# SEVERE CALCIUM ONE SOLUTION



# ONLY THE DIAMONDBACK 360<sup>®</sup> CORONARY ORBITAL ATHERECTOMY SYSTEM BRINGS IT ALL TOGETHER

CARDIOVASCULAR SYSTEMS, INC.

CSI.

DOI: 10.1002/ccd.29677

## INTERVENTIONAL ROUNDS

# WILEY

# Transradial approach for carotid artery stenting: A position paper from the Italian Society of Interventional Cardiology (SICI-GISE)

# Piero Montorsi MD<sup>1</sup> | Bernardo Cortese MD<sup>2</sup> | Carlo Cernetti MD<sup>3</sup> | Davide Lanzellotti MD<sup>3</sup> | Gaetano Di Palma MD<sup>2</sup> | Alfredo Marchese MD<sup>4</sup> | Alberto Cremonesi MD<sup>5</sup>

<sup>1</sup>Department of Clinical Sciences and Community Health, University of Milan, Centro Cardiologico Monzino, IRCCS, Milan, Italy

<sup>2</sup>Cardiovascular Research Team, Fondazione Ricerca e Innovazione Cardiovascolare, San Carlo Clinic, Paderno Dugnano-Milano, Italy

<sup>3</sup>U.O.C. Cardiologia, Ospedale San Giacomo, Castelfranco Veneto, Treviso, Italy

<sup>4</sup>U.O.C. Cardiologia Interventistica, Anthea Hospital-GVM Care & Research, Bari, Italy

<sup>5</sup>Cardiovascular Department, Humanitas Gavazzeni, Bergamo, Italy

#### Correspondence

Bernardo Cortese, Cardiovascular Research Team, San Carlo Clinic, Milan, Italy. Email: bcortese@gmail.com

## Abstract

Carotid artery stenting (CAS) is a valid and effective alternative to endoatherectomy when performed by experienced operators. The conventional approach used is the transfemoral one, but in the last 10 years a transradial (TR) approach, the standard access for cardiac catheterization, became widely adopted for peripheral vascular interventions, included the extracranial carotids. Preliminary experiences suggest this approach as safe and effective, especially in specific anatomical and clinical settings that have been shown to be associated with high risk of complications from the femoral route. Lacking international guidelines, this document, promoted by the Italian Society of Interventional Cardiology - Gruppo Italiano Studi Emodinamici (SICI-GISE), was drawn-up by a panel of interventional cardiologists with a documented experience on the subject, focusing on the indications, techniques and materials that should be used for this type of intervention and the most recent literature on the subject.

#### KEYWORDS

supra-aortic vessels anatomy, technical paper, transradial carotid stenting

# 1 | INTRODUCTION

Carotid artery stenting (CAS) has been proved to be a safe and effective alternative treatment to carotid endarterectomy in patients with significant carotid artery disease.<sup>1</sup> A sound endo-vascular experience, high centre/operator volume and updated technological background are "sine qua non" conditions for optimal results. The standard CAS procedure is usually performed through the femoral artery as result of a wide operator familiarity with this approach and the large size of the femoral artery allowing the use of

a wide device selection. However, anatomy variants of the aortic arch and supra-aortic vessels can make selective carotid arteries cannulation difficult or even impossible by the femoral route increasing the risk of cerebral embolization.<sup>2,3</sup> Furthermore, bleeding complications may complicate femoral catheterization accounting for significant clinical consequences.<sup>4</sup> Thus, CAS through an alternative vascular approach has been advocated in challenging anatomies or specific clinical conditions.<sup>5-8</sup>

Transradial approach (TRA) has become the standard of care for cardiac catheterization and coronary interventions.<sup>9</sup> Its benefits are well documented also in peripheral interventions, including extracranial carotid artery<sup>10</sup> leading to reduced risk of bleeding and accessrelated complications, early ambulation and discharge and, ultimately, cost saving.<sup>11,12</sup>

This document summarized the view of the Italian Society of Interventional cardiology - Gruppo Italiano Studi Emodinamici (SICI-

Abbreviations: AT, anchor technique; CAS, carotid artery stenting; CCA, common carotid artery; ECA, external carotid artery; LICA, left Internal carotid artery; RICA, right internal carotid artery; TBA, transbrachial approach; TFA, transfemoral approach; TRA, transradial approach; TRCAS, transradial carotid artery stenting; TT, telescoping technique.

Piero Montorsi and Bernardo Cortese contributed equally to this work and are joint first authors.

<sup>2</sup> WILEY-

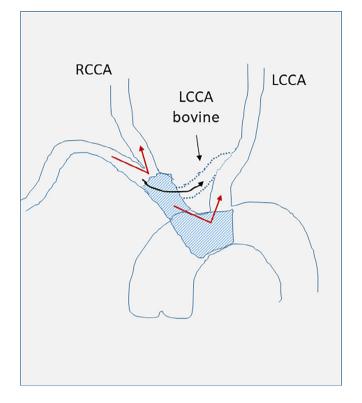


FIGURE 1 Vascular anatomy and critical areas in TRCAS. The acute angle (red and green lines) and the lack of anatomic support (blue hatched bars) account for the difficulty to enter these vessels. In case of bovine arch the engagement of the left CCA is easy and straightforward (black line) [Color figure can be viewed at wileyonlinelibrary.com]

GISE) on the advantages and limitations, clinical and anatomical indications, procedural aspects and tips and tricks of this technique.

