	1 (1.9)	4 (7.6)	NR
Pipinos et al. [38]	2009	43/0	NR/22 min	3 (0.0)	0 (0.0)	0
Leal et al. [35]	2010	31/31	53 min/22 min	1 (3.2)	0 (0.0)	0
Pinter et al. [34]	2011	42/41	NR/18 min	5 (11.9)	4 (9.7)	3
Clair et al. [19]	2011	245/245	72 min/15 min	26 (10.6)	6 (2.4)	NR
Castro-Alfonso et al.	2012	12/0	33.8 min/7.3 min	0 (0.0)	0 (0.0)	0

NR: not reported.
[a] Authors reported that some procedures were completed in stages.
[b] Patients presenting with contralateral ICA or vertebral artery occlusions were not included.
[c] After this case, all other cases presenting with contralateral ICA were excluded.

flow-reversal time was 20.6 mins (range: 200 s, 47 mins). Details of the reviewed studies are summarized in Table 2.

Concerning flow-reversal intolerance, of the 821 CAS cases reviewed, 713 (86.8%) were performed under local anesthesia, thereby allowing neurological evaluation. Of these 713 procedures, 28 patients (average: 3.8%, range: 0.0—9.7%) presented with flow-reversal intolerance. However, several investigators have shown that intolerance can be resolved by temporarily deflating the CCA balloon to restore antegrade flow [19,22,25,30,32]. This maneuver was also done during some of the more prolonged procedures [22]. When ICA antegrade flow was restored, however, it was not possible to rule out the occurrence of brain embolic events.

As for flow-reversal time, in the 821 procedures reviewed, the average duration time reported was 20.6 mins (range: 200 s, 47 mins) whereas, in our present series, the average flow-reversal time was 7.3 mins (range: 2.9—41.1 mins) and, excluding the first two cases, the mean flow-reversal time was 4.0 mins. When pre-dilatation was not performed, the mean flow-reversal time was 3.5 mins, compared with 5.3 mins when pre-dilatation was performed.

Thus, excluding the first two cases, the average flow-reversal time achieved in our present study was three to five times faster than in most of the studies already published. In addition, flow reversal during CAS was continuous, without interruption, thereby avoiding potential brain embolic events. Moreover, considering remodeling technique for the treatment of wide neck intracranial aneurysms, an intracranial artery occlusion can be done, by means of a micro-balloon, up to 5 min without brain ischemic injury. On extrapolating the remodeling technique results to CAS with continuous flow reversal lasting up to 5 min, it is possible to argue that ICA flow reversal may be tolerated in patients with no intracranial communications who are in need of carotid revasculatization. Thus, we believe that our technical proposition should also be tested with patients presenting no patent intracranial collaterals.

Conclusion

In our present selected subjects, the CAS procedure using the GORE flow reversal system appeared to be safe and effective, with improved technical performance of the procedure. This was observed in particular with the flow-reversal times achieved. Thus, studies comparing the GORE system and other protection devices are suggested to ascertain all of the benefits of flow reversal during CAS.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

References

[1] Roger VL, Go AS, Lloyd-Jones DM, Adams RJ, Berry JD, Brown TM, et al. American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics-2011 update: a report from the American Heart Association. Circulation 2011;123(4):e18—209.

