

# How to do **EVARs with no Contrast** and **without FORS / IOPS**



Vascular Surgery  
University of Bologna - DIMEC  
IRCCS University Hospital S.Orsola  
Bologna, Italy  
*[enrico.gallitto2@unibo.it](mailto:enrico.gallitto2@unibo.it)*

**E. Gallitto**

# Statement of financial interest

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Enrico Gallitto

- ✓ Cook Medical - Clinical proctor for F/B-EVAR
- ✓ No disclosure for the present talk

# Why EVARs with no Contrast ?

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- ✓ **Acute Kidney Injury**

after endovascular aortic procedure

EVAR / F-BEVAR

## Endovascular aneurysm repair (EVAR)– and transcatheter aortic valve replacement (TAVR)–associated acute kidney injury



Kenar D. Jhaveri<sup>1,4</sup>, Athanasios N. Saratzis<sup>2,4</sup>, Rimda Wanchoo<sup>1</sup> and Pantelis A. Sarafidis<sup>3</sup>

<sup>1</sup>Division of Nephrology, Northwell Health, Hofstra Northwell School of Medicine, Great Neck, New York, USA; <sup>2</sup>Leicester NIHR Cardiovascular Biomedical Research Unit, University of Leicester, UK; and <sup>3</sup>Department of Nephrology, Hippokraton Hospital, Aristotle University of Thessaloniki, Greece

*Kidney International, 2017*

# Mechanisms of Renal damage

## Contrast - induced injury

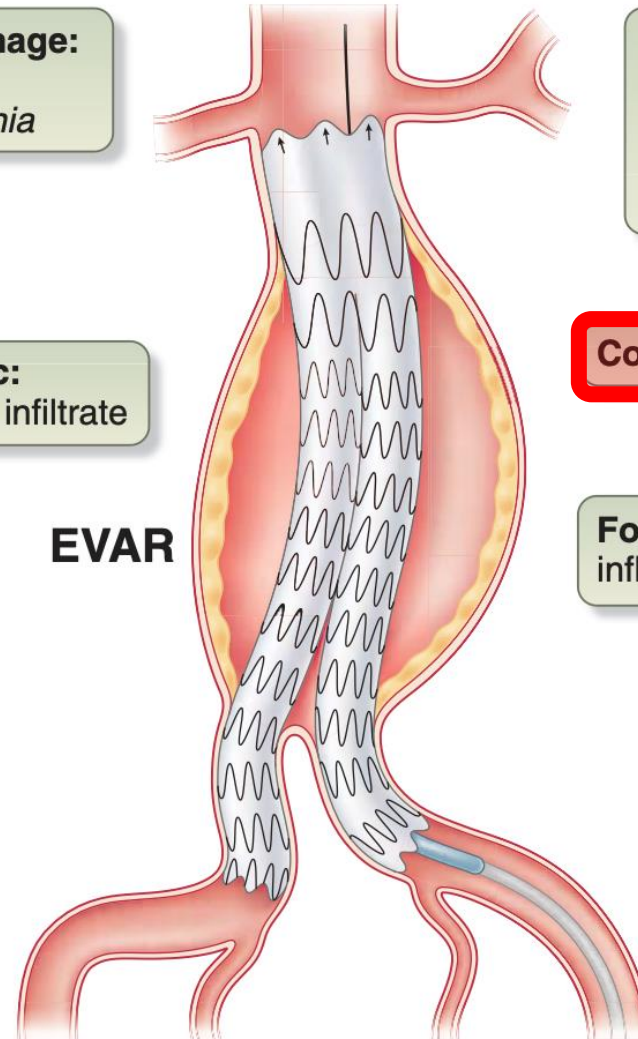
### Tubular

**Endothelial damage:**

- PVD, anemia, thrombocytopenia

**Aneurysm sac:**

- Inflammatory infiltrate



**Renal arteries:**

- Microemboli
- Occlusion
- Stenosis
- Dissection

**Contrast → tubular injury**

**Foreign body (graft) → inflammatory reaction**

**Ischemia-reperfusion injury (lower limbs)**

## Endovascular aneurysm repair (EVAR)– and transcatheter aortic valve replacement (TAVR)–associated acute kidney injury



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*Kidney International, 2017*

