University Heart Center Hamburg

GERMAN AORTIC CENTER HAMBURG

Stroke And Arch TEVAR: What´s The Cause?

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German Aortic Center Hamburg
University Heart Center
University Hospital Eppendorf

THE 24TH INTERNATIONAL EXPERTS SYMPOSIUM

CRITICAL ISSUES

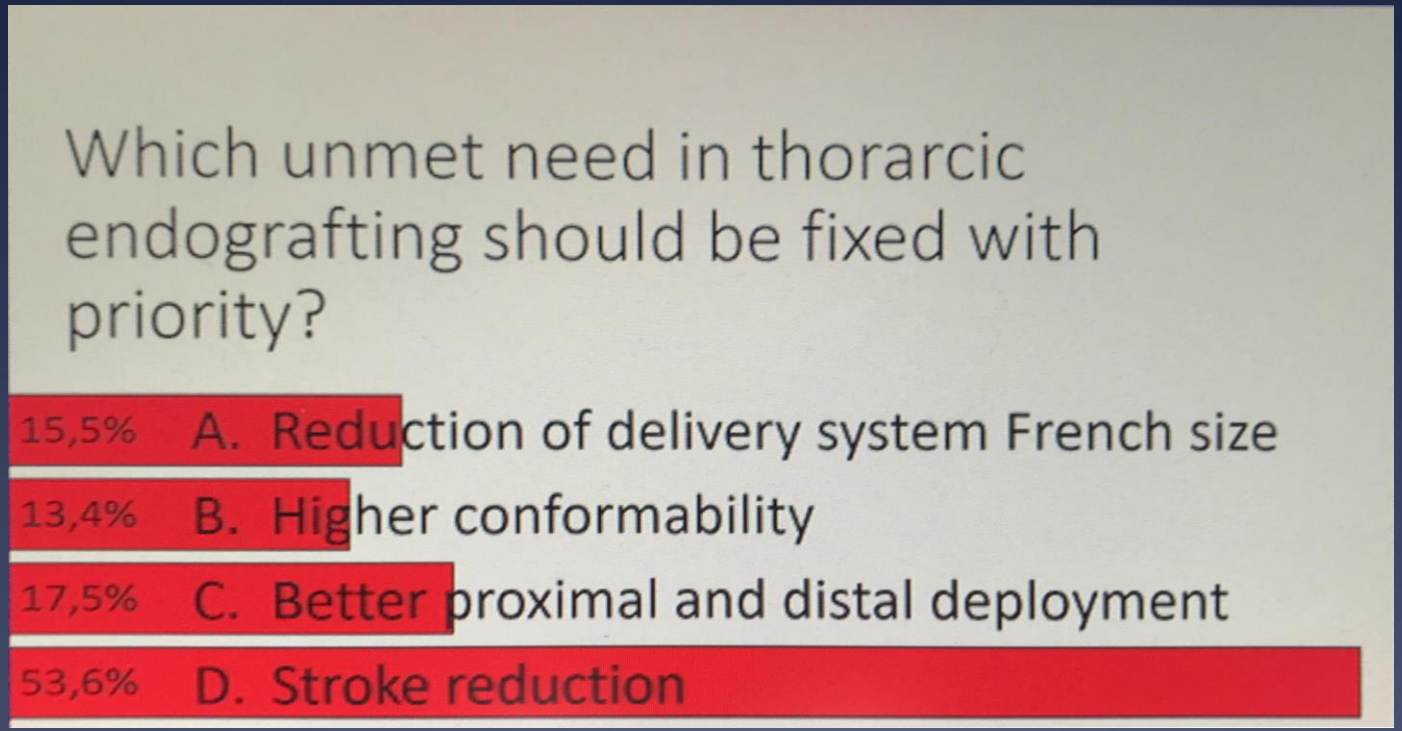
IN AORTIC ENDOGRAFTING

DECEMBER 17 & 18 2021

Disclosures

- Research-grants, travelling, proctoring speaking-fees, IP, royalties with Cook.
- Consultant with Philips
- Consulting, speaking-fees with Getinge
- Shareholder Mokita-Medical GmbH, Arterica
- IP, Consultant with Terumo Aortic

Vascular Communities View



Audience Poll at LINC 2020

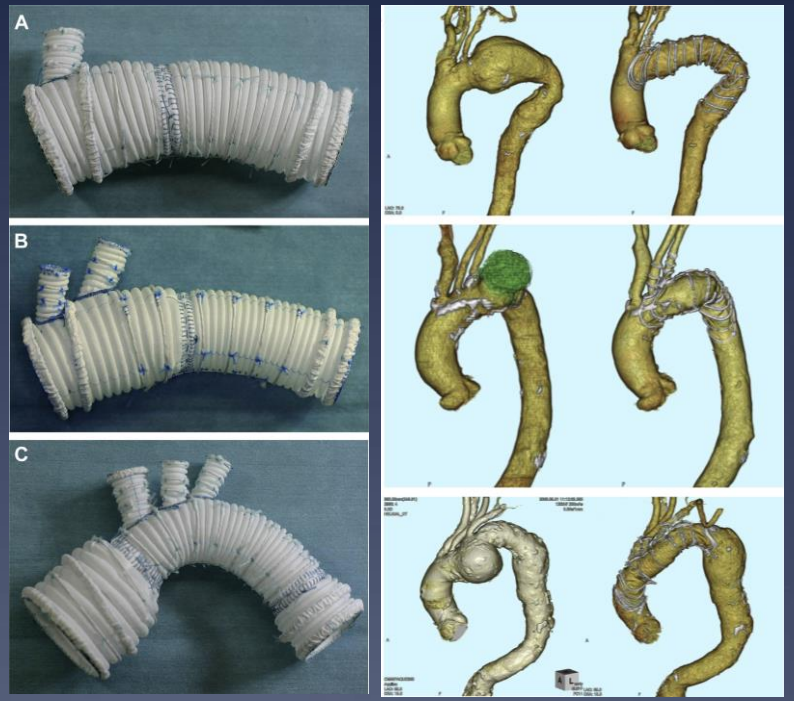
Stroke in TEVAR

- Incidence
  - in TEVAR: 4-5%
  - in arch TEVAR: 5-20%
- Mortality 20%

Feezor et al. 2007; J Endovasc Ther 14:568-73
Böckler et al. 2016; Eur J Vasc Endovasc Surg 51:791-800
Alsafi et al. 2014; J Vasc Surg 60:1499-506
Ullery et al. 2012; J Vasc Surg 56:1510-7
Kahlert et al. 2014; Ann Thorac Surg 98:53-8
Perera et al. 2015; Br J Surg 102: s2: 5

Branched Arch Repair

- 2003-2013
- N=89 Inoue Stent Graft (ISG)
  - 64 single branch
  - 18 double branch
  - 7 triple branch
- Mortality
  - 3% single branch
  - 0% double branch
  - 29% triple branch
- Stroke
  - 8% single branch
  - 33% double branch
  - 42% triple branch



Tazaki et al. 2017; J Vasc Surg: epub

Cook Zenith Branched Arch Endograft

Editor's Choice — Subsequent Results for Arch Aneurysm Repair with Inner Branched Endografts, ☆

R. Spear [a], S. Haulon [a,*], T. Ohki [b], N. Tsilimparis [c], Y. Kanaoka [b], C.P.E. Milne [a], S. Debus [c], R. Takizawa [b], T. Kölbel [c]

