Comparison of transradial and transfemoral approach for carotid artery stenting: RADCAR study (RADial access for CARotide artery stenting)

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Disclosure Statement of Financial Interest

I, Zoltán Ruzsa MD. PhD.

DO NOT have a financial interest /arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

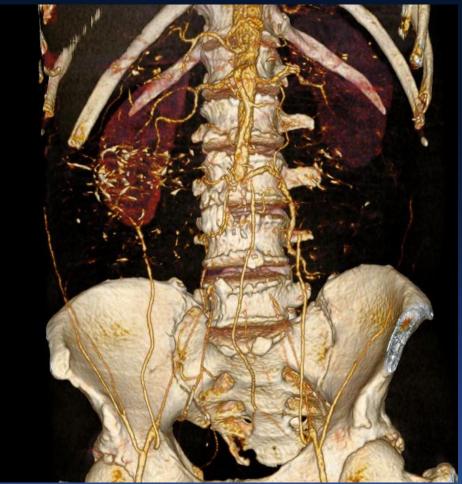




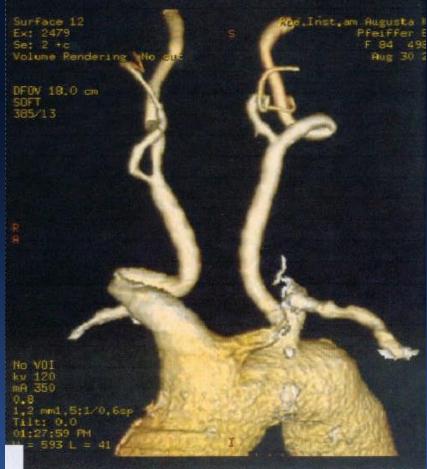


Background

Severe access ¹



Cannulation problems ^{3,4}



1. Yoo BS. Catheter Cardiovasc Interv. 2002 Jun;56(2):243-5. 2. Gan HW. Catheter Cardiovasc Interv. 2010 Mar 1;75(4):540-3. 3. Shaw JA. Catheter Cardiovasc Interv. 2003 Dec;60(4):566-9.







Background (Transradial CAS)

	Publ. year	Study	Patient No	Success (%)	Cross over (%)	Asympt RAO (n, %)	Major vasc complication	MACCE
Pinter et al. ¹	2007	Pilot	20	90	10	5	0	0
Folmar J et al. ²	2007	Pilot	42	83	?	0	0	2.3
Patel et al. ³	2010	Pilot	20	80	?	0	0	5
Bakoyiannis C et al. ⁴	2010	Pilot	9	100	0	0	0	0
Mendiz Oa et al ⁵	2011	Pilot	79	98.8	?	0	0	2
Ruzsa et al. ⁶	2012	Pilot	68	97.1	2.85	2.94	1.4	1.4
Etxegoien N et al 7	2013	Pilot	382	91	?	6	0	0.6

- 1. Pinter et al. J Vasc Surg. 2007 Jun;45(6):1136-41.
- 2. Folmar J et al. Catheter Cardiovasc Interv. 2007 Feb 15;69(3):355-61.
- 3. Patel et al. Catheter Cardiovasc Interv. 2010 Feb 1;75(2):268-75.
- 4. Bakoyiannis C et al. Int Angiol. 2010 Feb;29(1):41-6.
- 5. Mendiz OA. Vasc Endovascular Surg. 2011 Aug;45(6):499-503.
- 6. Ruzsa et al. Cardiologia Hungarica. 2012; 42 : 6–X

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7. <u>Etxegoien N. Catheter Cardiovasc Interv.</u> 2012 Dec 1;80(7):1081-7.





Methods

Study population.

- The clinical and angiographic outcomes of 260 consecutive patients with high risk for carotid endarterectomy (9) treated by CAS with cerebral protection were evaluated in a prospective randomized multicenter study between 2010 and 2012.

- Patients were randomized to TR (n =130) or TF (n =130) groups.

Endpoints

The following parameters were applied to evaluate the potential advantages of TR access:

- Primary endpoint: MACCE, rate of major and minor access site complications.
- Secondary endpoints: angiographic outcome of the CAS, and consumption of the angioplasty equipment, fluoroscopy time and X Ray dose, procedural time, cross over to another puncture site and hospitalisation days.

Inclusion and exclusion criteria.

- Inclusion criteria were: (1) Symptomatic (history of stroke or transient ischemic attack within 6 months) internal carotid artery stenosis (>70%) determided by magnetic resonance imaging or computer tomography and (2) critical asymptomatic (80%) ICA stenosis.