#### **TR-CAS: ROLE OF IMAGING** 2

A thorough imaging of the aortic arch and supra-aortic vessels anatomy by computed tomography angiography or magnetic resonance angiography is mandatory.<sup>13,14</sup> Overall, vessel tortuosity, sharp bifurcation angles and lack of anatomic pathways supporting CAS equipment passage are frequently encountered from TR approach (Figure 1). The  $45^\circ$  LAO (for the left axes) and RAO (for the right axes) views are the most used projections during CAS that can be easily reproduced by the imaging (Figure 2). The type-2 bovine aortic arch (in case of left ICA stenosis) sets apart due to its natural anatomic pathway that substantially supports TRCAS procedure. Finally, aortic arch should be always investigated for atherosclerotic disease impinging into the lumen and increasing the risk of systemic embolization, included the cerebral circulation, during CAS equipment navigation.

#### TRANSRADIAL CAS: INDICATIONS, 3 ADVANTAGES AND LIMITS

Vascular anatomies and clinical conditions that would benefit most from TRACS are shown in Figure 3 and Table 1, respectively. Type-2 bovine

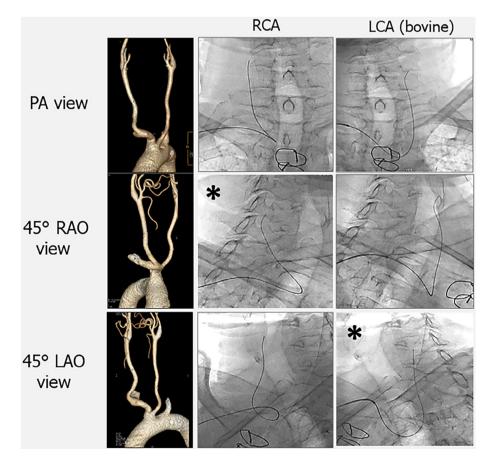


FIGURE 2 TRCAS in right and left (bovine) vascular anatomy in the three most common angiographic views (PA, RAO 45° and LAO 45°). The working view (asterisk) is the RAO 45° for RICA and the LAO 45° for LICA-bovine and for LICA taking off from the aorta [Color figure can be viewed at wileyonlinelibrary.com]

aortic arch with LICA stenosis is an established indication for TRCAS due to the favorable anatomic pathway allowing a surprisingly easy target vessel incannulation and CAS equipment passage.<sup>13,15</sup> While right ICA stenosis associated with type 2-3 aortic arch is another appealing setting, the so-called "plongeant" right common innominate artery is a peculiar indication. Finally, aortic arch disease and lack of peripheral vascular accesses represent "obligatory" indications. In all these settings, TRCAS guarantees a full (or partial) avoidance of navigation through the aortic arch reducing the risk of cerebral embolization.<sup>2,3</sup> Clinical settings that may require TRCAS are patients at high risk of bleeding and vascular complications or those requiring early ambulation. An early patient mobilization might counterbalance the post-procedural hemodynamic instability (i.e., hypotension and bradycardia) a well know predictor of MACCE rate.<sup>16</sup> through an activation of the sympathetic system. If this holds true, length of stay, intensity of care and costs would benefit together with patient comfort and satisfaction. Contraindications to TRCAS are those for coronary interventions.<sup>17,18</sup> Increased procedural time and radiation exposure are both a concern with TRCAS.

# 4 | TRANSRADIAL CAS: EQUIPMENT (TO KEEP ON THE SHELF)

The basic equipment for TRCAS should include all the tools currently used from the standard femoral approach and same specific catheters (Figure 4 and Table 2).

### 4.1 | Sheath (radial access)

The 6-Fr glide sheath slender (Terumo) is the standard of care in TRCAS owing the smallest outer diameter and accommodating most of the CAS devices. If CAS with proximal protection is planned, an 8-Fr 5.5 cm-long (brachial) sheath inserted for half of its length may be a good choice.<sup>8</sup> Alternatively, a "sheathless approach" (6-Fr sheath first followed by device insertion through the skin) may be considered.

### 4.2 | Wires

Regular, hydrophilic and stiff-exchangeable wires (i.e., 0.035", 260 cm-long) are commonly utilized. Standard or stiff 0.014" coronary wires help in specific anatomy settings as temporary extra support to improve equipment advancement.

#### 4.3 | Diagnostic catheters

Standard coronary catheters (4,5,6-Fr) are commonly used either to engage the target vessel or as a part (4-Fr) of a "coaxial system." Some peripheral catheters, such as the wire-braided Simmons-2, 125 cmlong, becomes the first choice for left-sided carotid origin from the aorta and right-sided stenosis with sharp RSCA-CCA bifurcation angle.

#### TABLE 1 Indications/contraindication for TRCAS

#### Anatomical indications

- Bovine aortic arch (type I and II) with left ICA stenosis
- Right internal carotid artery stenosis, especially if type II-III aortic arch coexists
- Innominate artery stenosis or occlusion and right ICA stenosis
- Extensive atherosclerosis of the aortic arch
- Absence of peripheral vascular accesses or extensive PAD
- "Plongeant" innominate artery with right internal carotid stenosis

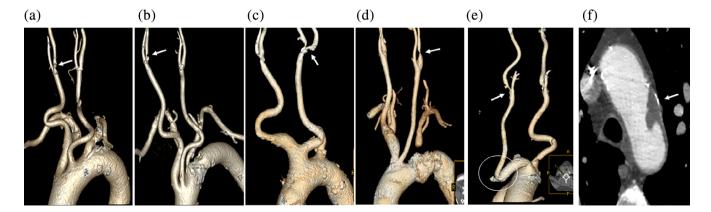
#### Anatomical (relative) contraindications

- Unfavorable radial-to-subclavian artery pathway (variants, previous TR interventions)
- Aortic arch variants (aberrant right subclavian artery, "lusoria")
- Occluded ipsilateral ulnar artery

#### **Clinical indications**

- High risk of bleeding (i.e., elderly, female, obese patients, severe CRF. Patients requiring chronic anticoagulation or with hemocoagulative disorders)
- Patients requiring early mobilization after intervention

Abbreviations: CRF, chronic renal failure; ICA, internal carotid artery; PAD, peripheral arterial disease; TRCAS, transradial carotid artery stenting.