[a] Aortic Centre, CHRU Lille, France
[b] Vascular Surgery, Jikei University, Tokyo, Japan
[c] German Aortic Center, University Heart Center Hamburg, Germany

- n = 27; Hamburg, Tokio, Lille
- 4/2013- 11/2014
- Technical success 27/27
- 30d Mortality 0/27
- 1y mortality 1/27
- Stroke/TIA 3/27

Spear et al 2016; Eur J Vasc Endovasc Surg 51: 380-5

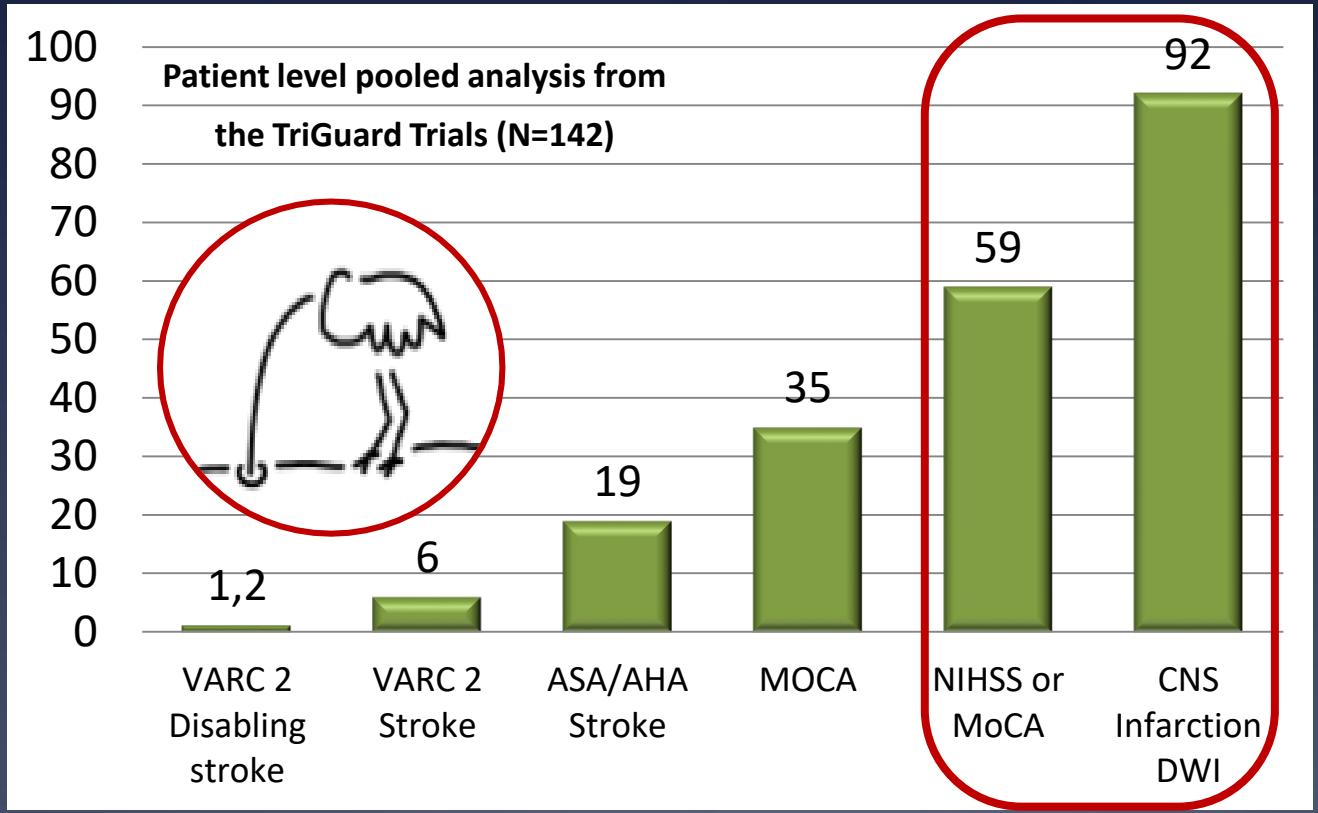
Bolton – Relay Branched Stentgraft

European experience

- Multicenter
- n = 15, 12 male, Age 76
- All elective
- Technical success 15/15
- Mortality 1/15 (7%)
- Stroke 3/15 (20%)

Czerny, M et al. 2018; Eur J Cardio Thorac Surg 53:1007-12

Stroke Rate Depends on Definition



Lansky et al. 2017; JACC; 69: 679-91 Lansky et al. 2018; Eur Heart J 39:1687-97

Cerebral damage is frequently overlooked on postop. visit

Silent Brain Infarcts: Not So Silent!

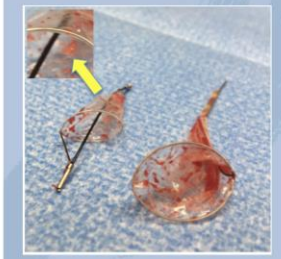
- Postoperative confusion
- Cognitive dysfunction
- Future stroke
- Impaired mobility
- Depression
- Dementia
- Parkinson disease
- Alzheimer disease

Gupta et al. 2016; Stroke 47:719-25
Vermeer et al. 2007; Lancet Neurol 6:611-9
Ghanem et al. 2017; PLoS ONE 12: e0168852

The Cause of Stroke in TEVAR

- Particle embolism during wire manipulation and graft release
- Air embolisation from stent-graft
- Hemodynamic stroke

Embolic depris captured during TEVAR procedures



- Five cases of TEVAR using Claret Cerebral Protection System.
- Subsequently analyzed by team of Dr Virmani at CVPath Institute
  - Debris includes acute thrombus, despite short procedures and high ACT, organized thrombus, artery tissue, and foreign material.
  - Debris characterization differs from TAVR, as expected, in lower rates of calcified debris.

Type of Procedure, Center	# of patients in series	Any debris	Acute Thrombus	Organizing Thrombus	Arterial Wall	Calcification	Foreign Material
TEVAR, West-German Heart and Vascular Center Essen	n=5	100%	100%	70%	80%	10%	80%

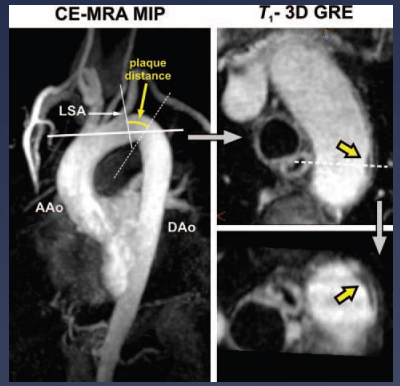
Note: percentages reflect percent of patients in the series in which each particular tissue type was captured.
Some filters captured several types of debris, so percentages will not add to 100%

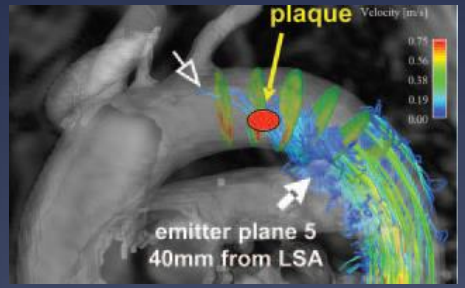
Courtesy of Dr. Janosi, Essen

Embolization Pathways in Cryptogenic Stroke

Retrograde Embolism From the Descending Aorta
Visualization by Multidirectional 3D Velocity Mapping in Cryptogenic Stroke