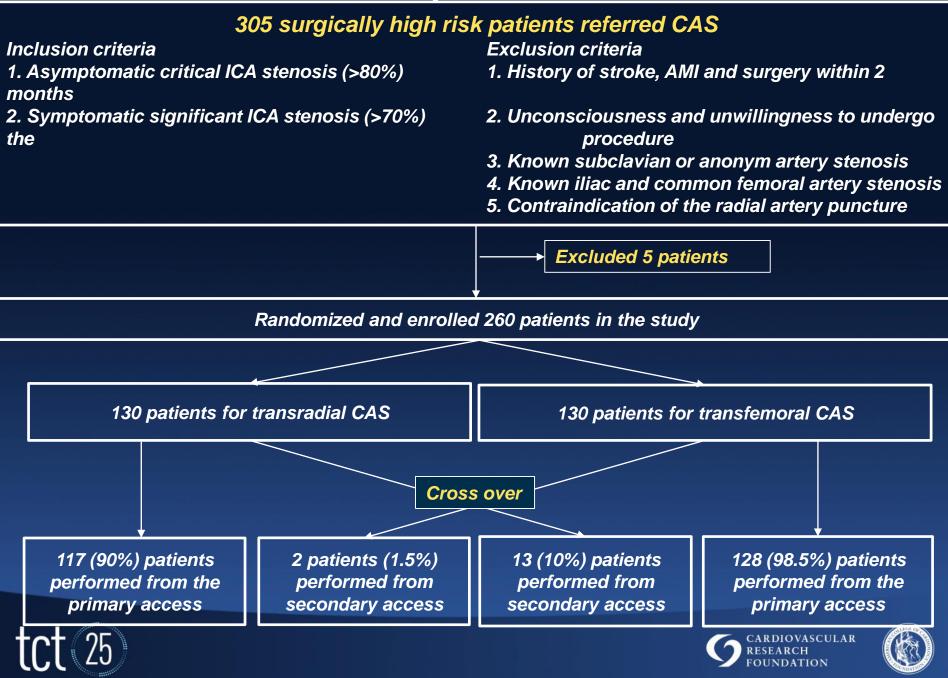
- Exclusion criteria were: (1) history of acute or recent stroke (<2 months), myocardial infarction, and surgery or trauma within the preceeding 2 months, (2) unconsiousness or unwillingness to undergo the procedure, (3) known subclavian or brachiocephalic artery stenosis, (4) known iliac or common femoral stenosis, (5) contraindications of the transradial access (Negative Allen test, non-palpable radial artery).



