Is There a Higher Risk of Stroke With the Radial Approach?

Reasons and Results

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Disclosures

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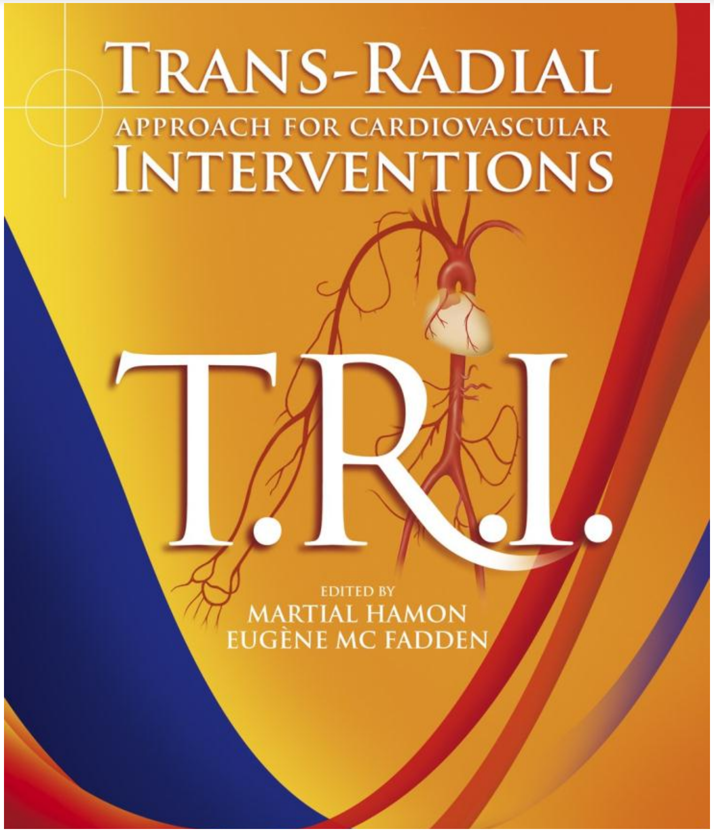
  GlaxoSmithKline, Lilly, The Medicines Company.

- **Lectures, Consulting Fees/Honoraria:**
  Terumo, The Medicines Company, Biotronik, Cordis, Medtronic.



www.angiosoft.net

Cerebrovascular accidents after diagnostic and interventional cardiac catheterization

Mechanisms of cerebrovascular accidents

Embolism of athero-thrombotic material (*causes & preventive actions*)
- Catheters (thrombosis during procedure) (*appropriate heparinization/flushing*)
- Left ventricle (mural thrombus post MI) (*Echo/avoiding ventriculo*)
- Atherosclerotic aorto-femoral plaques* (*manipulation of catheters: scraping debris*)

Air embolism (quite frequent) (*easily preventable: catheter filling/flushing*)

Contrast media (osmotic disruption of the blood-brain barrier) (*low osmotic agent*)

Miscellanous (intracranial bleeding in ACS, antithrombotic regimens…)

** Keeley EC et al. J Am Coll Cardiol 1998;1861-5*

Periprocedural Stroke and Cardiac catheterization

First Author	Patients & Fup	Incidence of Stroke In-hospital & postdischarge	N	%	95% CI	Independent Predictors of Stroke OR and 95% CI — Predictive variables	OR	95% CI	P
Lazar et al (1995)	**6,465 in-hospital**	Total Ischemic Hemorrhagic Uncertain	27 _ _ _	0.42% _ _ _	[0.27-0.60] _ _ _	Female gender Vascular disease Extensive CAD Ejection fraction LVH	3.2 3.1 3.0 0.4 2.9	[1.4 - 7.4] [1.2 - 8.0] [1.2 - 7.4] [0.2 - 1.0] [1.2 - 7.3]	p < 0.01 p < 0.05 p < 0.05 p < 0.05 p < 0.05
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PERI-PROCEDURAL STROKE RATE IS LOW