# Acute Kidney Injury post EVAR

## 5.5% - 19%

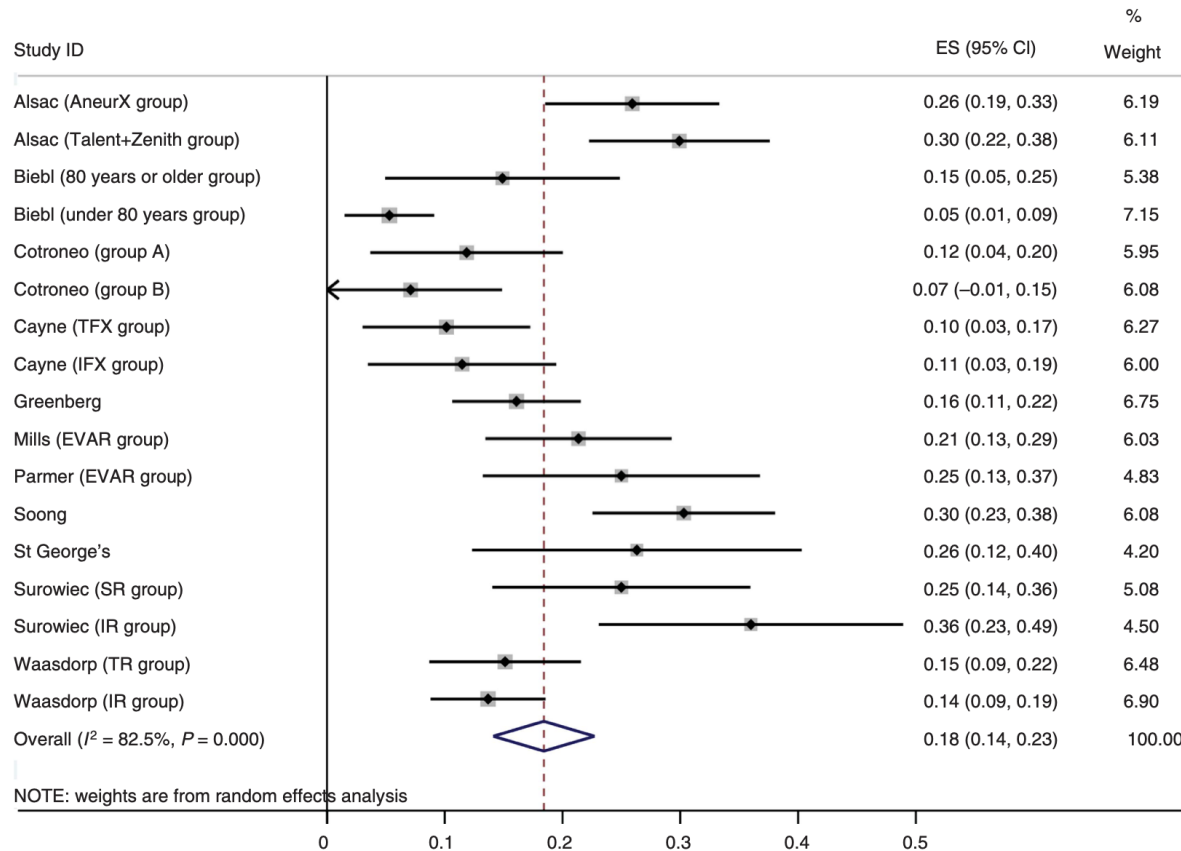
Reference	Type	Date	EVAR (n)	AKI criterion	AKI incidence	AKI (n)	AKI stage > 2 (n)	Dialysis	Urine output available
Pirgakis <i>et al.</i> <sup>37</sup>	Retrospective	2014	87	AKIN	17%	15	None	1	No
Ueta <i>et al.</i> <sup>39</sup>	Prospective	2014	47	AKIN	14%	6	Stage 2: 1	None	No
Pisimisis <i>et al.</i> <sup>38</sup>	Retrospective	2013	208	RIFLE	17%	36	NA	NA	No
Saratzis <i>et al.</i> <sup>4</sup>	Prospective	2015	149	AKIN & KDIGO	19%	28	Stage 2: 3	None	Yes
Saratzis <i>et al.</i> <sup>49</sup>	Retrospective	2015	484	AKIN	12%	58	NA	None	No
Saratzis <i>et al.</i> <sup>5</sup>	Retrospective	2015	947	KDIGO	18%	167	Stage 2: 12; Stage 3: 2	None	No
Castagno <i>et al.</i> <sup>130</sup>	Retrospective	2016	146	Aneurysm Score	5.5%	8	NA	None	No
Obata <i>et al.</i> <sup>131</sup>	Prospective	2016	95	AKIN	9.4%	9	Stage 2: 1	None	No

AKI, acute kidney injury; AKIN, Acute Kidney Injury Network Criteria; EVAR, endovascular aneurysm repair; KDIGO, Kidney Disease Improving Global Outcomes; NA, not available; RIFLE, risk, injury, failure, loss, end-stage renal disease.

# A systematic review and meta-analysis indicates underreporting of renal dysfunction following endovascular aneurysm repair

Alan Karthikesalingam<sup>1</sup>, Sandeep S. Bahia<sup>1</sup>, Shaneel R. Patel<sup>1</sup>, Bilal Azhar<sup>1</sup>, Dan Jackson<sup>2</sup>, Lynne Cresswell<sup>2</sup>, Robert J. Hinchliffe<sup>1</sup>, Peter J.E. Holt<sup>1</sup> and Matt M. Thompson<sup>1</sup>

*Kidney International, 2014*



**Clinically relevant**

**Renal function deterioration**

**@ 1 year 18%**

**(95% CI: 14 - 23%;  $I_2$  of 82.5%)**

# Incidence, Prognostic Significance, and Risk Factors of Acute Kidney Injury Following Elective Infrarenal and Complex Endovascular Aneurysm Repair

Vinamr Rastogi <sup>a,b,\*</sup>, Jorg L. de Bruin <sup>a</sup>, Elke Bouwens <sup>a,c</sup>, Sanne E. Hoeks <sup>c</sup>, Sander ten Raa <sup>a</sup>, Marie Josee van Rijn <sup>a</sup>, Bram Fioole <sup>d</sup>, Marc L. Schermerhorn <sup>b</sup>, Hence J.M. Verhagen <sup>a</sup>