Andreas Harloff, MD; Christoph Strecker, MD; Patrick Dudler, MD; Andrea Nuβbaumer; Alex Frydrychowicz, MD; Manfred Olschewski, MS; Jelena Bock, MS; Aurelien F. Stalder, MS; Anna L. Stroh, MD; Cornelius Weiller, MD; Jürgen Hennig, PhD; Michael Markl, PhD



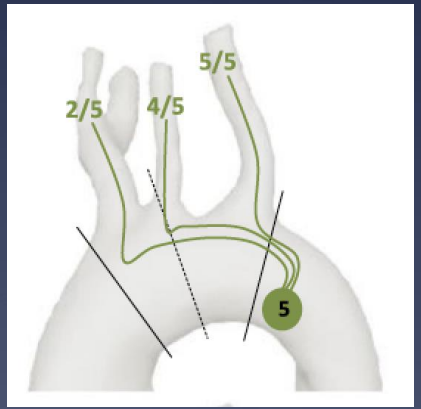


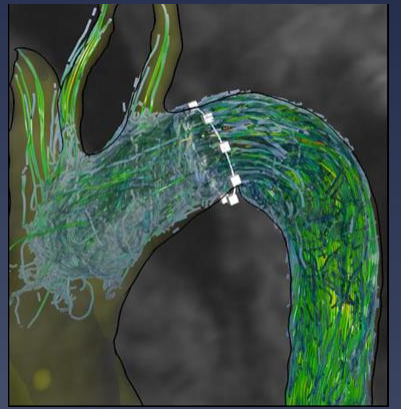
Conclusions: *Substantial diastolic retrograde flow originating from complex plaques in the descending aorta was detected by multidirectional 3D MRI velocity mapping and constitutes a stroke mechanism...*

Harloff et al. 2009; Stroke 40:1505-8

Aortic atheroma as a source of stroke – assessment of embolization risk using 3D CMR in stroke patients and controls

Thomas Wehrum[1,2*], Iulius Dragonu[1,2,6], Christoph Strecker[1,2], Florian Schuchardt[1,2], Anja Hennemuth[3], Johann Drexl[3], Thomas Reinhard[4,2], Daniel Böhringer[4,2], Werner Vach[5,2], Jürgen Hennig[6,2] and Andreas Harloff[1,2]

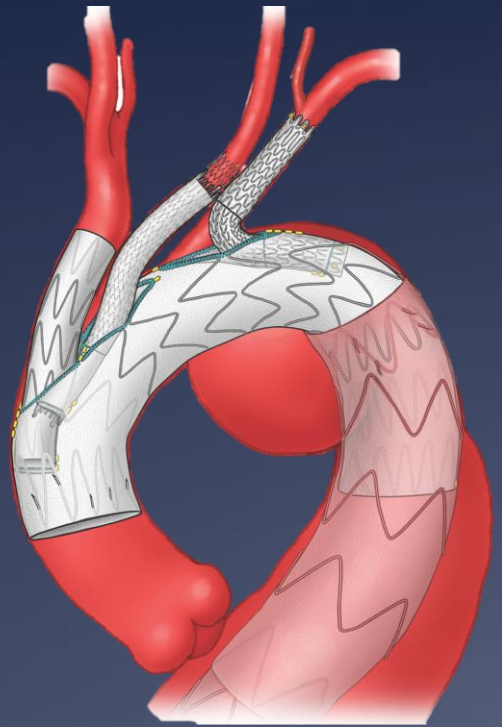




which can only in part be assessed by TEE. Furthermore, plaques of the distal arch (i.e. the proximal descending aorta) which are located downstream of the left subclavian artery were identified as a potential source of stroke in patients with otherwise cryptogenic stroke etiology [4].

Wehrum et al. 2017; J Cardiovasc Magn Res Imag 19:67

Air-Embolism in Branched Arch TEVAR



Stroke by Air-Embolism in TEVAR

Air bubbles are released by thoracic endograft deployment: An in vitro experimental study

Kamuran Inci[1], Giasemi Koutouzi[2], Valery Chernoray[3], Anders Jeppsson[4], Håkan Nilsson[3] and Mårten Falkenberg[2]