First Author	Patients & Fup	Incidence of Stroke	N	%	95% CI	Predictive variables	OR	95% CI	P
Fuchs et al (2002)	**9,662 in-hospital**	Total Ischemic Hemorrhagic Uncertain	43 21 20 2	0.44% 0.22% 0.21% 0.02%	[0.32-0.60] [0.13-0.33] [0.13-0.32] [0.00-0.07]	IABP , emergency use IABP, prohylactic use Age>80 years Vein graft intervention	9.6 5.1 3.2 2.7	[3.9-23.9] [1.8-14.0] [1.4-7.7] [1.3-5.8]	p < 0.001 p = 0.002 p = 0.008 p = 0.01
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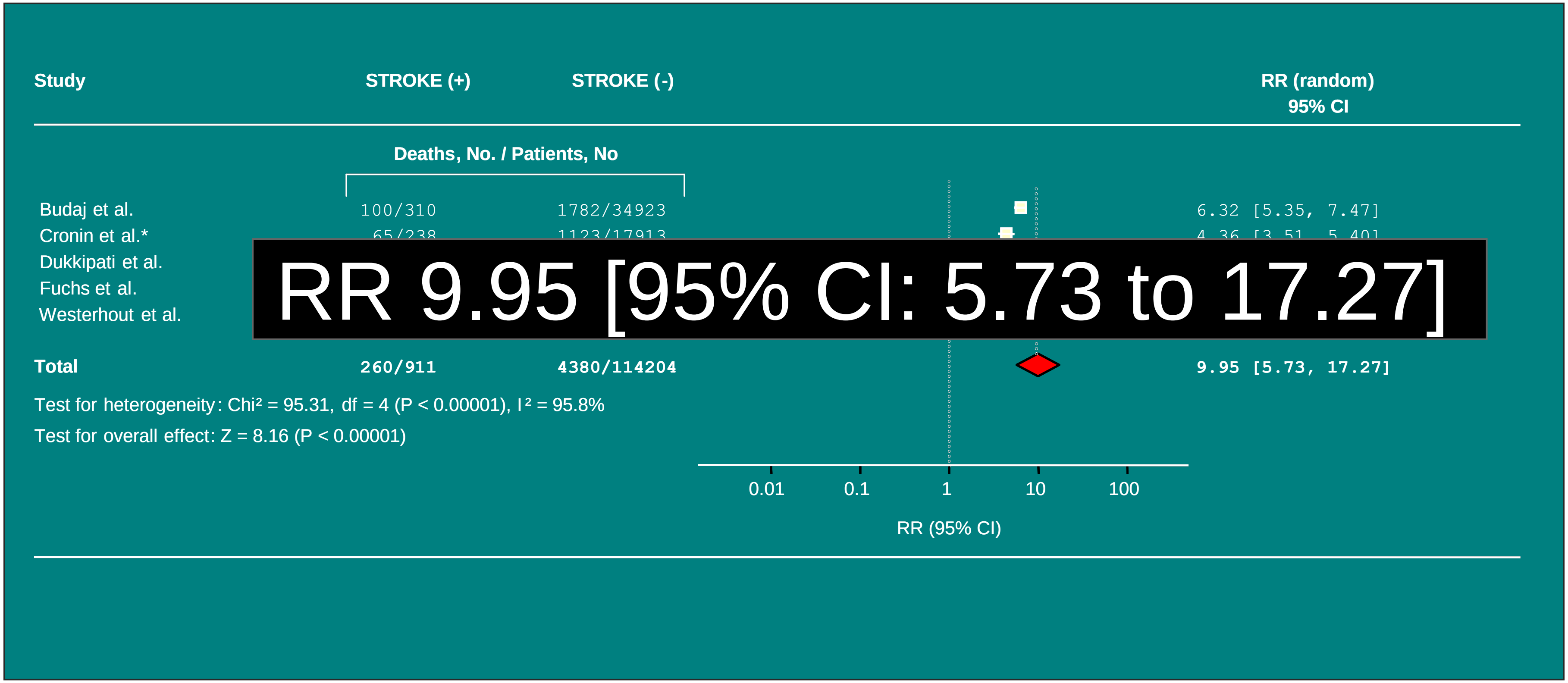
MAJORITY ARE ISCHAEMIC

First Author	Patients & Fup	Incidence of Stroke	N	%	95% CI	Predictive variables	OR	95% CI	P
		Uncertain	36	0.17%	[0.12-0.24]	Renal failure Urgent procedures IABP	3.1 2.7 2.2	[1.8-5.2] [1.3-5.5] [1.1-4.3]	p < 0.0001 p <0.009 p = 0.028
Wong et al (2005)	**76,903 in-hospital**	Total Ischemic Hemorrhagic Uncertain	140 _ _ _	0.18% _ _ _	[0.15-0.21] _ _ _	Age GPI AMI Carotid disease Renal failure Heart failure IABP	1.0 1.5 3.4 3.4 2.0 2.9 3.5	[1.0-1.1] [1.0-2.1] [2.6-5.8] [2.1-5.4] [1.0-3.9] [1.9-4.4] [1.5-8.3]	p < 0.001 p = 0.027 p < 0.001 p < 0.001 p = 0.037 p < 0.001 p = 0.004

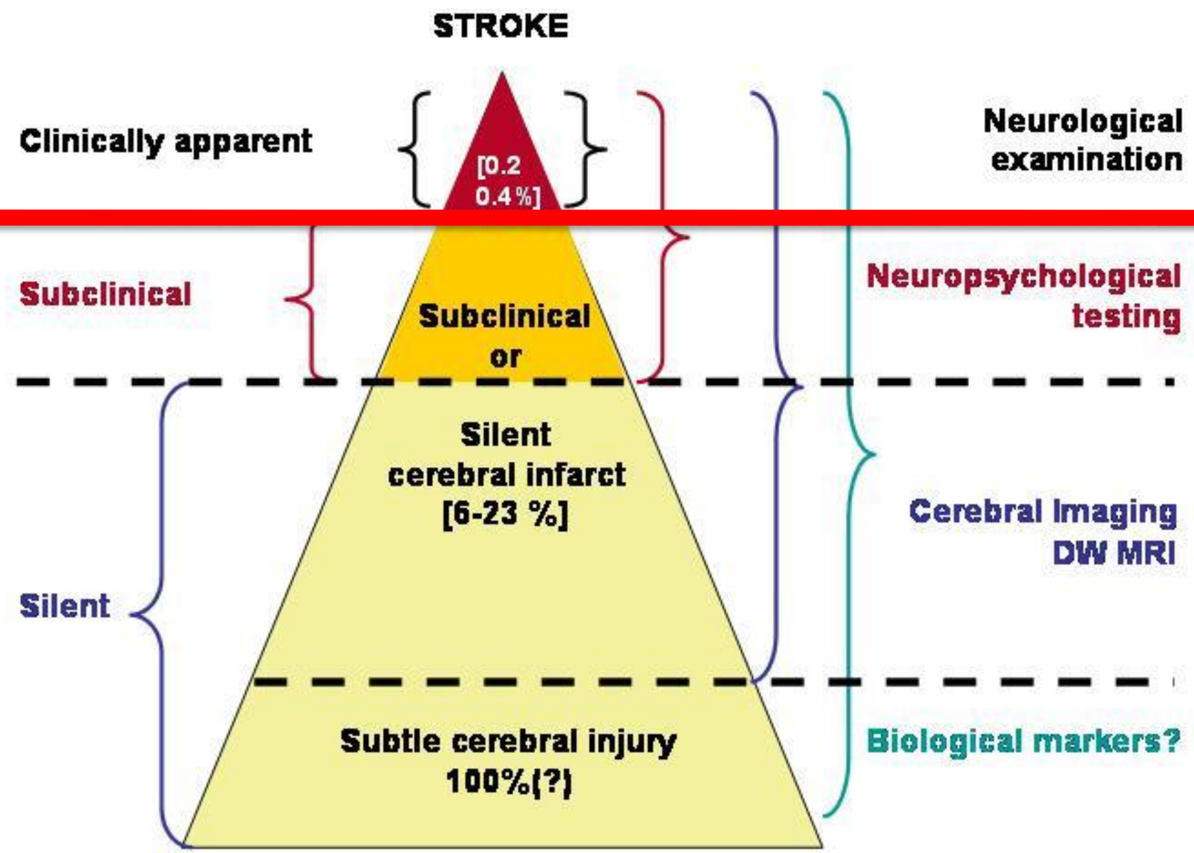
Mortality in patients with peri-procedural stroke