*EJVS, 2022*

	Post EVAR (%)	Post F/B-EVAR (%)
AKI	9	23

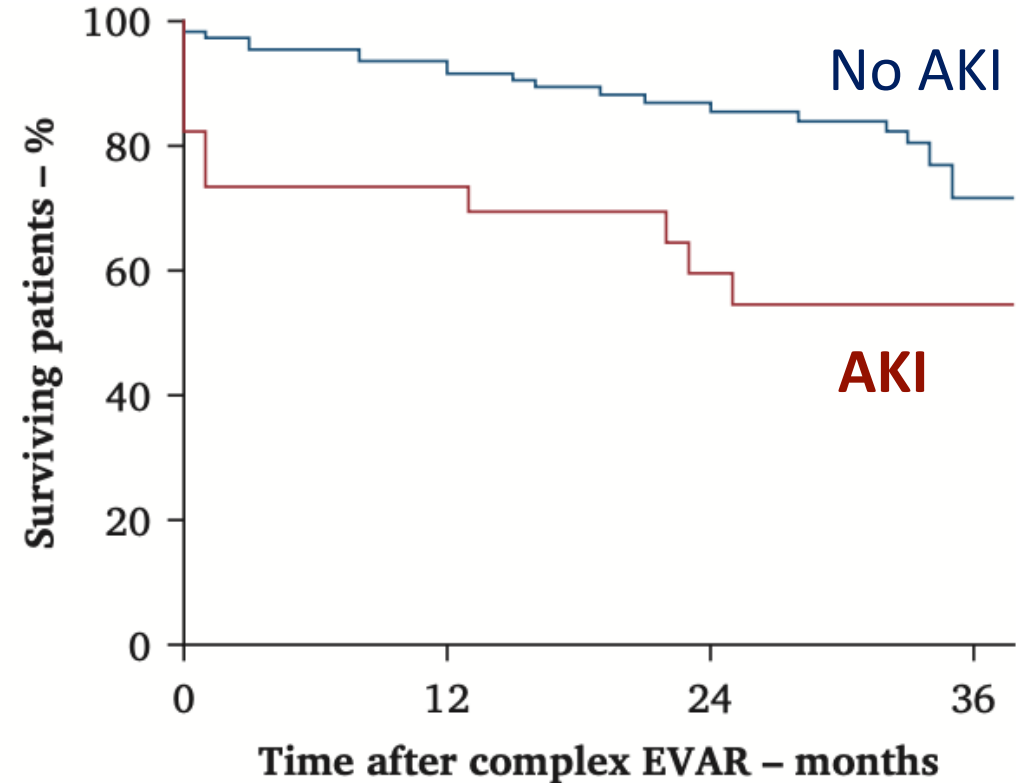
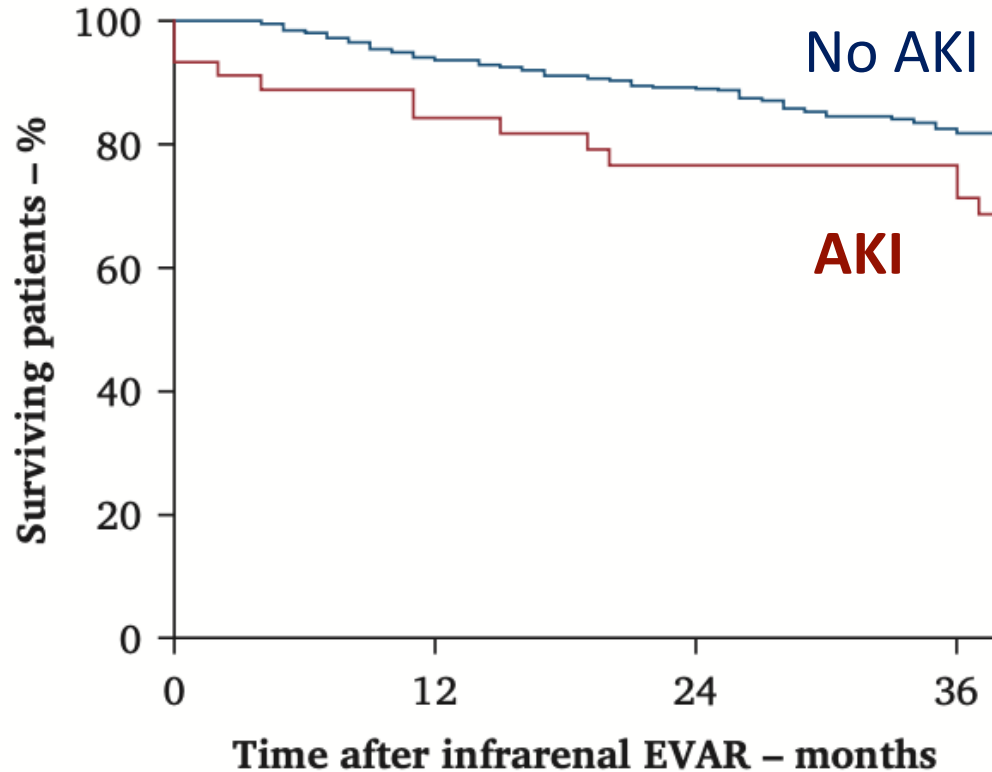
**Iodinated contrast media independent risk factors for AKI**