100μm Air-bubble

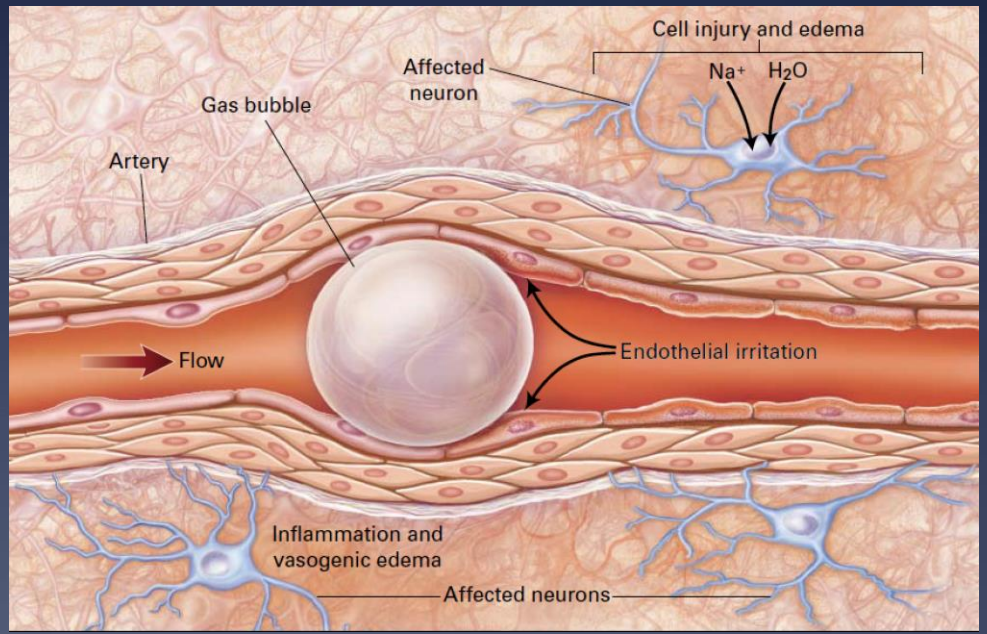
Inci et al. 2016 Sage Open Med 4:1-5

10μm Air-bubble in Human Cerebral Capillary after CPB

Moody et al.1990; Ann Neurol 28:477-86

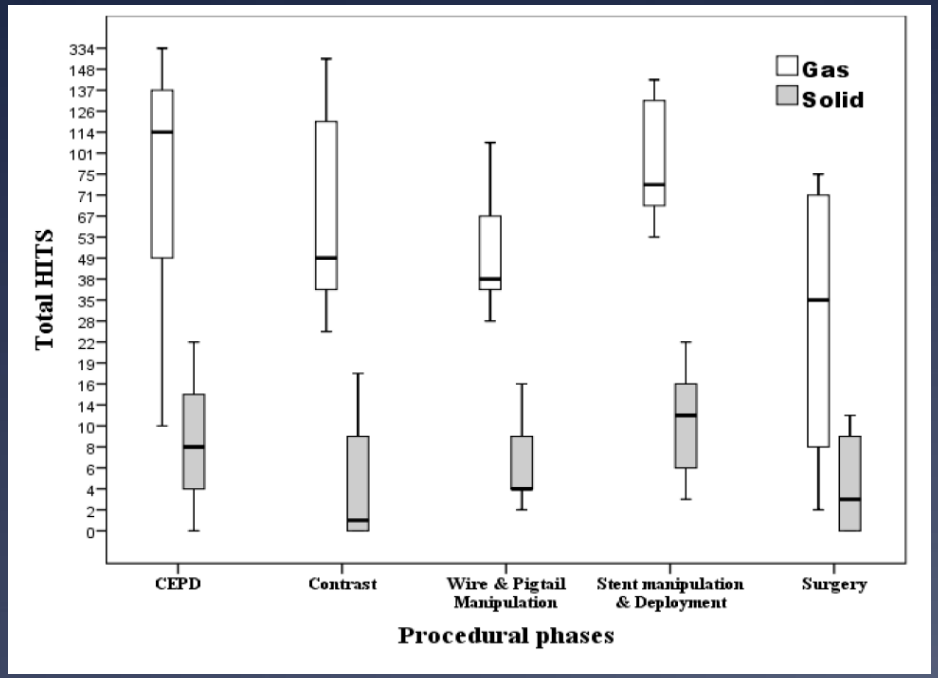
Pathophysiology of Air-Embolism

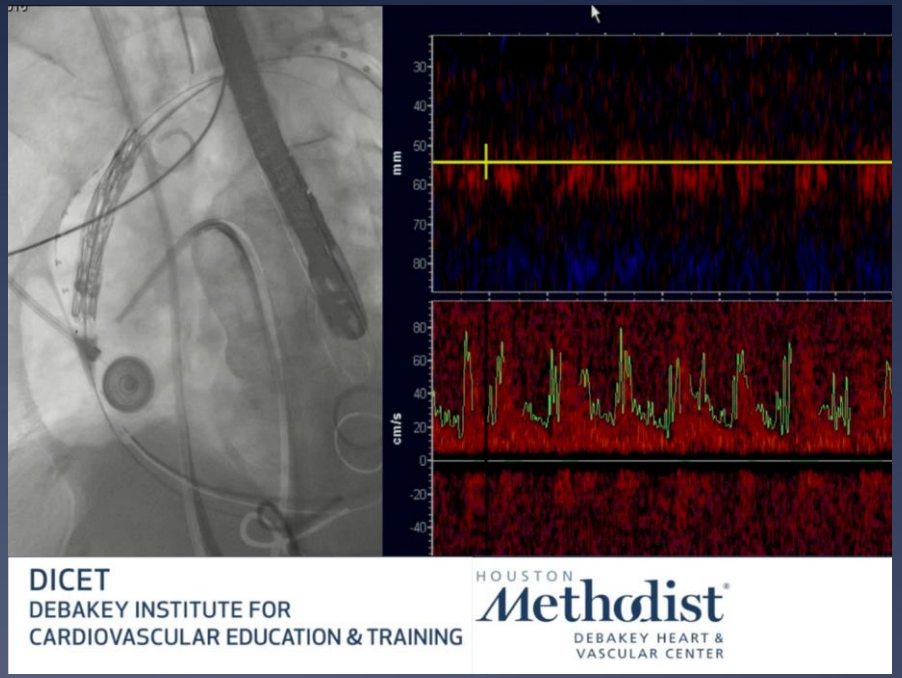
- Ischemia by arterial blockage
- Shear-stress of passing bubbles
- Inflammatory response
- Brain metabolism ↓
- Nerval function ↓
- Blood-brain barrier damage
- Cerebral blood flow ↓
- Disturbance of blood distribution
- Intracranial pressure ↑



Furlow et al. 1982; Stroke 13: 847-52 vHulst et al. 2003; Clin Physiol Funct Imaging 23: 237-46 Muth et al. 2000; N Engl J Med 342: 476-82

TCD: 90% of HITs during TEVAR are Gaseous

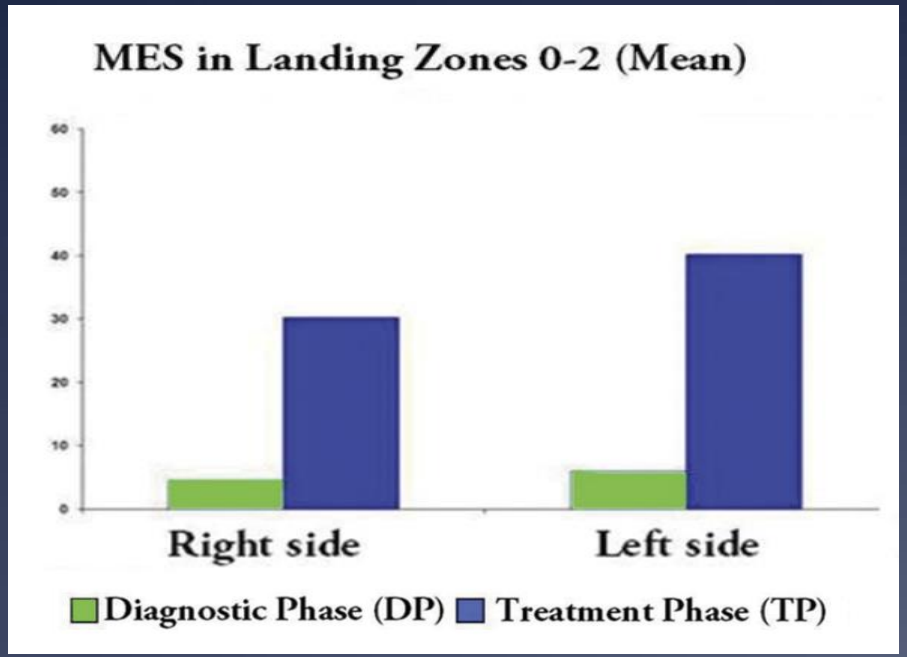




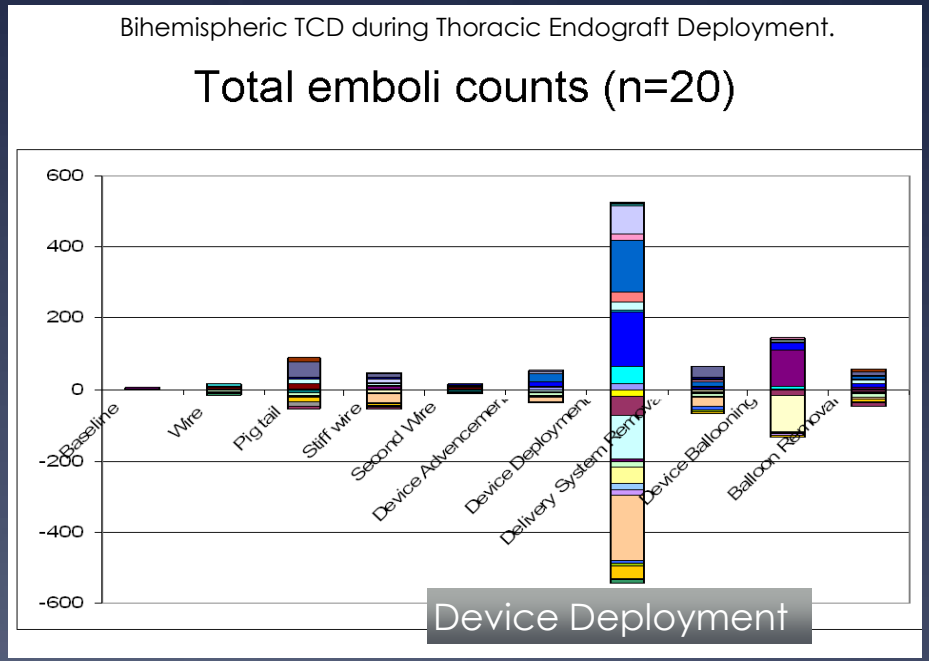
Courtesy of Carlos Bechara, Alan Lumsden, Houston Methodist Center