Hamon et al, Circulation 2008

STROKE RISK IN THE CATH LAB

- Clinically apparent stroke are uncommon
- Unsuspected silent cerebral infarction in PCI up to 15-22% of cases!



Cerebral embolism and brain injury after PCI

Silent stroke in cardiac catheterization: Diffusion-Weighted MRI studies

- Silent and apparent cerebral embolism after retrograde catheterization of the aortic valve in valvular stenosis: a prospective, randomized study.
  Omran et al. Lancet 2003;361:1241-1246.

- Cerebral infarction incidence and risk factors after diagnosis and interventional cardiac catheterization-prospective evaluation at DW MRI.
  Busing et al. Radiology 2005;235:177-183.

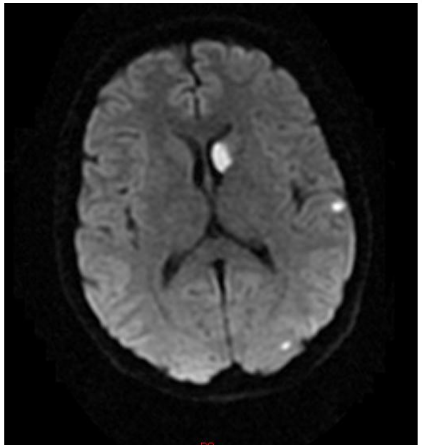
- Cerebral emboli during left heart catheterization may cause acute brain injury.
  Lund et al. Eur Heart J 2005;26:1269-1275.

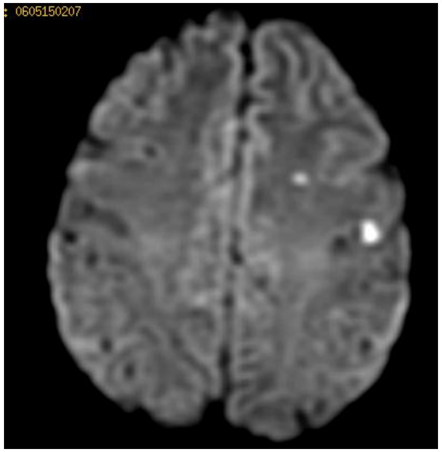
- Cerebral Microembolism during Cardiac catheterization and risk of acute brain injury. A prospective DW MRI study.
  Hamon et al. Stroke 2006;37:2035-2038.

- Risk of acute brain injury related to cerebral microembolism during cardiac catheterization performed by right upper lim arterial access.
  Hamon et al. Stroke 2007;38:2176-2179.

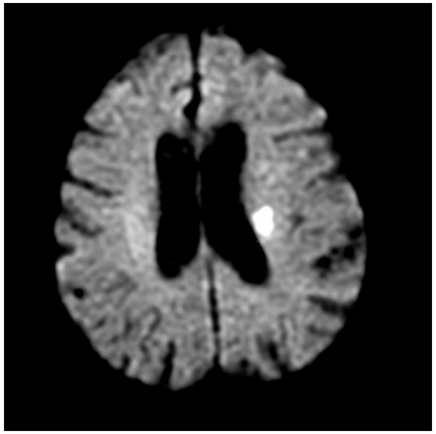
BRAIN INJURY IN THE CATH LAB

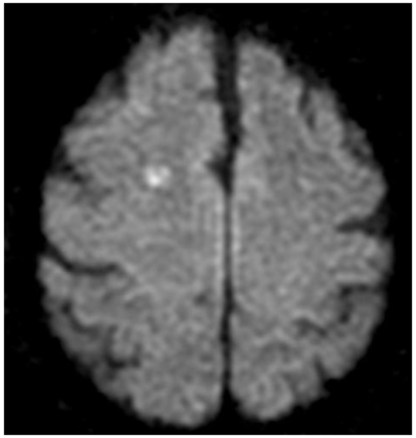
DW-MRI





Diffusion-weighted Magnetic Resonance Imaging (DW-MRI)





GOLD STANDARD FOR DETECTION OF SUBCLINICAL BRAIN INJURY

Cerebral emboli during left heart catheterization may cause acute brain injury

47 pts, left catheterization (5 PCI), transcranial Doppler, Cerebral MRI
754 cerebral microemboli: 92.1% gaseous , 7.9% solid

	Transradial	Transfemoral	p
%	78.7	21.3	
Solid microemboli: median (range)	57 (18-372)	36 (12-66)	0.012
New cerebral lesions MRI* (%)	15.2	0	0.567
*associated with			
- solid microemboli: median (range)	90 (60–372)	42 (12–246)	0.016
- longer fluoroscopy time	11.3 (3.8–14.8)	5.2 (1.4–33.6)	0.039