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[2] Petty GW, Brown Jr RD, Whisnant JP, Sicks JD, O'Fallon WM, Wiebers DO. Ischemic stroke subtypes: a population-based study of incidence and risk factors. Stroke 1999;30:2513—6.
[3] Sacco RL, Kargman DE, Gu Q, Zamanillo MC. Race-ethnicity and determinants of intracranial atherosclerotic cerebral infarction. The Northern Manhattan Stroke Study. Stroke 1995;26:14—20.
[4] Fine-Edelstein JS, Wolf PA, O'Leary DH, Poehlman H, Belanger AJ, Kase CS, et al. Precursors of extracranial carotid atherosclerosis in the Framingham Study. Neurology 1994;44:1046—50.
[5] Théron J, Raymond J, Casasco A, Courtheoux F. Percutaneous angioplasty of atherosclerotic and postsurgical stenosis of carotid arteries. Am J Neuroradiol 1987;8:495—500.
[6] Writing Committee Members, Brott TG, Halperin JL, Abbara S, Bacharach JM, Barr JD, et al. ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS guideline on the management of patients with extracranial carotid and vertebral artery disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American Stroke Association, American Association of Neuroscience Nurses, American Association of Neurological Surgeons, American College of Radiology, American Society of Neuroradiology, Congress of Neurological Surgeons, Society of Atherosclerosis Imaging and Prevention, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology. Society of NeuroInterventional Surgery, Society for Vascular Medicine, and Society for Vascular Surgery. Stroke 2011;42(8):e420—63.
[7] Coppi G, Moratto R, Silingardi R, Rubino P, Sarropago G, Salemme L, et al. PRIAMUS-proximal flow blockage cerebral protection during carotid stenting: Results from a multicenter Italian registry. J Cardiovasc Surg (Torino) 2005;46:219—27.
[8] Higashida RT, Popma JJ, Apruzzese P, Zimetbaum P, MAVErIC I, MAVErIC II. Evaluation of the medtronic exponent self-expanding carotid stent system with the medtronic guardwire temporary occlusion and aspiration system in the treatment of carotid stenosis: combined from the MAVErIC (Medtronic AVE Self-expanding CaRotid Stent System with distal protection In the treatment of Carotid stenosis) I and MAVErIC II trials. Stroke 2010;41:e102—9.
[9] Kastrup A, Groschel K, Krapf H, Brehm BR, Dichgans J, Schulz JB. Early outcome of carotid angioplasty and stenting with and without cerebral protection devices: a systematic review of the literature. Stroke 2003;34:813—9.
[10] Kastrup A, Gröschel K, Nägele T, Riecker A, Schmidt F, Schnaudigel S, et al. Effects of age and symptom status on silent ischemic lesions after carotid stenting with and without the use of distal filter devices. Am J Neuroradiol 2008;29:608—12.
[11] Massop D, Dave R, Metzger C, Bachinsky W, Solis M, Shah R, et al. Stenting and angioplasty with protection in patients at high-risk for endarterectomy: SAPPHIRE worldwide registry first 2,001 patients. Catheter Cardiovasc Interv 2009;73:129—36.
[12] Safian RD, Bresnahan JF, Jaff MR, Foster M, Bacharach JM, Maini B, et al. Protected carotid stenting in high-risk patients with severe carotid artery stenosis. J Am Coll Cardiol 2006;47:2384—9.
[13] Silver FL, Mackey A, Clark WM, Brooks W, Timaran CH, Chiu D, et al. Safety of stenting and endarterectomy by symptomatic status in the Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST). Stroke 2011;42:675—80.
[14] White CJ, Iyer SS, Hopkins LN, Katzen BT, Russell ME, BEACH Trial Investigators. Carotid stenting with distal protection in high surgical risk patients: The BEACH trial 30 day results. Catheter Cardiovasc Interv 2006;67:503—12.
[15] Asakura F, Kawaguchi K, Sakaida H, Toma N, Matsushima S, Kuraishi K, et al. Diffusion-weighted magnetic resonance imaging in carotid angioplasty and stenting with balloon embolic protection devices. Neuroradiology 2006;48:100—12.
[16] Barbato JE, Dillavou E, Horowitz MB, Jovin TG, Kanal E, David S, et al. A randomized trial of carotid artery stenting with and without cerebral protection. J Vasc Surg 2008;47:760—5.
[17] Vos JA, van den Berg JC, Ernst SM, Suttorp MJ, Overtoom TT, Mauser HW, et al. Carotid angioplasty and stent placement: comparison of transcranial Doppler US data and clinical outcome with and without filtering cerebral protection devices in 509 patients. Radiology 2005;234:493—9.
[18] Parodi JC, La Mura R, Ferreira LM, Mendez MV, Cersósimo H, Schönholz C, et al. Initial evaluation of carotid angioplasty and stenting with three different cerebral protection devices. J Vasc Surg 2000;32:1127—36.
[19] Clair DG, Hopkins LN, Mehta M, Kasirajan K, Schermerhorn M, Schönholz C, et al. Neuroprotection during carotid artery stenting using the GORE flow reversal system: 30-day outcomes in the EMPiRE Clinical Study. Catheter Cardiovasc Interv 2011;77:420—9.
[20] North American Symptomatic Carotid Endarterectomy Trial. Methods, patient characteristics, and progress. Stroke 1991;22:711—20.
[21] Adami CA, Scuro A, Spinamano L, Galvagni E, Antoniucci D, Farello GA, et al. Use of the Parodi anti-embolism system in carotid stenting: Italian trial results. J Endovasc Ther 2002;9:147—54.
[22] Parodi JC, Ferreira LM, Sicard G, La Mura R, Fernandez S. Cerebral protection during carotid stenting using flow reversal. J Vasc Surg 2005;41(3):416—22.
[23] Grunwald IQ, Papanagiotou P, Struffert T, Politi M, Krick C, Romaike BF, et al. Reversal of flow during carotid artery stenting: Use of the Parodi anti-embolism system. Neuroradiology 2007;49:237—41.
[24] Parodi JC, Wönholz C, Parodi FE, Sicard G, Ferreira LM. Initial 200 cases of carotid artery stenting using a reversal-of-flow cerebral protection device. J Cardiovasc Surg (Torino) 2007;48:117—24.
[25] Rabe K, Sugita J, Gödel H, Sievert H. Flow-reversal device for cerebral protection during carotid artery stenting-acute and long-term results. J Interv Cardiol 2006;19:55—62.
[26] Ohki T, Veith FJ, Grenell S, Lipsitz EC, Gargiulo N, McKay J, et al. Initial experience with cerebral protection devices to prevent embolization during carotid artery stenting. J Vasc Surg 2002;36(6):1175—85.
[27] Criado E, Doblas M, Fontcuberta J, Orgaz A, Flores A, Wall LP, et al. Transcervical carotid stenting with internal carotid artery flow reversal: feasibility and preliminary results. J Vasc Surg 2004;40(3):476—83.
[28] Pipinos II, Johanning JM, Pham CN, Soundararajan K, Lynch TG. Transcervical approach with protective flow reversal for carotid angioplasty and stenting. J Endovasc Ther 2005;12:446—53.
[29] Ribo M, Molina CA, Alvarez B, Rubiera M, Alvarez-Sabin J, Matas M. Transcranial Doppler monitoring of transcervical carotid stenting with flow reversal protection: a novel carotid revascularization technique. Stroke 2006;37(11):2846—9.
[30] Criado E, Fontcuberta J, Orgaz A, Flores A, Doblas M. Transcervical carotid stenting with carotid artery flow reversal: 3-year follow-up of 103 stents. J Vasc Surg 2007;46:864—9.
[31] Matas M, Alvarez B, Ribo M, Molina C, Maeso J, Alvarez-Sabin J. Transcervical carotid stenting with flow reversal protection: experience in high-risk patients. J Vasc Surg 2007;46:49—54.