Grover et al. 2018; J Vasc Surg 68:1656-66

HITS Most Frequent During Deployment



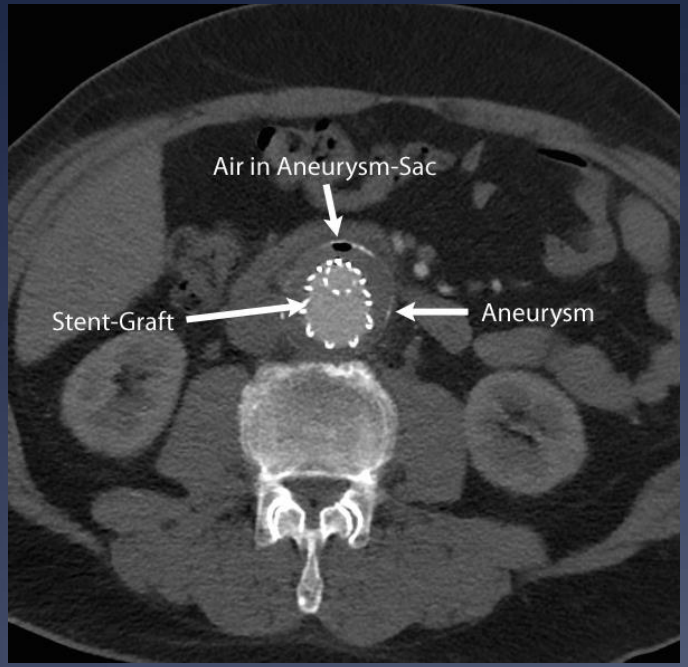
Bihemispheric TCD during Thoracic Endograft Deployment.



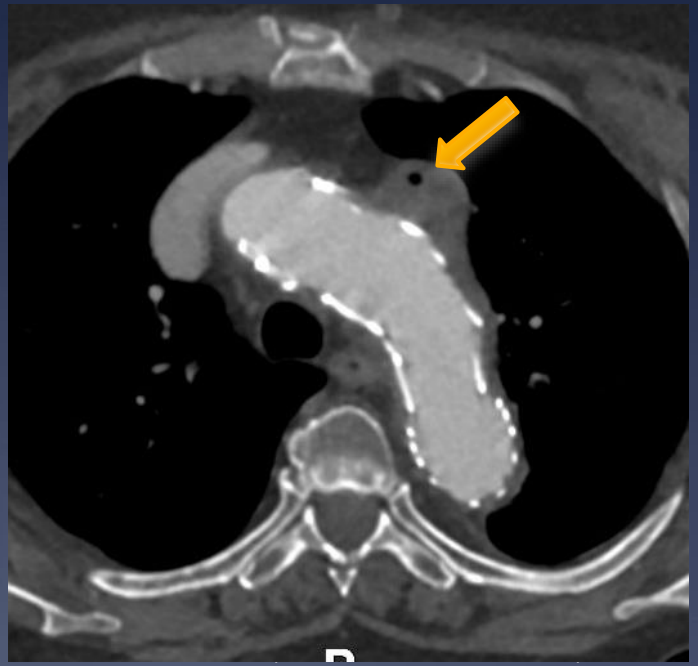
Bismuth et al.2011; J Vasc Surg 54:364-9

Courtesy of Carlos Bechara, Houston Methodist

Air Embolism in EVAR//TEVAR



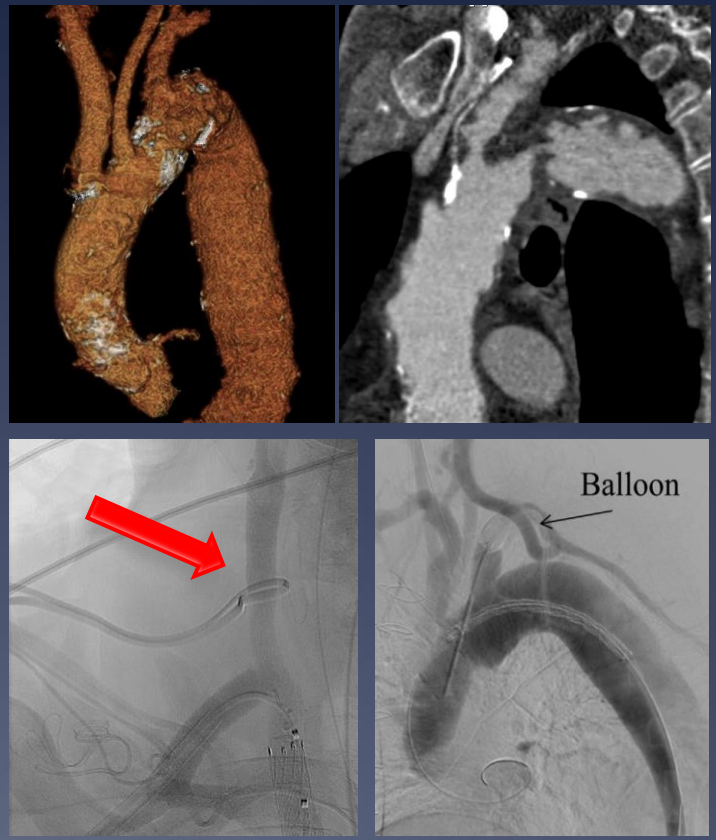
5 days after EVAR



2 days after TEVAR

Protection Strategies

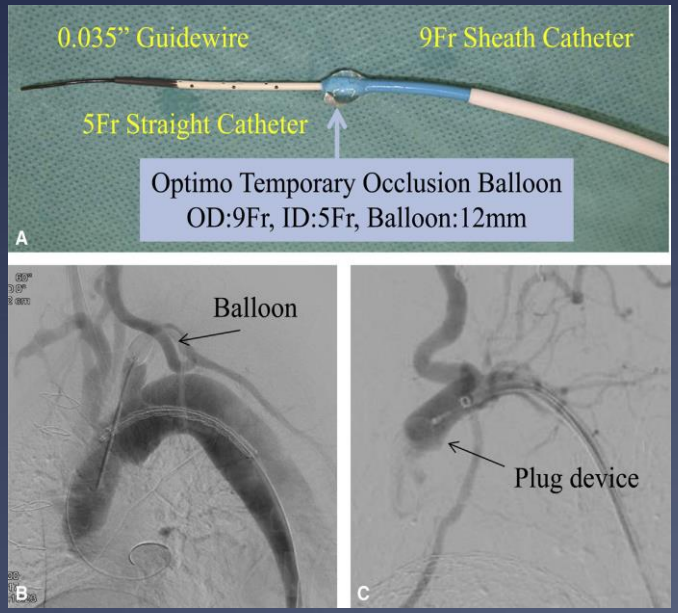
- Patient selection
- Minimize catheter/wire manipulation
- Heparinization: ACT 250-350 sec.
- Temporary occlusion of carotid arteries
  - Vessel-loop
  - Balloon
  - Clamp