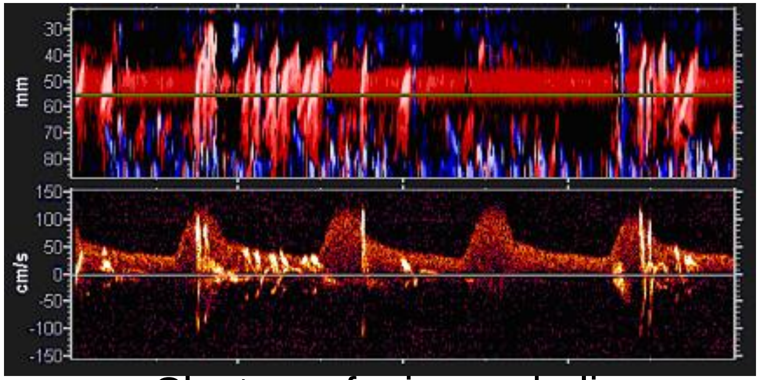
6F diagnostic catheters + 0.038'', J tip, 220 cm guidewire

(Non randomized, non consecutive series, monocentric, small sample, no adjustment, unknown radial experience…)

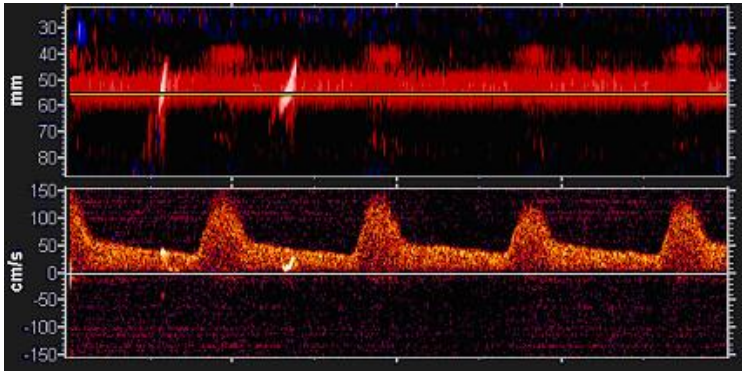
Lund, European Heart Journal 2005

BRAIN INJURY IN THE CATH LAB

Trans-cranial doppler (TCD)



Clusters of microemboli
entering the brain

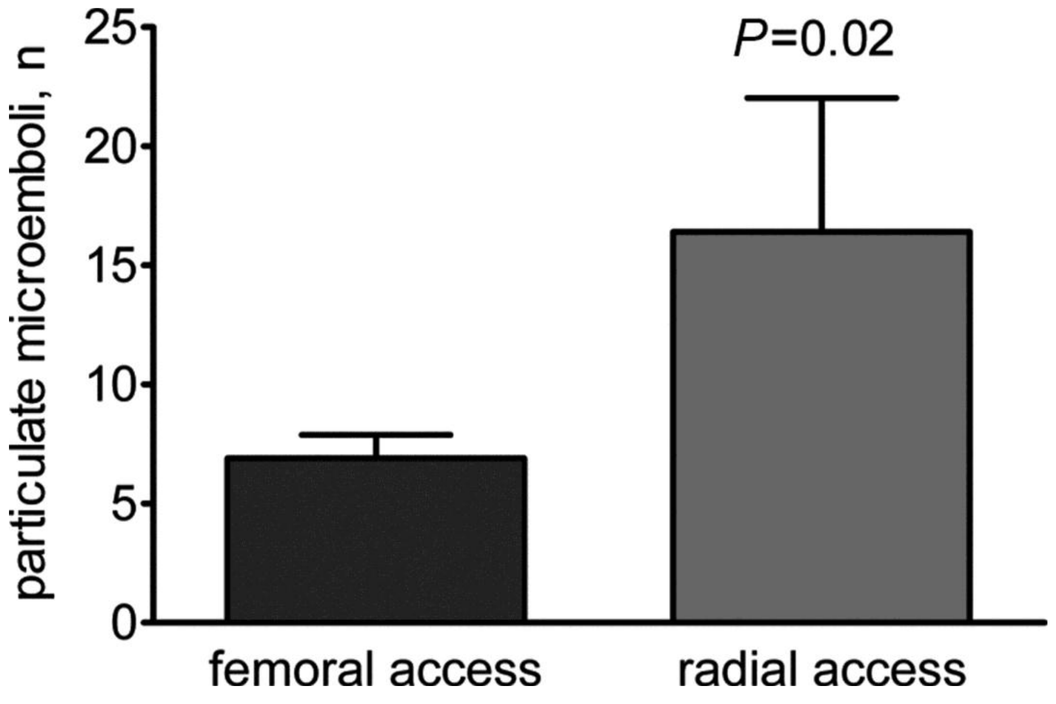


A solid microembolus
detected by multifrequency

GOLD STANDARD FOR DETECTION OF SUBCLINICAL BRAIN EMBOLIZATION

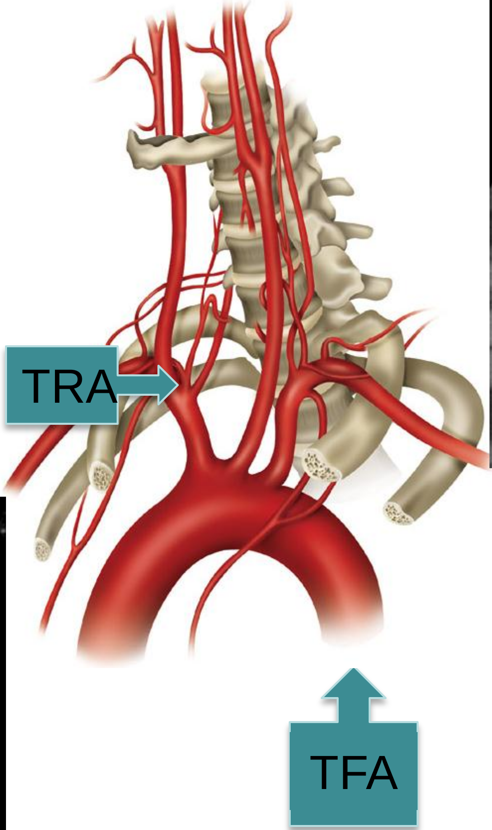
Cerebral Microembolism During Coronary Angiography
A Randomized Comparison Between Femoral and Radial Arterial Access