	Odds ratio (95% CI)	p value
<i>AKI development following infrarenal EVAR</i>		
Prior CKD, eGFR <60 mL/min/1.73 m <sup>2</sup>	2.2 (1.03–4.8)	.042
Neck diameter per 10 mm	2.9 (1.1–8.4)	.019
Neck length per 10 mm	1.0 (0.82–1.3)	.86
Infrarenal fixation (ref.: suprarenal fixation)	0.51 (0.11–1.6)	.30
Contrast use per 10 mL	0.98 (0.84–1.1)	.80
<i>AKI development following complex EVAR</i>		
Prior CKD, eGFR <60 mL/min/1.73 m <sup>2</sup>	1.6 (0.6–4.2)	.35
Suprarenal/TAAA (ref.: juxtarenal)	2.0 (0.25–12)	.45
Branched device (ref.: fenestrated)	1.4 (0.23–11)	.74
Contrast use per 10 mL	1.1 (1.01–1.2)	.034

# Incidence, Prognostic Significance, and Risk Factors of Acute Kidney Injury Following Elective Infrarenal and Complex Endovascular Aneurysm Repair

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*EJVS, 2022*

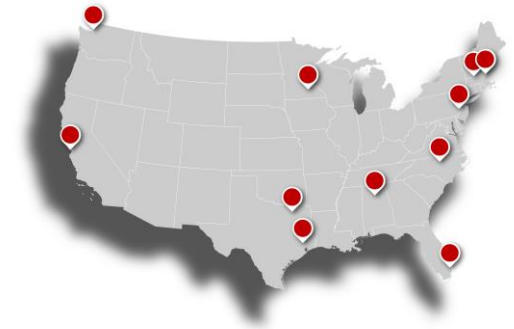




## Severity of acute kidney injury is associated with decreased survival after fenestrated and branched endovascular aortic aneurysm repair

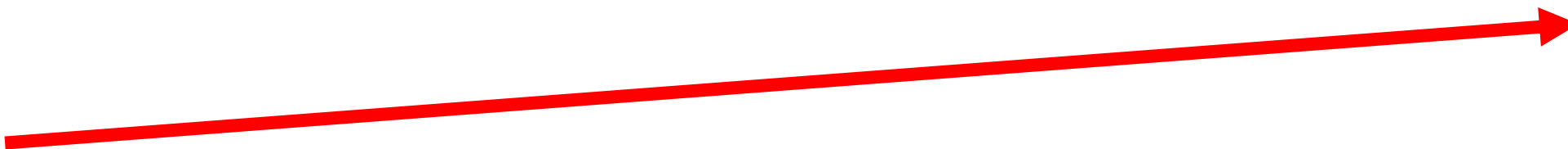
Eric J. Finnesgard, MD, MS,<sup>a</sup> Adam W. Beck, MD,<sup>b</sup> Matthew J. Eagleton, MD,<sup>c</sup> Mark A. Farber, MD,<sup>d</sup> Warren J. Gasper, MD,<sup>e</sup> W. Anthony Lee, MD,<sup>f</sup> Gustavo S. Oderich, MD,<sup>g</sup> Darren B. Schneider, MD,<sup>h</sup> Matthew P. Sweet, MD, MS,<sup>i</sup> Carlos H. Timaran, MD,<sup>j</sup> Jessica P. Simons, MD, MPH,<sup>a</sup> and Andres Schanzer, MD,<sup>a</sup> on Behalf of the United States Aortic Research Consortium, Worcester and Boston, MA; Birmingham, AL; Chapel Hill, NC; San Francisco, CA; Boca Raton, FL; Houston and Dallas, TX; Philadelphia, PA; and Seattle, WA

*JVS, 2023*



- ✓ Acute Kidney Injury **18%** of cases
- ✓ Grade of Severity related to amount of Iodinated Contrast Media