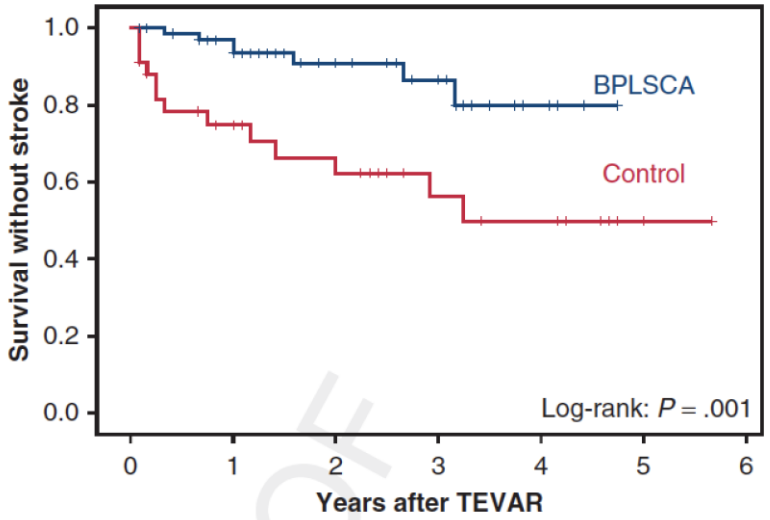
LSA Balloon Occlusion

Balloon protection of the left subclavian artery in debranching thoracic endovascular aortic repair

Yoshimasa Seike, MD,[a] Hitoshi Matsuda, MD, PhD,[a] Yosuke Inoue, MD,[a] Atsushi Omura, MD, PhD,[a] Kyokun Uehara, MD, PhD,[a] Tetsuya Fukuda, MD, PhD,[b] and Junjiro Kobayashi, MD, PhD[a]



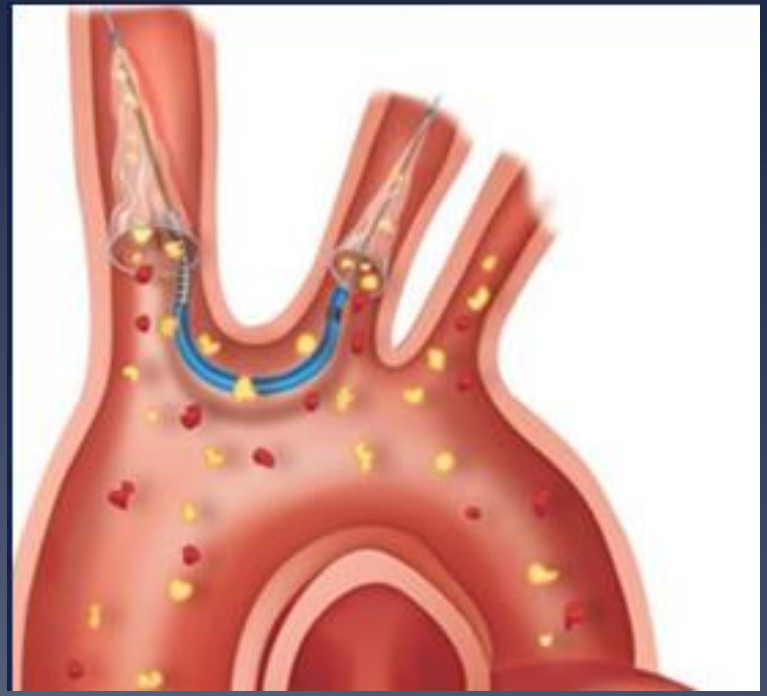
N=157 patients; 71 with LSA balloon-Protection (BPLSCA)



Seike et al. 2018; J Thor Cardiothor Surg 157:1336-45

Protection Strategies

- CEP-devices
  - Filter devices, e.g. Sentinel by Claret Med.
  - Deflectors, e.g. Triguard by Keystone Heart
  - Other....
- Carbondioxide flushing
- ?



CO^2 - Flushing

Carbon Dioxide Flushing Technique to Prevent Cerebral Arterial Air Embolism and Stroke During TEVAR

Journal of Endovascular Therapy
1–3

DOI: 10.1177/1526602816633705
www.jevt.org
SAGE

- 2014-2015: n=36
- All complex arch TEVAR:
  - Branched arch
  - Fenestrated arch
  - Ascending TEVAR
- All zone 0 -1
- Stroke: 1/36 (3%)
  - minor non-disabling stroke

Kölbel et al 2016; J Endovasc Surg 23: 393-5

CO^2-Flushing

CO2-Flushing Becoming Standard of Care

Received: 1 December 2017 | Revised: 14 March 2019 | Accepted: 4 May 2019
DOI: 10.1002/joom.1034

RESEARCH ARTICLE

WILEY

Implementing new technologies for complex care: The role of embeddedness factors in team learning

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[2]Department of Surgery, Leiden University Medical Center, Albinusdreef 2, 2333 ZA Leiden, The Netherlands

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Handling Editors: Lawrence Fredendall, Anand Nair, Jeffery Smith and Anita Tucker

Abstract

Bearing the rising health care costs of our aging global population is one of the most urgent challenges society is facing. We study the implementation of new medical technologies as one way to increase the effectiveness of care, particularly in the area of aortic disease—a condition that affects an increasing number of patients globally. Our research focus is the implementation of complex endovascular treatment techniques by a multidisciplinary aortic treatment group, in addition to their traditional open treatment of aortic disease. We find that relational and cognitive embeddedness factors support team learning, which in turn enables the team to achieve its self-set goals of treating more patients; offering more tailor-made care; and providing endovascular treatment in emergency situations. At the end of our data collection period, the first steps toward the team's ultimate goal of offering patient-centered care were also taken.

KEYWORDS
technology implementation, team learning, health care, embeddedness, medical suppliers, longitudinal study