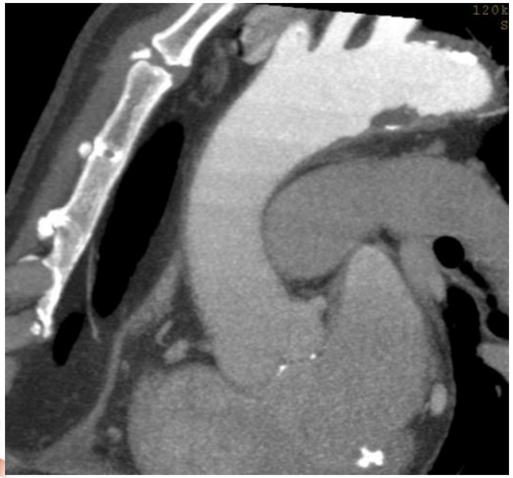
Number of particulate cerebral microemboli during coronary angiography (Radial n=20; Femoral n=23)

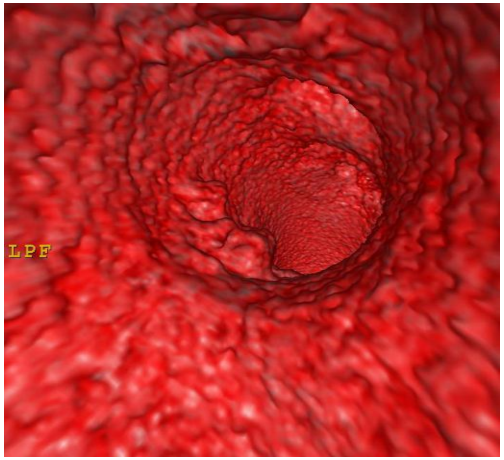


Jurga J et al. Stroke 2011;42:1475-1477

Impact of Arterial Access sites
On the risk of stroke







Retrograde progression of aortic atheroma with age

From Descending Aorta to the Arch and Ascending Aorta

Keeley EC et al. J Am Coll Cardiol 1998;1861-5

Khoury Z Am J Cardiol 1997; 79: 23-27

THE SCIPION TRIAL

Silent Cerebral Infarcts Following Cardiac Catheterization :

A Randomized Comparison Of Radial And Femoral Approaches

Martial Hamon[1], Janusz Lipiecki[2], Didier Carrié[3], Francesco Burzotta[4], Nicolas Durel[2], Guillaume Coutance[1], Nicolas Boudou[3], Cesare Colosimo[4], Carlo Trani[4], Nicolas Dumonteil[3], Rémy Morello[1], Fausto Viader[1], Béatrice Claise[2], Michèle Hamon[1]

[1] University Hospital, Caen, FRANCE, [2] University Hospital, Clermond-Ferrand, FRANCE, [3] University Hospital, Toulouse, FRANCE, [4] The Policlinica, Catholica University Hospital, Roma, ITALY

CHUCaen

Inserm
Institut national
de la santé et de la recherche médicale

STUDY DESIGN

Trials

BioMed Central

Study protocol

Open Access

Silent cerebral infarct after cardiac catheterization as detected by diffusion weighted Magnetic Resonance Imaging: a randomized comparison of radial and femoral arterial approaches

Michèle Hamon[1], Francesco Burzotta[2], Catherine Oppenheim[3], Rémy Morello[4], Fausto Viader[5], Martial Hamon*[6] for the SCIPION Investigators[7]

PROSPECTIVE MULTICENTER RANDOMIZED TRIAL:

1) University Hospital of Caen, Normandy, France
2) University Hospital of Clermont-Ferrand
3) University Hospital of Toulouse
4) Catholic University of the Sacred Heart, Rome, Italy

OBJECTIVES

1. to assess the rate of DW-MRI-detected silent brain infarct after left cardiac catheterization including retrograde catheterization of aortic valve, in patients with aortic valvular stenosis.

1. to determine if the use of Radial access, compared to Femoral, is associated with reduced risk of silent cerebral lesions

PRIMARY END-POINT

THE OCCURRENCE OF NEW LESIONS
AFTER CARDIAC CATHETERIZATION, AS DETECTED BY
DW-MRI, BETWEEN THE 2 GROUPS (RADIAL VERSUS FEMORAL)

METHODS: PATIENTS

INCLUSION CRITERIA

- Consecutive patients with severe aortic stenosis scheduled for cardiac catheterization (coronary artery angiography and attempt to cross the stenosis valve for gradient assessment).

EXCLUSION CRITERIA

- Contraindication to MRI or inability to give written informed consent.

RANDOMIZATION

- After informed consent signed, eligible patients were randomized 1:1 to a strategy of Radial or Femoral access

SAMPLE SIZE CALCULATION

- 152 patients, randomized 1:1, power 80%, $p<0.05$ (*Omran et al, Lancet 2003 vs Hamon et al, Stroke 2006*)

	n	Heparin	Fluoroscopy Time (min) DWI+/DWI−	Catheter Size (French)	Serial DW MRI	New Cerebral Infarction Observed %	New Cerebral Infarction Mid-Point [95% CI]	Indication
Omran 2003[3]	101	5000 IU	6.1/2.9	6 F-7 F	100%	22%	23% [15–31]	Aortic stenosis
Lund 2005[5]	47	5000 IU	11.3/5.2	6 F	89%	13.5%	15.7% [6–26]	CAD
Busing 2005[4]	48	2500 IU	10.1/7.4	5 F-6 F-7 F	94%	15%	17% [7–28]	CAD
Hamon 2006	46	5000 IU	7.0/5.4	5 F	100%	2.2%	5.9%* [0.01–12.5]	Aortic stenosis

METHODS: DW-MRI

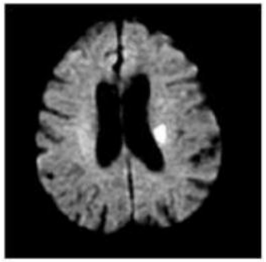
MRI performed **within 24 hrs before and 48 hrs** after cardiac cath.