**FIGURE 3** CT-angiography of the aortic arch and supra-aortic vessel in different anatomic settings. Type 2 and 3 aortic arch with RICA stenosis (a-b). Type 2 and 1 bovine arch with LICA stenosis (c-d). "Plongeant" innominate artery with RICA stenosis (e). Aortic arch atherosclerosis (f) [Color figure can be viewed at wileyonlinelibrary.com]

⁴\_\_\_WILEY-

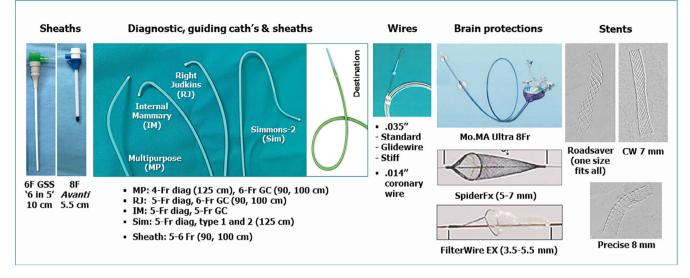


FIGURE 4 Endovascular equipment currently used for TRCAS [Color figure can be viewed at wileyonlinelibrary.com]

	Fr	Length (cm)	Inner diameter (inches)	Inner diameter (mm)	Outer diameter (mm)	Compatible stent
Sheath						
GlideSheath Slender, Terumo <sup>a</sup>	6	11	0.88	2.22	2.46	
Avanti (brachial), Cordis	8	5.5	0.89	2.95	3.30	
Introducer sheath						
Destination, Terumo	5	90	0.076	1.9	2.29	5Fr compatible <sup>b</sup>
	6	90	0.087	2.2	2.52	All types and sizes
Shuttle Flexor, Cook	6	90	0.087	2.2	2.62	All types and sizes
Diagnostic catheter						
Multipurpose	4,6	125, 100	0.038	0.97	1.5, 2.0	
Right Judkins	5,6	125, 100	0.038	0.97	1.65, 2.0	
Internal Mammary	5	100	0.038	0.97	1.65	
Simmons-1 and 2	5	125	0.038	0.97	1.65	
Guiding catheter						
Right Judkins	6	90, 100	0.070	1.8	1.98	5Fr compatible <sup>b</sup>
Multipurpose	6	90, 100	0.070	1.8	1.98	5Fr compatible <sup>b</sup>
Mach (BSI)	7	90	0.081	2.0	2.4	5Fr compatible <sup>b</sup>
Sheathless guide						
Eaucath, Ashai	6.5	100	0.70	1.79	2.16	5Fr compatible <sup>b</sup>
	7.0	100	0.81	2.0	2.49	5Fr compatible <sup>b</sup>
Proximal protection						
Mo.Ma, Medtronic	8	95	0.083	2.12	2.80	5Fr compatible <sup>c</sup>

#### TABLE 2 CAS equipment for TR carotid stenting

<sup>a</sup>GSS 5 in 6 sheath.

<sup>b</sup>Carotid Wallstent 7 mm (Boston Scientoific), Precise Pro 8 mm (Cordis), Roadsaver any size (Terumo).

<sup>c</sup>All 5Fr compatible stent + (if >8 mm CCA diameter) Vivexx any size (Bard), Sinus any size (Optimed).

Both guiding catheter and sheaths are equally effective in most of the supra-aortic anatomies. Standard 6-Fr coronary guides (i.e., right Judkins, Multipurpose) are "user-friendly" device accepting 5-Fr compatible stents that allows the treatment of a wide spectrum of plaque composition and target vessel CCA diameters. The introducer-sheath owns a larger internal (all stent type and size allowed) and external lumen than the guiding catheter with a high navigability in complex anatomy but less torquability, stability and a higher risk of arterial spasm.

#### 4.5 | Carotid stents

No substantial difference in the type of stent as compared to TFA. We suggest keeping on the shelf three 5 Fr-compatible stents: an open-cell (i.e., Precise Pro, Cordis), a closed-cell (i.e., Carotid Wallstent, Boston Scientific Corporation, Santa Clara, CA) and a double mesh design stent (Roadsaver, Terumo Tokyo, Japan).

### 4.6 | Brain protection devices

Distal filter is the brain protection universally adopted for TRCAS.<sup>5-8</sup> While the safety and efficacy of proximal protection in TRCAS has been reported<sup>8</sup> its use should be included at the end of the learning curve due to difficult device navigation in the complex anatomy of the supra-aortic vessels.

## 4.7 | Closure devices

The role of dedicated system for radial artery closure is well established. Manual compression is required following ulnar and brachial artery catheterization.

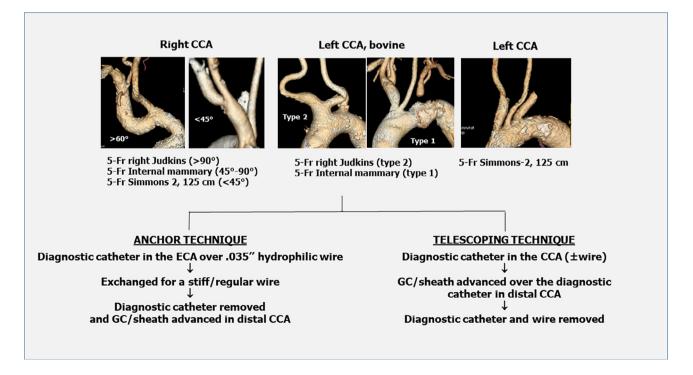
# 5 | TRCAS: TECHNIQUE (AND TIPS & TRICKS)

The anchor (AT) and the telescopic (TT) techniques are the two most used TRCAS strategies according to vascular anatomy and operator preference (Figure 5).