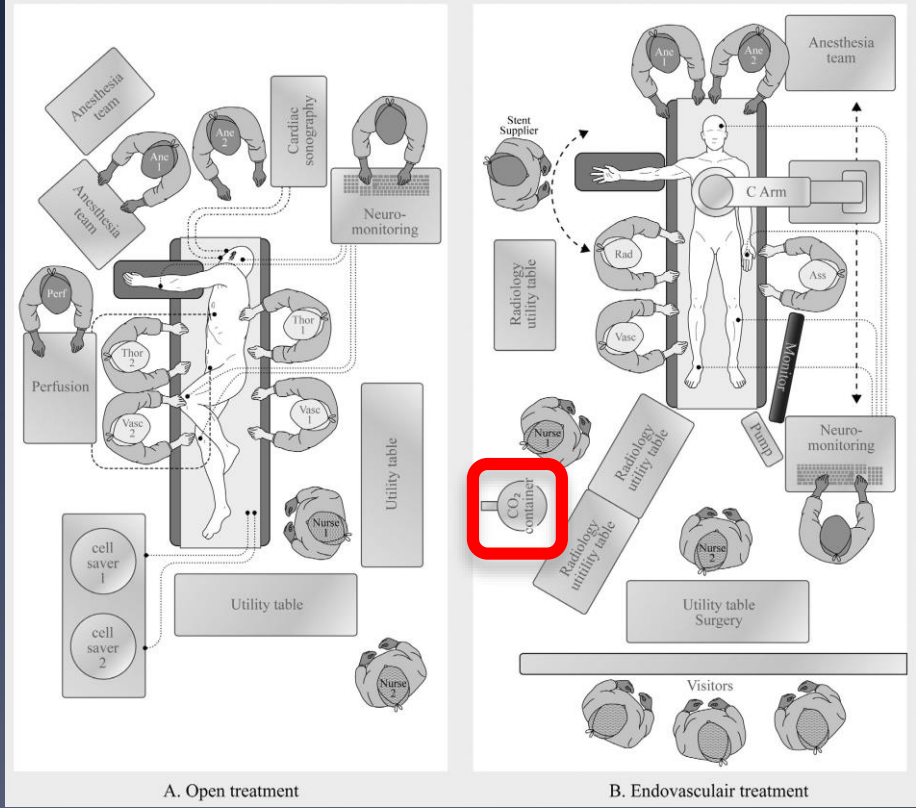
1 | INTRODUCTION

In modern industry, harmony among people in a group, as in teamwork, is in greater demand than the art of the individual craftsman.
Taiichi Ohno, founder of the Toyota Production System, (1978)

Implementing new technologies in health care is a difficult and complex task. The Dutch Ministry of Health, Welfare and Sport found that avoidable deaths increased in 2015–2016 compared to 2011–2012 only in academic hospitals (Langelaan et al., 2017). The report suggests that a contributing factor was insufficient cooperation and communication between different specialists in various disciplines, during treatments where the physicians' technical skills were important (Klopotowska, Schutijser, Bruijne, & en Wagner, 2016). We examine the challenge of new technology implementation by focusing on how embeddedness factors impact team learning using an in-depth case study approach of one medical group.

Our study took place at the Leiden University Medical Centre (LUMC), one of the eight university hospitals in the Netherlands. More specifically, we looked at how open reconstruction of complex aortic disease by members of the vascular surgery and thoracic surgery departments is supplemented (and later partly substituted) by endovascular reconstruction of complex aortic disease by the endovascular treatment team (ETT) composed of members of the vascular surgery and the interventional radiology departments. All treatment decisions, however, continue to be taken by the Aorta Group, which brings together members of the vascular surgery, thoracic surgery, and interventional radiology departments.

Cardiovascular disease is one of the leading causes of global mortality and morbidity. According to the World



A. Open treatment

B. Endovasculair treatment

Stevens et al. 2020; J Oper Manag 66:112-34

TEVAR with CO^2 Flushing

Results: Neurological and DW-MRI outcomes

- No difference in clinical stroke
- Significant reduction in the incidence of new DW-MRI infarcts with CO_2 flushing
- Significant reduction in the total number of new DW-MRI infarcts
- Significant reduction in the surface area of new DW-MRI infarcts

Characteristic	Saline (n=112)	CO_2 (n=75)	P-value
Incidence of new infarction on any cerebral imaging	57/77 (74)	28/65 (43)	0.0002
Clinical stroke	14(13)	5(7)	0.196
Incidence of new infarction on DW-MRI	53/73 (73)	28/65(43)	0.0004
Median total number of DW-MRI infarcts (range)	2(0-25)	0(0-31)	0.0003

FEWER and SMALLER DW-MRI infarcts with CO_2 flushing

Richard Gibbs, Imperial College, presented at CX Aortic Vienna, October, 7th 2021

Arch-TEVAR with CO^2 Flushing

Silent Brain Infarction After Endovascular Arch Procedures: Preliminary Results from the STEP Registry

Philippe Charbonneau [a], Tilo Kölbel [b], Fiona Rohlffs [b], Wolf Eilenberg [b], Olivier Planche [c], Matthias Bechstein [b], Robin Ristl [b], Roger Greenhalgh [d], Stephan Haulon [a,*], on behalf of STEP collaborators

[a] Aortic Centre, Hôpital Marie Lannelongue, Groupe Hospitalier Paris Saint Joseph, Université Paris Saclay, Paris, France
[b] German Aortic Centre, Department of Vascular Medicine, University Heart and Vascular Centre, Hamburg, Germany
[c] Radiology Department, Hôpital Marie Lannelongue, Groupe Hospitalier Paris Saint Joseph, Paris, France
[d] Vascular Surgical Research Group, Imperial College, London, UK

WHAT THIS PAPER ADDS

This is the largest study to evaluate the incidence and distribution of silent cerebral infarction (SBI) following endovascular repair for disease of the aortic arch. It is also the first cohort to include total endovascular arch repair and devices flushed with carbon dioxide (CO_2). Post-operative diffusion weighted magnetic resonance imaging demonstrated a SBI incidence of 50%.

Objective: Few data exist concerning the rate of silent cerebral ischaemic events following endovascular treatment of the aortic arch. The objective of this work was to quantify these lesions using the STEP registry (NCT04489277).

Methods: This multicentre retrospective cohort study included consecutive patients treated with an aortic endoprosthesis deployed in Ishimaru zone 0—3 and brain diffusion weighted magnetic resonance imaging (DW-MRI) within seven days following the procedure. DW-MRI was performed to identify the location and number of new silent brain infarctions (SBI). All endografts were carbon dioxide flushed prior to implantation.

Charbonneau et al. 2021, Eur J Vasc Endovasc Surg 61: 239-45

Arch-TEVAR with CO^2 Flushing

Silent Brain Infarction After Endovascular Arch Procedures: Preliminary Results from the STEP Registry

Philippe Charbonneau [a], Tilo Kölbel [b], Fiona Rohlffs [b], Wolf Eilenberg [b], Olivier Planche [c], Matthias Bechstein [b], Robin Ristl [b], Roger Greenhalgh [d], Stephan Haulon [a,*], on behalf of STEP collaborators

Characteristics	Patients (n = 91)
Urgency	
Elective	71 (78)
Urgent	20 (22)
Indication	
Degenerative aneurysm	34 (37)
Acute aortic dissection	6 (7)
Chronic aortic dissection	38 (42)
Aortic ulcer/intramural haematoma	8 (9)
Most proximal covered zone (Ishimaru)	
0	23 (25)
1	10 (11)
2	47 (52)
3	11 (12)

Characteristics	Patients with lesion (n = 45)
Total number of ischaemic lesions	245
Right	92
Left	153
Number of ischaemic loci	3 (2–7)
Hemisphere	
Right only	4 (9)
Left only	15 (33)
Bilateral	26 (58)

	Without DW-MRI lesion (n = 46)	With DW-MRI lesion (n = 45)	p
Hospital centre B *vs.* centre A	35 (76)	27 (60)	.11
Urgent procedure *vs.* elective	4 (9)	16 (36)	.005
Indication			.29
Aneurysm	21 (46)	13 (29)	
Dissection	19 (41)	25 (56)	
Other	6 (13)	7 (16)	
Arch type			.46
I	30 (65)	31 (69)	
II	13 (28)	9 (20)	
III	3 (7)	5 (11)	
Atheroma Feezor grade 4–5 *vs.* 1–3	28 (61)	22 (49)	.17
Aortic diameter > 55 mm	30 (65)	22 (49)	.49
Ishimaru zone 0–1 *vs.* 2–3	13 (28)	20 (44)	.026
Arch branched and fenestrated graft *vs.* tubular	15 (33)	23 (51)	.038
Proximal stent diameter ≥ 40 mm	18 (39)	23 (51)	.038