- Main outcome measure : Occurrence of new cerebral infarct on serial DW-MRI

For **DW-MRI**, the diffusion gradients were successively and separately applied in three orthogonal directions.
Apparent diffusion coefficient (ADC) maps were calculated.

For analysis of DW-MRI (DICOM-CD provided by Centers) a neuroradiologist (blinded to randomization and patient status) visually determined:

- **the presence**
- **size**
- **number**
- **vascular distribution**



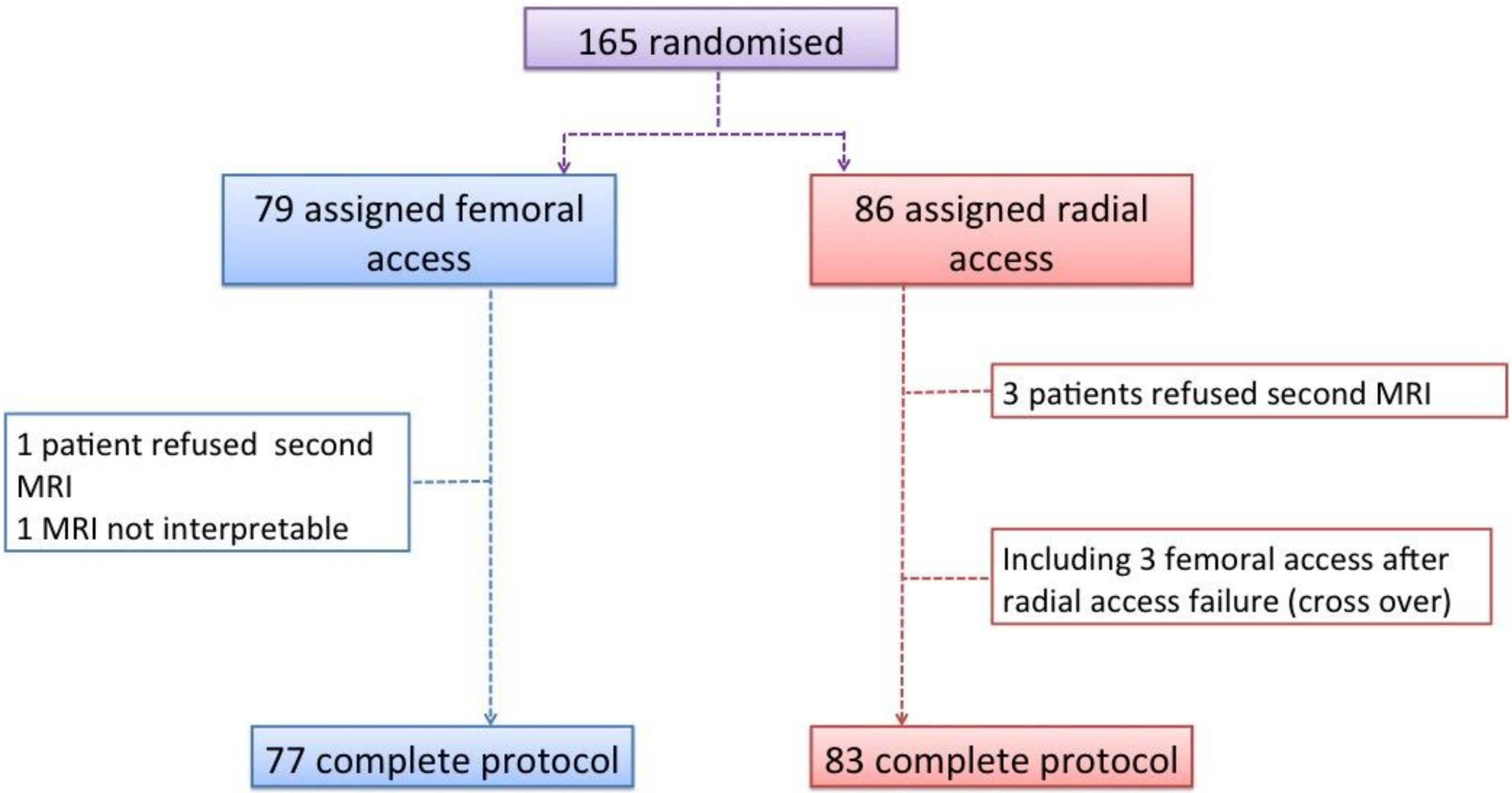
of any focal diffusion abnormalities (bright lesions) consistent with embolic lesions.

METHODS: TRANSCRANIAL DOPPLER SUBSTUDY

- **Transcranial Doppler** studies were performed in a subgroup of patients


High-power/high-intensity, transient unidirectional signals corresponding to the definition of microembolic signature were used for the analysis.