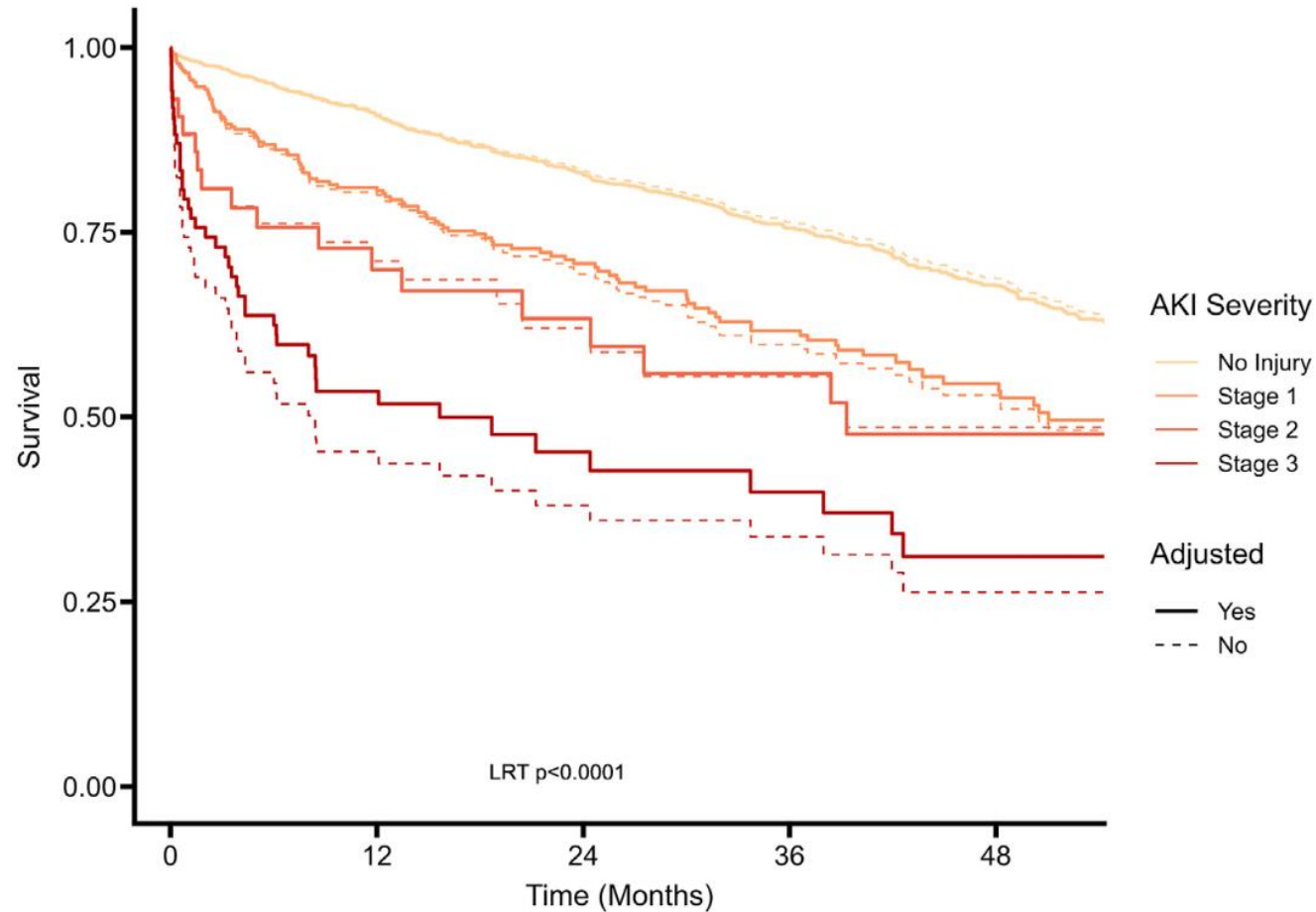
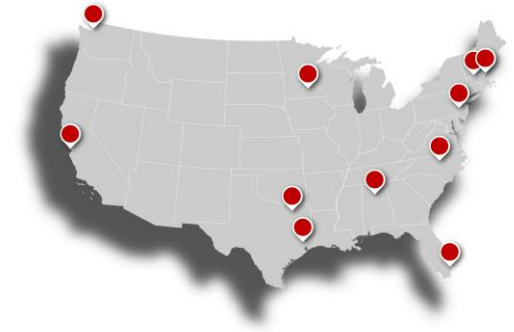
Variable	No injury (n = 1981)	Stage 1 (n = 316)	Stage 2 (n = 42)	Stage 3 (n = 74)	P value
Contrast, mL	105 [70.5-150]	106 [75-160]	132.5 [80.8-197.1]	134 [99.5-201.2]	<.0001



## Severity of acute kidney injury is associated with decreased survival after fenestrated and branched endovascular aortic aneurysm repair

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*JVS, 2023*



**Mortality** is related to different **stages of AKI**

# Why EVARs with no Contrast ?

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✓ Acute Kidney Injury  
after endovascular aortic procedure  
EVAR / F-BEVAR

✓ **Automated CO<sub>2</sub> angiography**  
Feasible alternative to ICM

## Renal Benefits of CO<sub>2</sub> as a Contrast Media for EVAR Procedures: New Perspectives on 1 Year Outcomes

Journal of Endovascular Therapy  
1-10  
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DOI: 10.1177/15266028231162258  
www.jevt.org  
SAGE