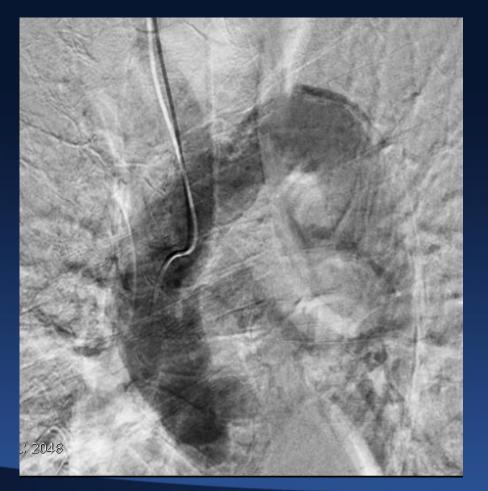




Study Flow chart



Aortography with 15 ml contrast



Pulling back and rotating the Simmons catheter





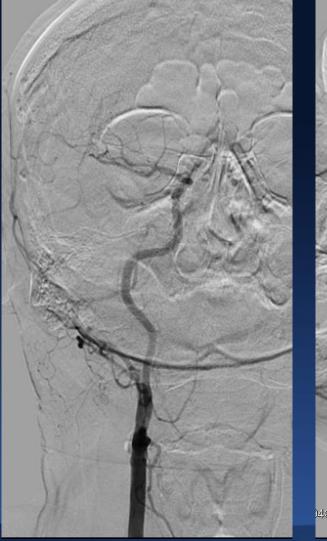




Selective angiography in AP and LAO90 view





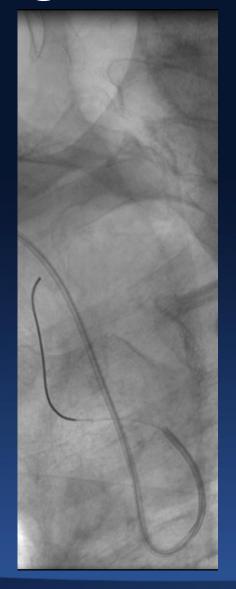










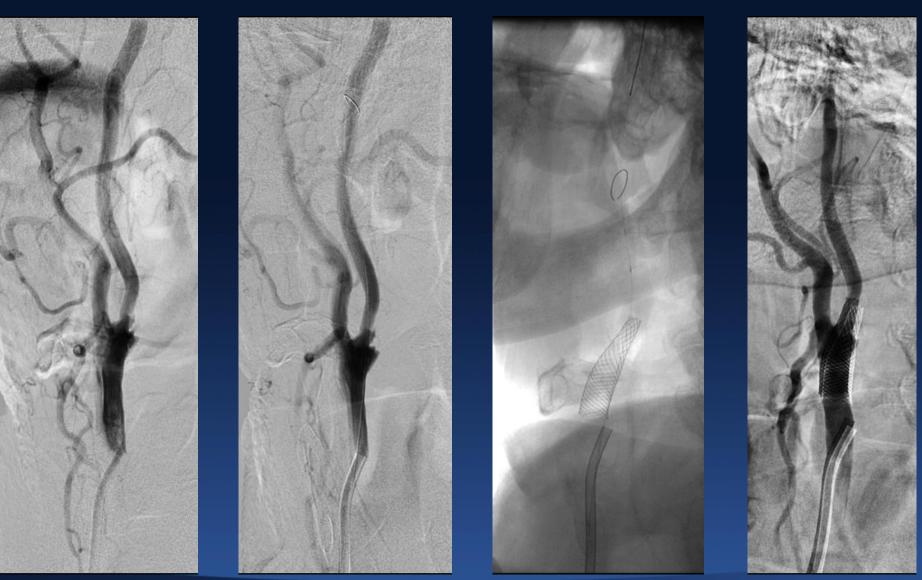


















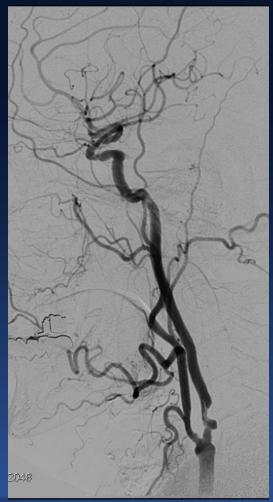
Left sided lesion

Aortography with 15 ml contrast

Selective angiography in AP and LAO90 view





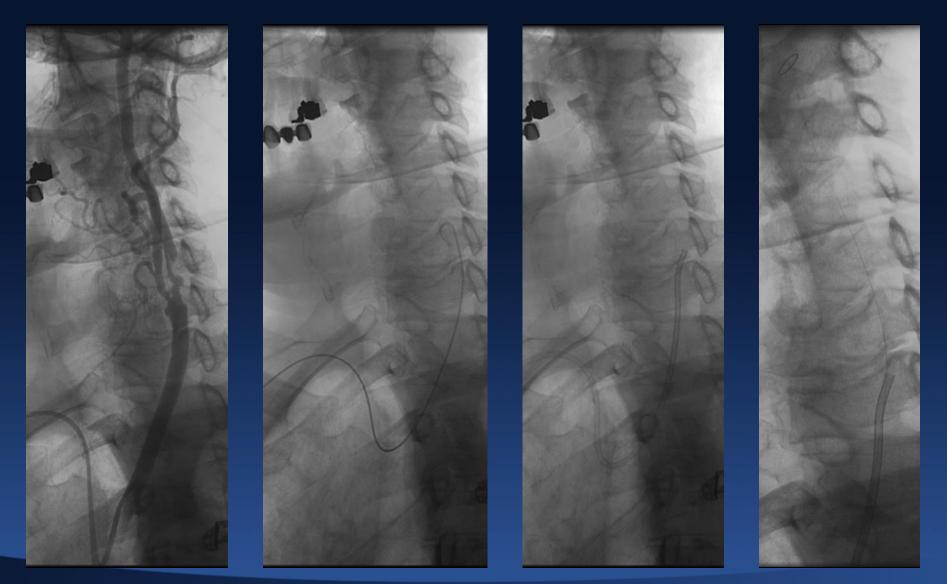








Left sided lesion









Left sided lesion









Demographic and clin	ical data of	all study p	atients
	Radial group	Femoral group	P value
	(n=130)	(n=130)	
Age	66.8±8.9	66.7±10.2	0.856
Male (%)	60.8	65.4	0.441
Hypertension (%)	77.7	88.5	0.021
Hyperlipidaemia (%)	56.2	47.7	0.172
Diabetes mellitus (%)	36.2	36.9	0.898
Obesity (%)	14.6	34.6	0.0003
Smoker (%)	28.5	26.9	0.889
Peripheral artery disease (%)	13.9	13.8	1.000
Coronary artery disease (%)	24.6	24.6	0.776
Positive family history (%)	6.9	9.2	0.495
Dialysis (%)	6.2	3.1	0.237