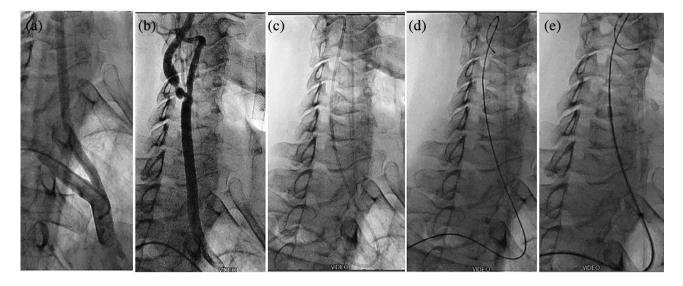
## 5.1 | Right CCA access

The AT is indicated in case of bifurcation angle >45° and a straight CCA (Figure 6). The target ostium is engaged with either a 5-Fr right Judkins or an internal mammary catheter. The wire is advanced up to the bifurcation followed by the catheter. If catheter fails to advance, a CCA angiogram should be taken in order to position the wire distal into the ECA for an optimal support. Once catheter is in the distal ECA, the hydrophilic wire is exchanged for a 0.035″, 260 cm long stiff wire and either a guide or a sheath is loaded on the stiff wire. A telescoping technique (with a 4-Fr 125-cm multipurpose catheter) is frequently required in case of sharp bifurcation, suboptimal wire positioning or ECA occlusion/stenosis.

In case of sharp bifurcation angle (<45°), the TT using a Simmons-2, 125 cm-long diagnostic catheter loaded into a 6-Fr  $\,$ 



Wii fy⊥



**FIGURE 6** Right ICA TRCAS w the anchor technique. Right subclavian/right CCA bifurcation engaged with a 5F internal mammary catheter (a). DSA baseline view (b). 5Fr mammary catheter in distal ECA. Terumo wire removed (c). Stiff wire in distal ECA. Catheter removed (d). Positioning of a guiding catheter below the bifurcation through a coaxial system (4F Multipurpose, 125 cm-long into 6F right Judkins guide)

guide/sheath is recommended (Figure 7). The technique requires six steps carried out in either LAO  $45^{\circ}$  (step 1-3) or RAO  $45^{\circ}$  views (steps 4-6): (1) Place the Sim-2 in the descending aorta over a 0.035" hydrophilic wire. (2) Withdraw the wire to the tip of the catheter while pushing it towards the ascending aorta. (3) Turn the catheter tip to the left while pulling it back (a few centimeters) to enter the innominate artery. (4) Pull the Sim-2 back while maintaining the tip of the catheter to the right of the catheter body to enter the CCA (the catheter tip will diverge from the rest of the catheter while entering the vessel). (5) Keep pulling back the Simmons-2 unless the final position is achieved. Since the right CCA is shorter that the left CCA, check the catheter position before placing a hydrophilic wire in the ECA (Figure 8). Advance the guide or sheath (that have been parked in the subclavian artery) over the Sim-2 up to the bifurcation removing both the diagnostic catheter and the wire. In case of pull-back failure to enter the right CCA, use the wire to facilitate the vessel engagement or inject contrast medium to check the anatomy.

### 5.2 | Left CCA access

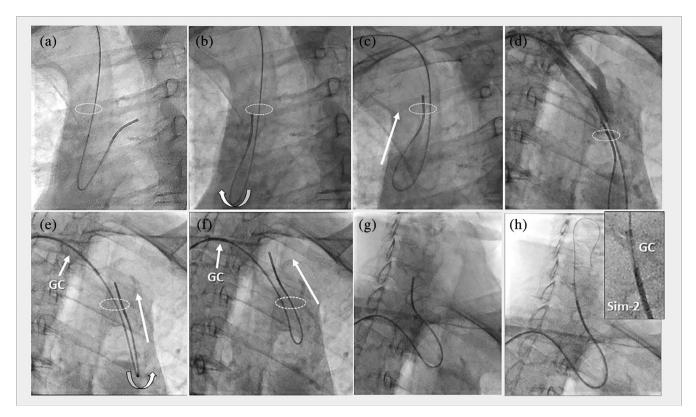
The engagement of the left CCA originating from the aortic arch requiring TT in all cases. The 5-Fr Simmons-2, 125 cm-long catheter loaded into a 6F 90 cm guiding catheter or long sheath is the recommended strategy. While less easy to handle than the type-1 curve, it provides a more distal positioning in the common carotid accounting for a better support for the coaxial advancement of the 6-Fr guide/ sheath (Figure 8). A 90 cm long guiding catheter/sheath is preferable to the standard 100 cm length allowing a longer tract of the Simmons-2 to stick out from the guide facilitating catheter reshaping. Thus, the coaxial system is advanced until the innominate artery. At that site, the 6-Fr guide is blocked, and the 5-Fr is fully advanced

(up to 35 cm) into the ascending aorta, reshaped, and manipulated to enter the left common ostium as for the right CCA. Once engaged, a 0.035" hydrophilic wire is placed in the distal ECA and the 6-Fr guide/ sheath is slowly advanced over the 5-Fr up to the bifurcation through a "push-and-pull" technique (Figure 9). Different techniques are available in case of failure to enter the CCA, including the catheter looping and retrograde engagement technique (CLARET).<sup>19</sup>

In case of LICA stenosis with bovine type 2 configuration, the right subclavian-innominate-left CCA anatomic pathway answers for an easy and predictable target vessel engagement with any type of technique and equipment with a negligible risk of prolapse into the aortic arch. Type-1 bovine arch may be trickier to engage for the acute angle between the innominate and the left CCA without anatomic support.