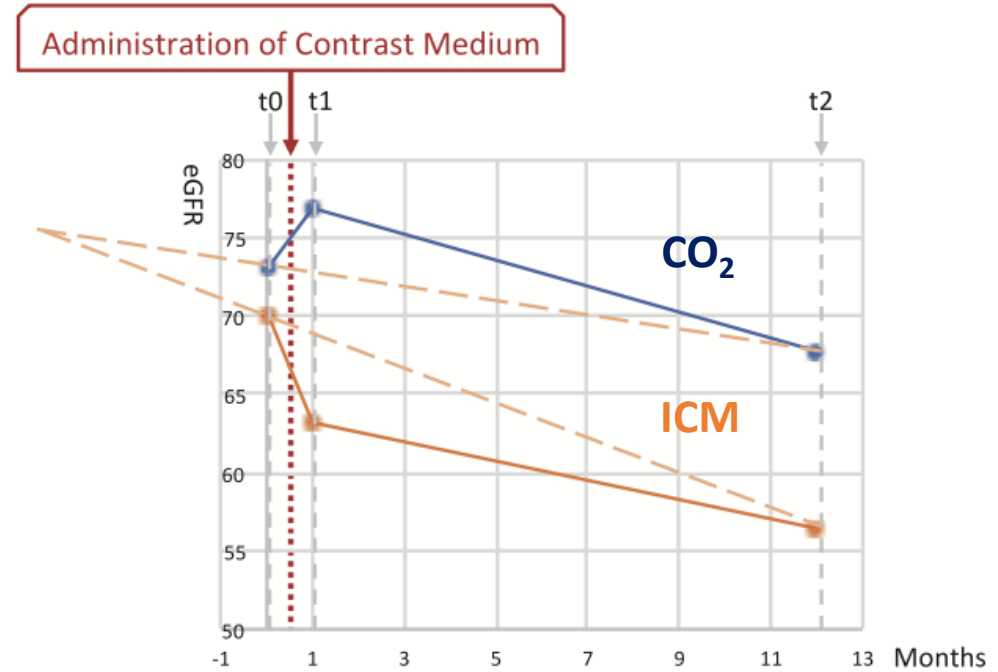
Marco Busutti, MD, PhD<sup>1,2\*</sup>, Alice Sensoni, MD<sup>2\*\*</sup>,  
Andrea Vacirca, MD, PhD<sup>3,4</sup>, Chiara Abenavoli, MD<sup>1</sup>,  
Chiara Donadei, PhD<sup>2</sup>, Anna Laura Croci Chiocchini, MD, PhD<sup>1</sup>,  
Matteo Righini, MD<sup>5</sup>, Giorgia Comai, MD, PhD<sup>1</sup>, Alessia Pini, MD<sup>3</sup>,  
Gianluca Faggioli, MD, PhD<sup>3,4</sup>, Enrico Gallitto, MD, PhD<sup>3,4</sup>,  
Gaetano La Manna, MD, PhD<sup>1,2</sup>, and Mauro Gargiulo, MD, PhD<sup>3,4</sup>

JET, 2023

# Renal function worsening @1y

## Postoperative

	ICM (%)	CO <sub>2</sub> + ICM (%)	P
<b>AKI</b>	<b>27</b>	<b>9</b>	<b>.04</b>



	eGFR t0	eGFR t1	eGFR t2 - 1 year FU
CO <sub>2</sub> /CO <sub>2</sub> +ICM	73 ± 21	77 ± 20	68 ± 21
ICM	70 ± 17	63 ± 16	57 ± 17

eGFR t0 = eGFR pre-treatment; eGFR t1 = eGFR post-treatment;  
eGFR t2 = eGFR at 1 year follow up

# Why EVARs with no Contrast ?

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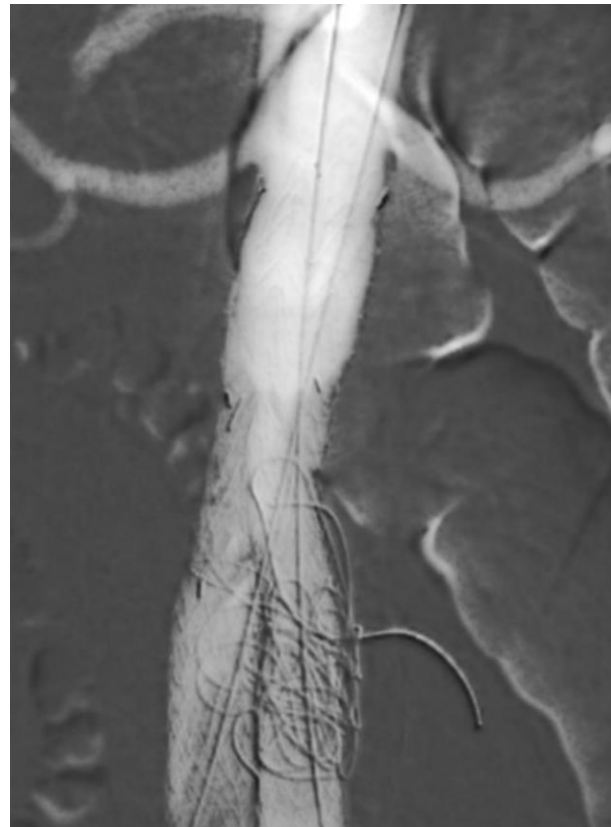
✓ Acute Kidney Injury  
after endovascular aortic procedure  
EVAR / F-BEVAR