Charbonneau et al. 2021, Eur J Vasc Endovasc Surg 61: 239-45

Endovascular cTAAD-Repair

Endovascular Treatment of Post Type A Chronic Aortic Arch Dissection With a Branched Endograft

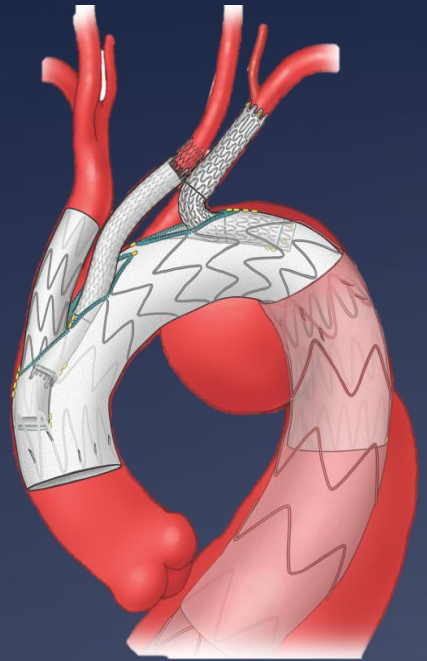
Early Results From a Retrospective International Multicenter Study

Dorian Verscheure, MD, Stéphan Haulon, MD, PhD,* Nikolaos Tsilimparis, MD, PhD,†*
Björn Sonesson, MD, PhD,‡ Martin Claridge, MD,¶¶ Dominique Fabre, MD, PhD, and Tilo Kölbel, MD, PhD†*

- Patients: 70
  - Male 50
  - Age 69y
- Technical success 68 (97%)
- Stroke: 2 (3%)
- 30d-Mortality: 2 (3%)
- 1y-mortality 8 (11%)

Verscheuren et al. 2021; Ann Surg, 273:997-1003

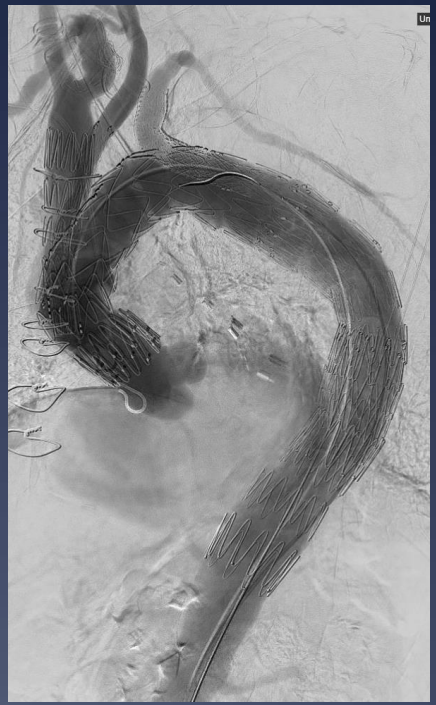
Branched Arch with 3 Inner Branches



Multicenter global early feasibility study to evaluate total endovascular arch repair using three-vessel inner branch stent-grafts for aneurysms and dissections

Emanuel R. Tenorio, MD, PhD,[a] Gustavo S. Oderich, MD,[a] Tilo Kölbel, MD, PhD,[b] Nuno V. Dias, MD, PhD,[c] Björn Sonesson, MD, PhD,[c] Angelos Karelis, MD,[c] Mark A. Farber, MD,[d] F. Ezequiel Parodi, MD,[d] Carlos H. Timaran, MD,[e] Carla K. Scott, MD,[e] Nikolaos Tsilimparis, MD, PhD,[f] Carlota Fernandez, MD,[f] Tomasz Jakimowicz, MD, PhD,[g] Katarzyna Jama, MD,[g] Jarin Kratzberg, PhD,[h] Justine Mougin, MD,[i] *and* Stéphan Haulon, MD, PhD,[i] *Houston and Dallas, Tex; Hamburg and Munich, Germany; Malmö, Sweden; Chapel Hill, NC; Warszawa, Poland; Bloomington, Ind; and Gif-sur-Yvette, France*

- International, 8 centers
- n = 39; 31 male, age 70y
- 2016-2019
- Technical success 39/39
- In-hospital mortality 2/39 (5%)
- Stroke 2/39 (5%)



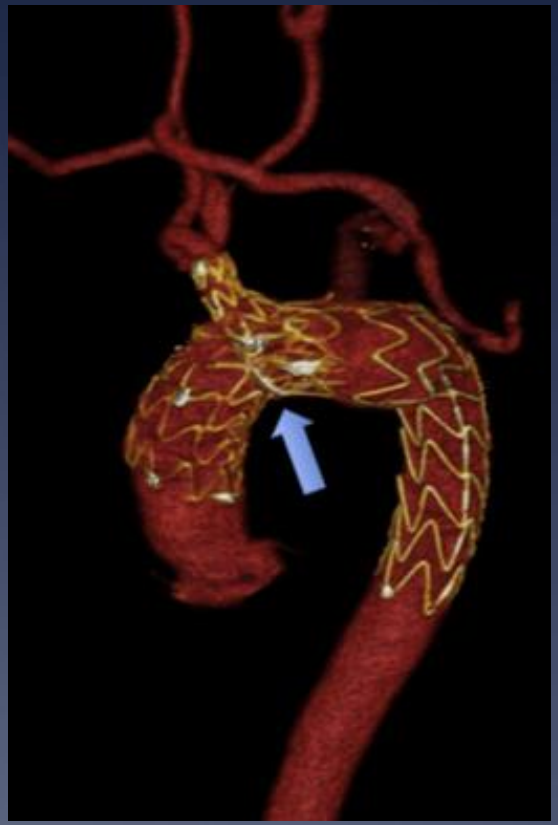
Tenorio et al. 2021; J Vasc Surg 764:1055-65

Nexus Branched Arch Endograft

NEXUS™ Arch: A Multicenter Study Evaluating the Initial Experience with a Novel Aortic Arch Stent Graft System

David Planer MD[1], Gabby Elbaz-Greener MD[1], Nicola Mangialardi MD[2,3], Thomas Lindsay MD[4], Augusto D'Onofrio MD[5], Hubert Schelzig MD[6], Lyubov Chaykovska MD[7,8], Andrew Hill MD[9], Andrew Holden MD[9], Michele Antonello MD[5], Kong T. Tan MD[4], Matteo Orrico MD[2,3], Sonia Ronchey MD[3], Yaniv Marmur BSc[10], Felice Pecoraro MD[11], Mario Lachat MD[7,8]

- International, 11 centers
- n = 29, 22 male, age 72y
- Procedural success 28/28
- 30d mortality 2/28 (7%)
- 30d stroke 1/28 (4%)



Planer et al. 2021: Ann Surg epub

Conclusion

- Stroke and SBI during TEVAR is relevant and needs to be avoided.
- Silent brain infarctions (SBI) during TEVAR are a frequent finding and associated with neurologic symptoms and cognitive dysfunction.
- The source of stroke and SBI during TEVAR appears multifactorial.