#### 5.3 | TRCAS with proximal protection

The 8F Mo.Ma system is positioned in the target vessel through the standard technique used from the femoral artery. A distal seating of a stiff wire and a "push-and-pull" technique are mandatory. However, in 1/3 of patients with difficult anatomy the system fails to enter the common carotid artery. To overcome these difficulties a new technique—the "no-mandrel 2-wires" technique (No.Ma2)—has been proposed and successfully tested.<sup>8</sup> Compared to the standard technique the mandrel is removed (to reduce system stiffness) and a second wire is positioned into the ECA through a 6-Fr guiding-catheter (to improve support) (Figure 10). The Mo.MA system is loaded over the two wires (one into the ECA channel and one into the main channel) and advanced into the target vessel making sure to keep the wires parallel during the entire maneuver (Figure 11).<sup>8</sup> Finally, this new technique has been proved to be effective also in cases with severe stenosis/occlusion of the ECA using the Mo.Ma



**FIGURE 7** TRCAS (telescoping technique) of a right ICA stenosis (arrow). Positioning of a 5-Fr Simmons-2, 125 cm catheter loaded on a 0.035" Terumo wire into the descending aorta (a). The catheter is reshaped by pulling the wire back into the catheter tip (b) and pushing the catheter towards the aortic valve (45° LAO) (c) while rotating it leftwards. Turn the amplifier into the 45° RAO. Pull back the catheter into the proximal innominate artery, turn it to the right so that to keep the diagnostic catheter to the left while continuing to pull it back. The tip of the catheter moves upward while entering the CCA (d, e). Once the Simmons-2 catheter is seated deep into the common carotid, advance a glidewire into the ECA (f). Finally, advance the guiding catheter over the 5-Fr Simmons-2 up to the bifurcation removing both the diagnostic catheter and the wire (g)



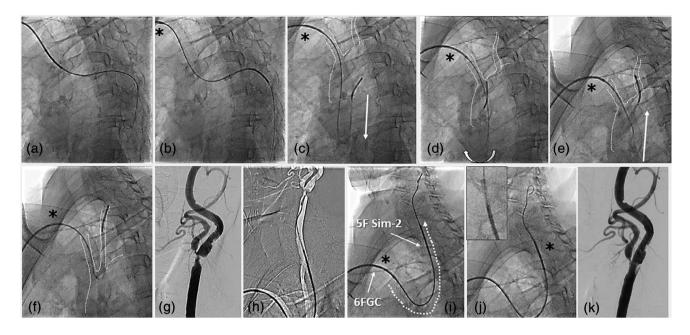
RCCA, Type-1 Sim

RCCA, Type-2 Sim

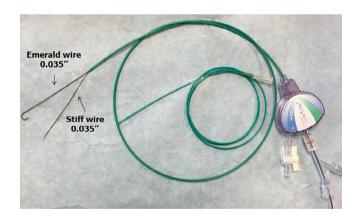
LCCA, Type-1 Sim



**FIGURE 8** Right and left common carotid artery cannulation with the 5-Fr Simmons type 1 and 2 catheter. The type 2 curve Sim catheter seats more distally than the type 1 curve in both the right or the left CCA axes. The tip of the type-2 Sim catheter (black arrows) is associated with a more distal seating and bifurcation angle widening (white lines) in both RCCA and LCCA as compared to the type-1 version. This accounts for a better support for sheath/GC advancement [Color figure can be viewed at wileyonlinelibrary.com]



**FIGURE 9** TRCAS (telescoping technique) of a left ICA stenosis. A 0.035" Terumo wire is positioned in the descending aorta (a). The Simmons-2 cath is advanced and the wire removed (b). The Simmons-2 cath is pushed forwards into the ascending aorta (c). Turn leftward the catheter while maintaining the tip to the right of the shaft (d). Pull the Simmons-2 back slowly until entering the LCCA ostium (e). Keep pulling back the Simmons-2 until it reaches the bifurcation (innominate-left common) (f). Baseline DSA of LCCA (g). Roadmap and positioning of a 0.035" standard wire below the stenosis (wire reshaping technique) (h). Keep the Simmons-2 still and slowly advance the 6F guiding catheter (dotted arrow) (i-j). Final result after stenting (k). \* = 6F guide parked in the innominate artery. (c-f) The white dotted profile of the aortic arch IA and LCCA take off



**FIGURE 10** The "no-mandrel 2 wires" technique [Color figure can be viewed at wileyonlinelibrary.com]

Ultra mono balloon version. Two wires are initially positioned in the distal CCA below the bifurcation (with the "wire reshaping" technique) and are loaded into the main channel of the Mo.MA device, having removed the mandrel.