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[32] Alvarez B, Ribo M, Maeso J, Quintana M, Alvarez-Sabin J, Matas M. Transcervical carotid stenting with flow reversal is safe in octogenarians: a preliminary safety study. J Vasc Surg 2008;47:96—100.
[33] Faraglia V, Palombo G, Stella N, Rizzo L, Taurino M, Bozzao A. Cerebral embolization during transcervical carotid stenting with flow reversal: a diffusion-weighted magnetic resonance study. Ann Vasc Surg 2009;23(4):429—35.
[34] Pinter L, Ribo M, Loh C, Lane B, Roberts T, Chou TM, et al. Safety and feasibility of a novel transcervical access neuroprotection system for carotid artery stenting in the PROOF Study. J Vasc Surg 2011;54(5):1317—23.
[35] Leal JI, Orgaz A, Fontcuberta J, Flores A, Doblas M, Garcia-Benassi JM, et al. A prospective evaluation of cerebral infarction following transcervical carotid stenting with carotid flow reversal. Eur J Vasc Endovasc Surg 2010;39(6):661—6.
[36] Kelso R, Clair DG. Flow reversal for cerebral protection in carotid artery stenting: a review. Perspect Vasc Surg Endovasc Ther 2008;20(3):282—90.
[37] Fang HY, Chung SY, Sun CK, Youssef AA, Bhasin A, Tsai TH, et al. Transradial and transbrachial arterial approach for simultaneous carotid angiographic examination and stenting using catheter looping and retrograde engagement technique. Ann Vasc Surg 2010;24(5):670—9.
[38] Pipinos II, Pisimisis GT, Burjonrappa SC, Johanning JM, Longo GM, Lynch TG, et al. One patent intracranial collateral predicts tolerance of flow reversal during carotid angioplasty and stenting. Ann Vasc Surg 2009;23:32—8.
[39] Criado E, Doblas M, Fontcuberta J, Orgaz A, Flores A, Lopez P, et al. Carotid angioplasty with internal carotid artery flow reversal is well tolerated in the awake patient. J Vasc Surg 2004;40(1):92—7.

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