STUDY FLOW CHART



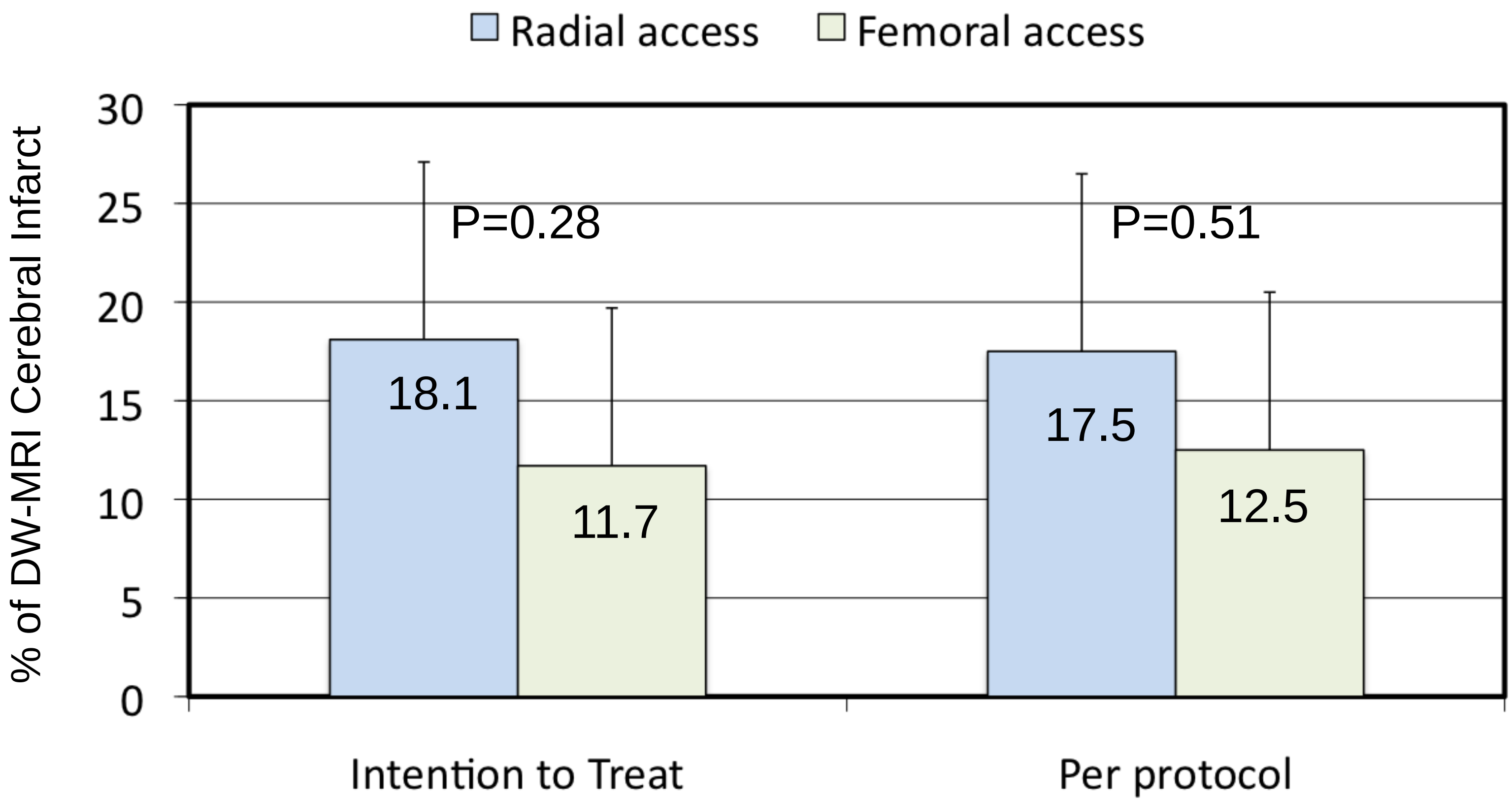
Baseline characteristics
Demographics and procedural parameters

	Femoral (n=77)	Radial (n=83)	p
Age (y)	73.4 ± 11.5	75.5 ± 8.6	0.18
Male (%)	54.5	54.2	1.00
BMI	27.5 ± 4.7	27.3 ± 4.9	0.78
Weight (kg)	76.2 ± 13.5	74.9 ± 16.5	0.61
Height (cm)	164 ± 8	166 ± 8	0.16
Mean Gradient (mmHg)	45.8 ± 14.2	47.9 ± 14.2	0.36
LVEF (%)	62.4 ± 12.4	60.7 ± 12.5	0.40
History of AF (%)	22.1	16.9	0.43
History of CAD (%)	11.7	12.0	1.00
History of stroke (%)	3.9	4.8	1.00
Carotid atherosclerosis (%)	24.7	19.3	0.45
Hypertension (%)	75.3	78.3	0.71
Hypercholesterolemia (%)	46.8	54.2	0.43
Diabetes mellitus	36.4	27.7	0.31
Catheter used > 3 (%)	80.5	62.7	0.01
Use of 6F catheters (%)	7.8	9.6	0.68
Crossing the aortic valve(%)	96.1	91.6	0.33
Fluoroscopy time (mn)	7.2 ± 5.6	7.8 ± 4.4	0.49
Procedure duration (mn)	25.3 ± 12.8	24.7± 13.3	0.82

DW-MRI Cerebral Infarcts after left heart catheterization
Primary endpoint

Intention to treat and per protocol analyses

24 (15%) patients had cerebral infarcts -> 22 (91.6%) asymptomatic



Univariate analysis comparing patients with or without new cerebral infarct on DW-MRI

	SBI (n=24)	No SBI (n=136)	p
Age (y)	77.6 ± 6.7	73.9 ± 10.5	0.10
Male (%)	50	55.1	0.66
BMI	27.5 ± 4.5	27.3 ± 4.8	0.84
Weight (kg)	72 ± 13.1	76.1 ± 13.4	0.22
Height (cm)	170 ± 8	165 ± 8	0.002
Mean Gradient (mmHg)	41.3 ± 15.1	47.8 ± 13.8	0.04
LVEF (%)	59.3 ± 15.9	61.9 ± 11.8	0.45
History of AF (%)	29.2	17.6	0.26
Previous CAD (%)	12.5	11.8	1.00
Previous stroke (%)	0.0	5.1	0.38
Carotid atheroscl. (%)	25.0	21.3	0.79
Hypertension (%)	58.3	80.1	0.03
Hypercholesterolemia (%)	41.7	52.2	0.38
Diabetes Mellitus	25.0	33.1	0.48
Catheter used > 3 (%)	75.0	70.6	0.81
Use of 6F catheters (%)	4.2	9.6	0.64
Crossing the aortic valve(%)	95.8	93.4	1.00
Fluoroscopy time (mn)	8.7± 4.7	7.3± 5.0	0.23
Procedure duration (mn)	25.3 ± 11.7	24.9 ± 13	0.88