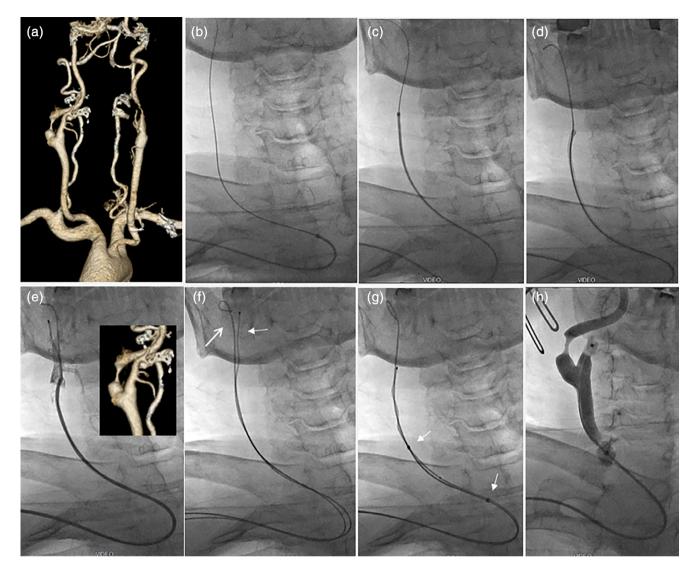
Finally, in tall patients (>180 cm), the 95-cm length of the Mo. Ma system may not be long enough for a correct positioning, especially in case of left-sided stenosis. In this case, either a high radial artery puncture (7–10 cm above the styloid process) or a brachial approach should be considered. Videos 1-5 provide short examples of TR CAS.

# 6 | OTHER UNCONVENTIONAL APPROACHES

Carotid stenting can be also performed from the right ulnar (if the predominance forearm vessel), the right brachial or the contralateral arm arteries.<sup>20</sup> While no consensus as to which alternative artery should be used first in case of right radial inadequacy, the final choice mainly depends on the operator experience and the vascular anatomy. Attention should be paid using the brachial approach for bleeding complications.<sup>21</sup> Montorsi et al. reported an overall major vascular complications rate of 1.82% in 214 patients submitted to TR/TB CAS. All events occurred in the TB subgroup (6.6%) and were confined in the early period of the learning curve (4 out of 24 patients). Notably, when heparin was replaced by bivalirudin, no other vascular complication occurred in 36 consecutive patients.<sup>8</sup> Potential reasons may be the quick and predictable onset and offset of this drug anticoagulation that allows a more effective hemostasis by manual compression. While bivalirudin used in peripheral vascular interventions has been associated with a more favorable in-hospital outcome,<sup>22</sup> its superiority in TR/TB CAS needs to be confirmed by further studies.

# 7 | MANAGEMENT OF ACCESS SITE

The technique of radial artery hemostasis is standardized, safe and effective through dedicated closure systems. Readers are encouraged



**FIGURE 11** TRCAS with proximal protection. (a) CT-angiography (LAO 45° view). Note the acute angle (<45°) of the bifurcation between the right subclavian and the right CCA. (b) Engagement of RCCA by 5Fr internal mammary artery. A 0.035" hydrophilic wire is positioned deep into the ECA. (c) The 5Fr catheter is pushed into the ECA. (d) The hydrophilic wire is exchanged for a stiff wire and a 6Fr guide is positioned into the ECA. (e) A second wire (regular wire) is positioned in the ECA (angio graphic control). (f) The 2 wires in place (the 6F guide removed). (g) The 8Fr Mo.Ma system is advanced into the RCCA. (h) Inflation of both proximal and distal balloons [Color figure can be viewed at wileyonlinelibrary.com]

to refer to specialized literature on this topic. As in PCI, postprocedure radial artery occlusion is an issue, occurring 5–12% of cases depending on patient population characteristics, diagnostic methods used (palpation vs. Doppler US) and size of the equipment used. A similar rate of RAO (4–6.6%) has been reported in the four major trials of TRCAS using either sheath or guide or proximal protection.<sup>5-8</sup> A post-procedural "patent-hemostasis" protocol with an occlusion time <4 hr are factors associated with a higher rate of radial patency at 30 days compared to conventional occlusive hemostasis.<sup>23</sup>

# 8 | TRANSRADIAL CAS: CLINICAL STUDIES

The feasibility of TRA for diagnostic and interventional procedures of supra-aortic vessels has been assessed in the past two decades with

favorable results.<sup>5-8</sup> The catheterization of either the right or left (nonbovine) carotid axes was achieved in 94–100% and 84–100% of patients, respectively. So far, three large observational studies and one controlled randomized trial for a total of >900 patients have been published<sup>5-8</sup> (Table 3). Favorable and comparable (vs. TFA in two studies) rates of both technical and procedural success were reported. The "cross-over" to femoral approach was between 5 and 10%, with failures mainly due to left-sided nonbovine carotid artery lesions. Furthermore, a low vascular complication occurred. These favorable results were confirmed by the RADial access for CARotid artery stenting (RADCAR) prospective, randomized trial. The study enrolled 260 patients at high risk for carotid endarterectomy, randomized to protected CAS through the TRA (n = 130) or the TFA (n = 130).<sup>10</sup> Primary endpoints were MACCE and access site complications, while secondary endpoints were angiographic outcome, fluoroscopy time,

### TABLE 3 Transradial CAS studies enrolling over 100 patients

MONTORSI ET AL.