✓ **Automated CO<sub>2</sub> angiography**  
Feasible alternative to ICM

**How ?**

# CO<sub>2</sub> aortography for EVAR

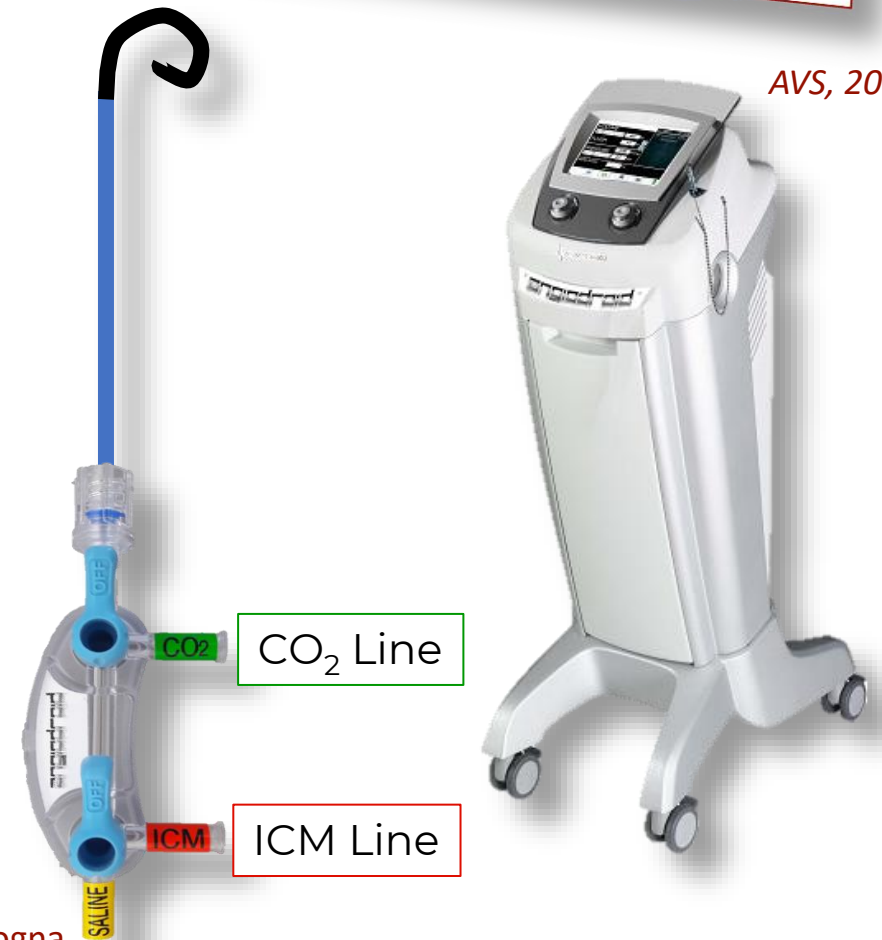
- ✓ Volume 100 mL
- ✓ Pressure 600 mmHg



## Standardization of a Carbon Dioxide Automated System for Endovascular Aortic Aneurysm Repair

Chiara Mascoli, Gianluca Faggioli, Enrico Gallitto, Vincenzo Vento, Rodolfo Pini, Andrea Vacirca, Giuseppe Indelicato, Mauro Gargiulo, and Andrea Stella, Bologna, Italy

AVS, 2018





## Standardization of a Carbon Dioxide Automated System for Endovascular Aortic Aneurysm Repair

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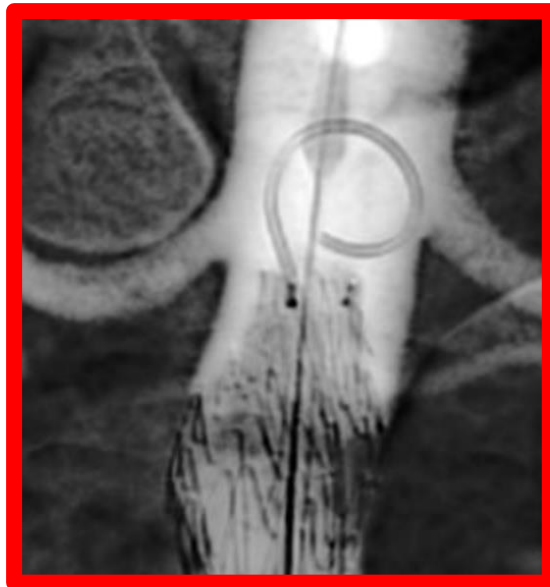
## CO<sub>2</sub> angiography in EVAR

AVS, 2018

### Feasible, Safe, Effective



Diagnostic angiography	%
Renal artery detection	61
Hypogastric detection	100



## Standardization of a Carbon Dioxide Automated System for Endovascular Aortic Aneurysm Repair

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## CO<sub>2</sub> angiography in EVAR