PREDICTORS OF MRI-DETECTABLE CEREBRAL INFARCTS

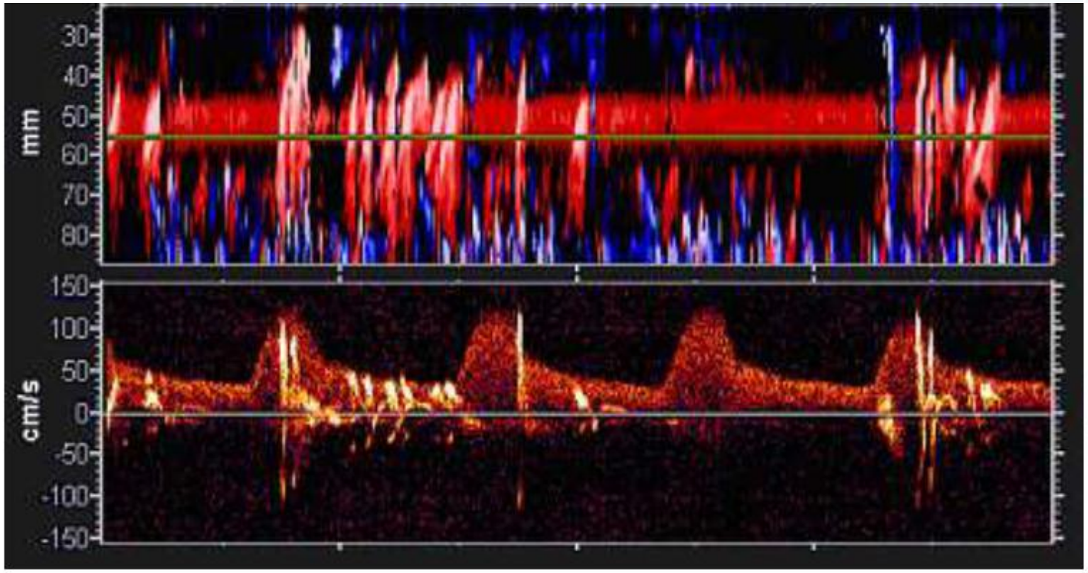
AT MULTIVARIABLE ANALYSIS

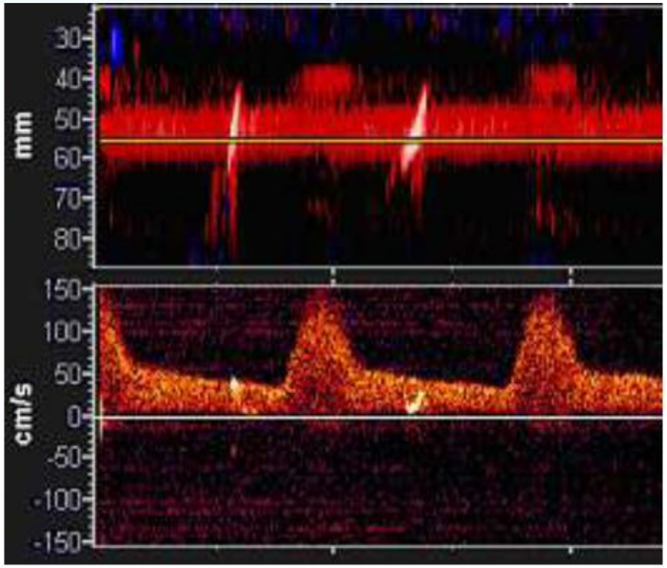
- **higher height of the patient** (OR 8.24; 95% CI 2.71 to 25.02) *(possibly related to the length of catheter in contact with the blood stream ?)*

- **lower transvalvular gradient** (OR 0.96; 95% CI 0.93 to 0.99) *(primary haemostatic abnormalities in the most severe aortic stenosis patients , less blocked valve more prone to debris detachment?)*

HIGH INTENSITY TRANSIENT SIGNAL AT TCD

Femoral	Radial	P
52.7 ± 21.7 (n = 15)	56.2 ± 36.4 (n = 6)	0.87





CONCLUSIONS

CHU CAEN

Silent cerebral embolization frequently occurs during left heart catheterization in patients with severe aortic stenosis

Radial approach does not reduce silent cerebral infarcts

Based on DW-MRI and transcranial doppler assessments in the SCIPION trial, the choice of vascular approach (radial or femoral) seems to have no impact on cerebral embolization and subsequent brain injury

Silent cerebral infarcts after cardiac catheterization: A randomized comparison of radial and femoral approaches

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Background Single center studies using serial cerebral diffusion-weighted magnetic resonance imaging in patients having cardiac catheterization have suggested that cerebral microembolism might be responsible for silent cerebral infarct (SCI) as high as 15% to 22%. We evaluated in a multicenter trial the incidence of SCIs after cardiac catheterization and whether or not the choice of the arterial access site might impact this phenomenon.

Methods and Results Patients were randomized to have cardiac catheterization either by Radial (n = 83) or Femoral (n = 77) arterial approaches by experimented operators. The main outcome measure was the occurrence of new cerebral infarct on serial diffusion-weighted magnetic resonance imaging. Patient and catheterization characteristics, including duration of catheterization, were similar in both groups. The risk of SCI did not differ significantly between the Femoral and Radial groups (incidence of 11.7% versus 17.5%; OR, 0.85; 95% CI, 0.62-1.16; *P* = .31). At multivariable analysis, the independent predictors of SCI were the patient's higher height and lower transvalvular gradient.

Conclusions The high rate of SCI after cardiac catheterization of patients with aortic stenosis was confirmed, but its occurrence was not affected by the selection of Radial and Femoral access. (Am Heart J 2012;0:1-6.e1.)

Hamon et al. Am Heart J 2012 Oct;164:449-454.