	Etxegoien et al. (2012) <sup>9</sup>	Ruzsa et al. (2014) <sup>10</sup>	Mendiz et al. (2016) <sup>11</sup>	Montorsi et al. (2016) <sup>12</sup>
Type of study	Retrospective	Prospective, CR vs. TF CAS	Retrospective	Retrospective
Enrollment (years)	2005-2011 Two centers	2010-2012 Single center	1999-2016 Single center	2007-2015 Single center
Patients (n)	382	130	101	214
Indication for CAS	High-surgical-risk for CEA in 79%	High-surgical-risk for CEA in all	High-surgical-risk for CEA in all	Selected anatomy first (n = 100), then all comers
Aortic arch 2–3 Bovine aortic arch	70% 4%	34% NR	88% NR	NR 41%
Target carotid axis	RICA 39% LICA 56.5%	RICA 43.8% LICA 56.2%	RICA 56.4% LICA 43.6%	RICA 56% LICA 44%
Type of cerebral protection	Distal filter in all	Distal filter in all	Distal filter in all	Distal filter (71%) Proximal protection (29%)
Type of vascular approach (%)	Right radial 100%	Right radial 99%	Right radial 97%	Right radial 72% Right brachial 28%
Intra-procedural anticoagulation	Heparin Bivalirudin (37%)	Heparin	Heparin	Heparin Bivalirudin (26.5%)
Vascular crossover to TF CAS	9.1% (35/382) Hostile anatomy in all	10% (13/130) Hostile anatomy in 6	4.9% (5/101) Hostile anatomy in all	5.6% (13/214) Hostile anatomy in 12 - 3.2% Mo.MA - 7.1% distal filter
MACCE Death, all strokes, MI) <sup>a</sup>	1.7% (6/347) 1 death, 1 major, 3 minor strokes	0.9% (1/117) 1 death	2% (2/101) 2 strokes	2.% (4/201) 1 major, 3 minor strokes - 0.0% Mo.Ma - 2.7% distal filter
Mayor acute vascular complications (0–30 days)	0% (0/347)	0.9% (1/117) 1 radial artery occlusion	0.0%	1.9% (4/214) 2 BA thrombosis, 2 BA pseudoaneurism - TR 0% (0/55) - TB 10% (4/60)
Radial artery occlusion (31 days to f/u)	6.0% (23/347) 5-6 Fr IS (95%)	6.8% (8/117) 7Fr GC (92%)	NR	4.0% (6/154) 6Fr GC (85%) - 6.6% (2/30) Mo.Ma <sup>b</sup> - 3.2% (4/124) filter <sup>c</sup>

Abbreviations: BA, brachial artery; CAS, carotid artery stenting; CR, controlled, randomized; GC, guiding catheter; IS, introducer sheath; LICA, left internal carotid artery; NR, not reported; RICA, right internal carotid artery; TBA, transbrachial approach; TFA, transfemoral approach; TRA, transradial approach. <sup>a</sup>MACCE rate: per protocol analysis (patients with cross over to FA or Crossover to filter for intolerance to Mo.Ma occlusion were excluded). <sup>b</sup>8Fr sheath in all patients. RAO detected by clinical inspection and Doppler US.

<sup>c</sup>6Fr GC in 85% of patients. RAO detected by clinical inspection.

X-ray dose, procedural time, crossover and duration of hospitalization. There was no difference between groups regarding the primary and secondary endpoints, but the length of hospitalization was shorter, and the radiation dose was 29% higher in the TR group.

Finally, the feasibility of TRCAS with proximal protection was assessed by Montorsi et al. in 60/214 consecutive pts.<sup>8</sup> The radial artery suitability was assessed on clinical ground only and if considered unfit for catheterization, the right brachial artery was chosen. Authors concluded that TR or TBCAS with proximal protection is safe and effective with low vascular complication rate, crossover to femoral artery approach and acceptable long-term radial artery patency. Interestingly, despite the larger size and stiffness of the 8Fr Mo.Ma system, there was no difference in radiation exposure compared to

used TRCAS with distal filter. Based on these results, TRCAS may include symptomatic patients and unstable plaques that would benefit most from the proximal protection device.<sup>24,25</sup> Large multicenter studies are warranted to confirm the TRCAS feasibility, safety and efficacy (MACCEs) and to compare results with the standard transfemoral approach.

# 9 | CONCLUSIONS

Transradial CAS is a safe and effective technique with low vascular complications that requires dedicated technique and equipment, a steep learning curve and a sound experience in TR interventions to

-WILEY <u>11</u>

achieve results as good as or even better than TFCAS. It is recommended to start a TRCAS program enrolling specific patients/ anatomies associated with an increased risk of cerebral embolization from the standard femoral route. A pre-intervention imaging with CTA/MRA is essential to identify the primary indications for TRCAS. Other types of vascular anatomy such as left-sided, non-bovine LICA stenosis should be addressed in the last part of the learning curve or left for femoral approach. The full TFCAS equipment may be also used from the radial approach, included the proximal protection device.

Given the wide expertise of interventional cardiologists with TR coronary interventions and the increasing use of this approach in both peripheral and structural heart interventions, included TAVI, an official involvement of the interventional cardiology societies is welcome and required to promote and disseminate this technique as a natural completion of the endovascular technique.

#### **CONFLICT OF INTEREST**

The authors declare no conflicts of interest.

#### DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

#### ORCID

Bernardo Cortese b https://orcid.org/0000-0002-5808-7810 Carlo Cernetti b https://orcid.org/0000-0002-3158-477X Alfredo Marchese b https://orcid.org/0000-0002-3445-0865