Angiographic data

	Radial group	Femoral group	p value	
	(n=117)	(n=128)		
Aortic arch morphology				
Arch type I. n (%)	79 (67.5)	108 (84.4)	0.002	
Arch type II-III n (%)	38 (32.5)	20 (15.6)	0.073	
Stenosis localisation				
- Left sided n (%)	50 (42.7)	75 (58.6)	0.131	
- Right sided n (%)	67 (57.3)	53 (41.4)		
Reference diameter	5.7±0.9	5.7±0.9	0.854	
(ICA) (mm)				
Stenosis diameter (%)	81.9	84.1	0.286	







Procedural data

	Radial group (n=117)	Femoral group (n=128)	p value			
Successful puncture in all patients n (%)	128 (98.5)	130 (100.0)	0.156			
Successful cannulation n (%)	119 (91.5)	129 (99.2)	0.003			
Successful procedure from primary access n (%)	117 (90.0)	128 (98.5)	0.003			
Cross over n (%)	10.0	1.5	0.003			
Puncture time (sec)	30±48	25±19	0.347			
Cannulation time (sec)	118±152	93±95	0.141			
Procedure time (sec)	1744±742	1665±744	0.409			
X Ray dose (mGy)	223±138	182±106	0.008			
Fluoroscopy time (sec)	613±289	579±285	0.359			
Contrast volume (ml)	117.9±39.3	110.1±36.3	0.111			
Hospitalization days	1.17±0.40	1.25±0.45	0.006			
Consumption of devices						
Diagnostic catheter / procedure (%)	122 (104.3)	110 (85.9)	0.011			
Guide catheter / procedure (%)	108 (92.3)	77 (60.2)	<0.001			
Guiding sheath (%)	9 (7.7)	51 (39.8)	<0.001			
Buddy wire (%)	45 (38.5)	69 (53.9)	0.016			
Balloon / procedure (%)	128 (109.4)	147 (114.8)	0.355			
Stent used / procedure (%)	112 (95.7)	126 (98.4)	0.204			

MACCE (Major Adverse Cerebral and Cardiac Events)

		Radial group (n=117)	Femoral group (n=128)	p value
MA	CCE n (%)	1 (0.9)	1 (0.8)	0.949
	Death	1 (0.9)	0 (0.0)	0.295
	Myocardial infarction	0 (0.0)	0 (0.0)	1.000
	Reintervention	0 (0.0)	0 (0.0)	1.000
	Stroke	1 (0.9)	1 (0.8)	0.949
	Vasc	ular complications		
Min	or n (%)	9 (7.7)	6 (4.7)	0.327
	Spasm	0 (0.0)	0 (0.0)	1.000
	Haematoma	1 (0.9)	6 (4.7)	0.072
	Asymptomatic RAO	8 (6.8)	0 (0.0)	0.003
	Other	0 (0.0)	0 (0.0)	1.000
Maj	jor n (%)	1 (0.9)	1 (0.8)	0.949
	Symptomatic RAO	1 (0.9)	0 (0.0)	0.295
	Bleeding and compartment syndrome	0 (0.0)	1 (0.8)	0.338
	Other	0 (0.0)	0 (0.0)	1.000
Tot	al vascular complication n (%)	10 (8.6)	7 (5.5)	0.344

Conclusion

- Carotid artery stenting with cerebral protection devices can be safely and effectively performed using radial access with acceptable morbidity and high technical success.
- In severe PAD, tortuose iliac artery and aortic arch abnormalities (Bovine arch, Arch II-III) the transradial angioplasty can be better than transfemoral angioplasty
- There are no differences in total procedure duration, fluoroscopy time between the two approaches, but the radiation dose is significantly higher in the radial group and the hospitalisation is shorter with the transradial access.







Case 1.- Bovine arch direct cannulation



Access: JR 7F Guiding: 7F JR3,5 Guidewire: Filter wire Stent: Carotis Wallstent 7x30 mm Balloon: Sterling 4x20 and 6x20 mm

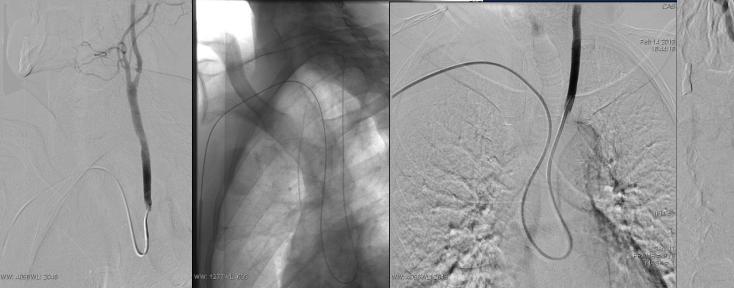




Case 2.-Loop technique



Access: 7F Guiding: 7F XF40 Guidewire: Filter wire Stent: Carotis Wallstent 7x30 mm Balloon: Sterling 5x20 mm



FRAME = 8/10 MASK = 1