#### REFERENCES

- Aboyans V, Ricco JB, Bartelink ML, et al. ESC guidelines on the diagnosis and treatment of peripheral arterial diseases, in collaboration with the European Society for Vascular Surgery (ESVS). Eur Heart J. 2018;39:763-821.
- Faggioli GL, Ferri M, Freyrie A, Fratesi F, Manzoli L, Stella A. Aortic arch anomalies are associated with increased risk of neurological events in carotid stent procedures. Eur J Vasc Endovasc Surg. 2007; 33:436-441.
- Werner M, Bausback Y, Braunlich S, et al. Anatomic variables contributing to a higher periprocedural incidence of stroke and TIA in carotid artery stenting: single center experience of 833 consecutive cases. Catheter Cardiovasc Interv. 2012;80:321-328.
- Brener MI, Bush A, Miller JM, Hasan RK. Influence of radial versus femoral access site on coronary angiography and intervention outcomes: a systematic review and meta-analysis. Catheter Cardiovasc Interv. 2017;78:823.
- Etxegoien N, Rhyne D, Kedev S, Sachar R, Mann T. The transradial approach for carotid artery stenting. Catheter Cardiovasc Interv. 2012;80:1081-1087.
- Ruzsa Z, Nemes B, Pintér L, et al. A randomised comparison of transradial and transfemoral approach for carotid artery stenting: RADCAR (RADial access for CARotid artery stenting) study. EuroIntervention. 2014;10:381-391.
- Mendiz OA, Fava C, Lev G, Caponi G, Valdivieso L. Transradial versus transfemoral carotid artery stenting: a 16-year single-center experience. J Interv Cardiol. 2016;29:588-593.
- 8. Montorsi P, Galli S, Ravagnani PM, et al. Carotid artery stenting with proximal embolic protection via a transradial or transbrachial

approach: pushing the boundaries of the technique while maintaining safety and efficacy. J Endovasc Ther. 2016;23:549-560.

- Hamon M, Pristipino C, Di Mario C, et al. Consensus document on the radial approach in percutaneous cardiovascular interventions: position paper by the European Association of Percutaneous Cardiovascular Interventions and Working Groups on acute cardiac care and thrombosis of the European Society of Cardiology. EuroIntervention. 2013;8:1242-1251.
- Staniloae CS, Korabathina R, Coppola JT. Transradial access for peripheral vascular interventions. Catheter Cardiovasc Interv. 2013; 81:1194-1203.
- Cortese B, Trani C, Lorenzoni R, et al. Safety and feasibility of iliac endovascular interventions with a radial approach. Results from a multicenter study coordinated by the Italian Radial Force. Int J Cardiol. 2014;175:280-284.
- 12. Cortese B, Rigattieri S, Aranzulla TC, et al. Transradial versus transfemoral ancillary approach in complex structural, coronary, and peripheral interventions. Results from the multicenter ancillary registry: a study of the Italian Radial Club. Catheter Cardiovasc Interv. 2017;116:1910.
- Montorsi P, Galli S, Ravagnani PM, Bartorelli AL. Matching the anatomy with the technique and vascular approach in carotid artery stenting. The role of systematic multidetector CT angiography. J Endovasc Ther. 2012;19:339-342.
- Berko NS, Jain VR, Godelman A, Stein EG, Ghosh S, Haramati LB. Variants and anomalies of thoracic vasculature on computed tomographic angiography in adults. J Comput Assist Tomogr. 2009;33:523-528.
- Montorsi P, Galli S, Ravagnani PM, et al. Carotid artery stenting in patients with left ICA stenosis and bovine aortic arch: a single-center experience in 60 consecutive patients treated via the right radial or brachial approach. J Endovasc Ther. 2014;21:127-136.
- Gupta R, Abou-Chebl A, Bajzer CT, Schumacher HC, Yadav J. Rate, predictors and consequences of hemodynamic depression after carotid artery stenting. J Am Coll Cardiol. 2006;47:1538-1543.
- Valgimigli M, Campo G, Penzo C, Tebaldi M, Biscaglia S, Ferrari R. Transradial coronary catheterization and intervention across the whole spectrum of Allen test results. J Am Coll Cardiol. 2014;63:1833-1841.
- Burzotta F, Trani C, Mazzari MA, et al. Vascular complications and access crossover in 10,676 transradial percutaneous coronary procedures. Am Heart J. 2012;163:230-238.
- Fang H, Chung S, Sun C, 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;24:670-679.
- Patel T, Shah S, Ranjan A, Malhotra H, Pancholy S, Coppola J. Contralateral transradial approach for carotid artery stenting: a feasibility study. Catheter Cardiovasc Interv. 2010;75:268-275.
- Kiemeneij F, Laarman GJ, Odekerken D, Slagboom T, van der Wiecken R. A randomized comparison of percutaneous transluminal coronary angioplasty by the radial, brachial and femoral approaches: the access study. J Am Coll Cardiol. 1997;29:1269-1275.
- 22. Kimmelstiel C, Pinto D, Aronow HD, et al. Bivalirudin is associated with improved in-hospital outcomes compared with heparin in percutaneous vascular interventions: observational, propensity-matched analysis from the premier hospital database. Circ Cardiovasc Interv. 2016;9:e002823.
- Pancholy S, Coppola J, Patel T, Roke-Thomas M. Prevention of radial artery occlusion-patent hemostasis evaluation trial (PROPHET study): a randomized comparison of traditional versus patency documented hemostasis after transradial catheterization. Catheter Cardiovasc Interv. 2008;72:335-340.
- Stabile E, Sannino A, Schiattarella GG, et al. Cerebral embolic lesions detected with diffusion-weighted magnetic resonance imaging following carotid artery stenting: a meta-analysis of 8 studies comparing filter cerebral protection and proximal balloon occlusion. JACC Cardiovasc Interv. 2014;7:1177-1183.

# <sup>12</sup> WILEY-

25. Montorsi P, Caputi L, Galli S, et al. Carotid Wallstent vs. Roadsaver stent and distal vs. proximal protection on cerebral microembolization during CAS. JACC Cardiovasc Interv. 2020;13:403-414.

## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

How to cite this article: Montorsi P, Cortese B, Cernetti C, et al. Transradial approach for carotid artery stenting: A position paper from the Italian Society of Interventional Cardiology (SICI-GISE). *Catheter Cardiovasc Interv*. 2021;1–12. https://doi.org/10.1002/ccd.29677