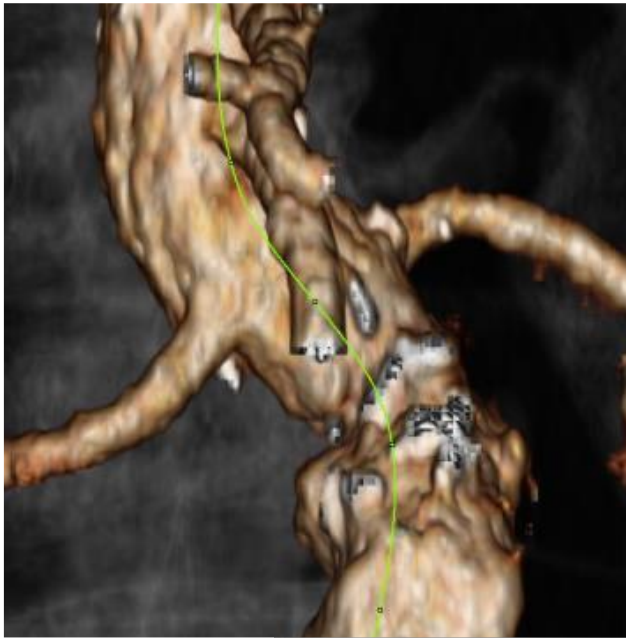
AVS, 2018

### Feasible, Safe, Effective

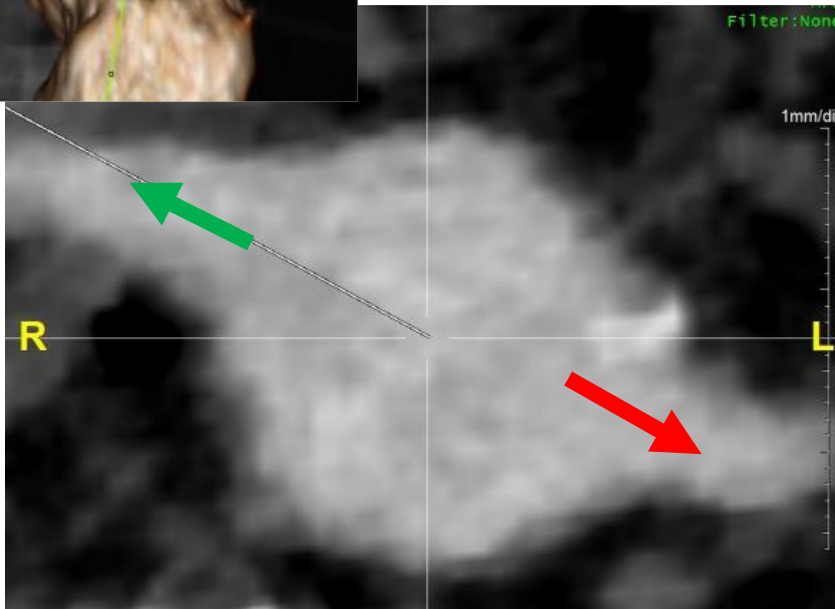


Diagnostic angiography	%
Renal artery detection	61
Hypogastric detection	100

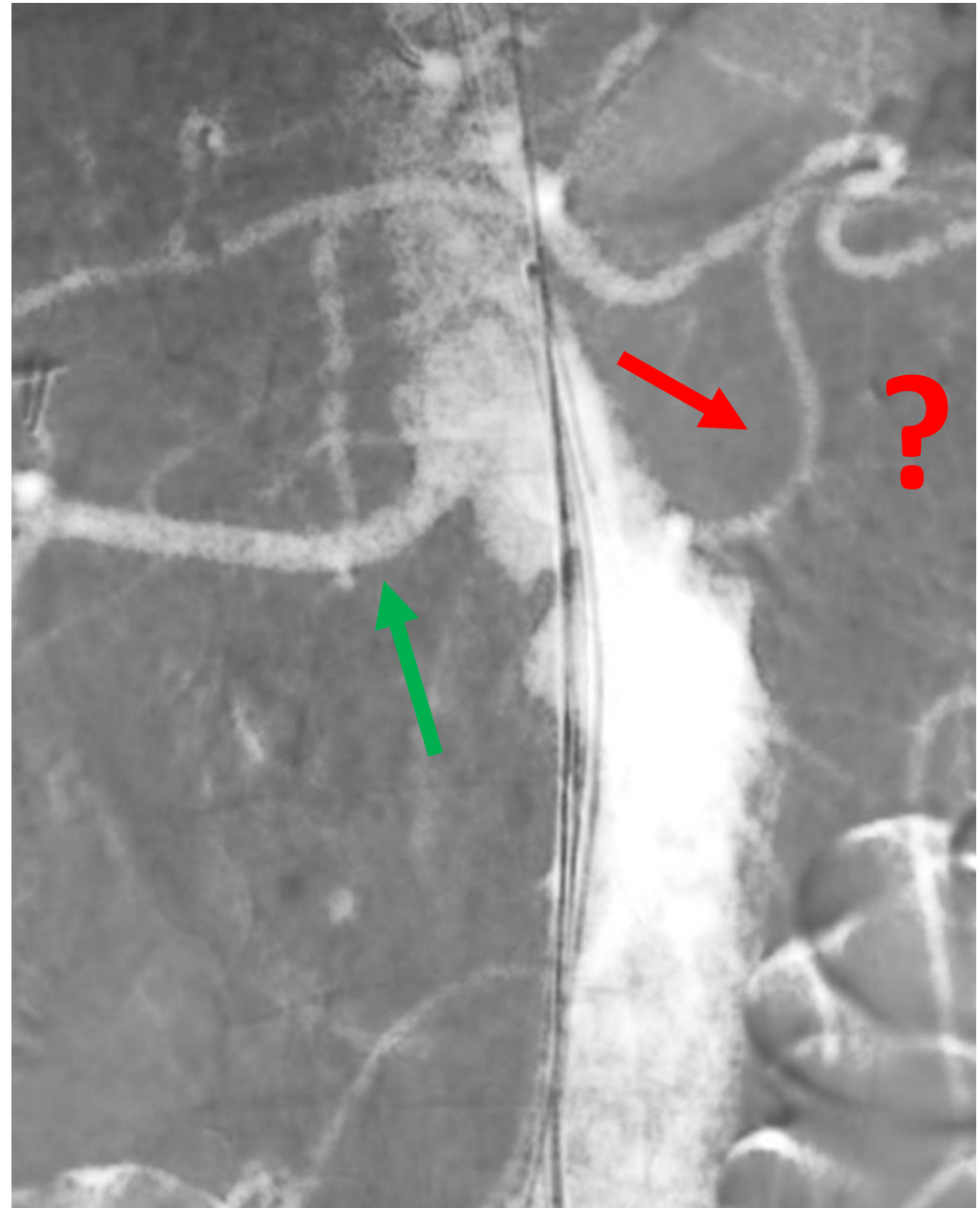




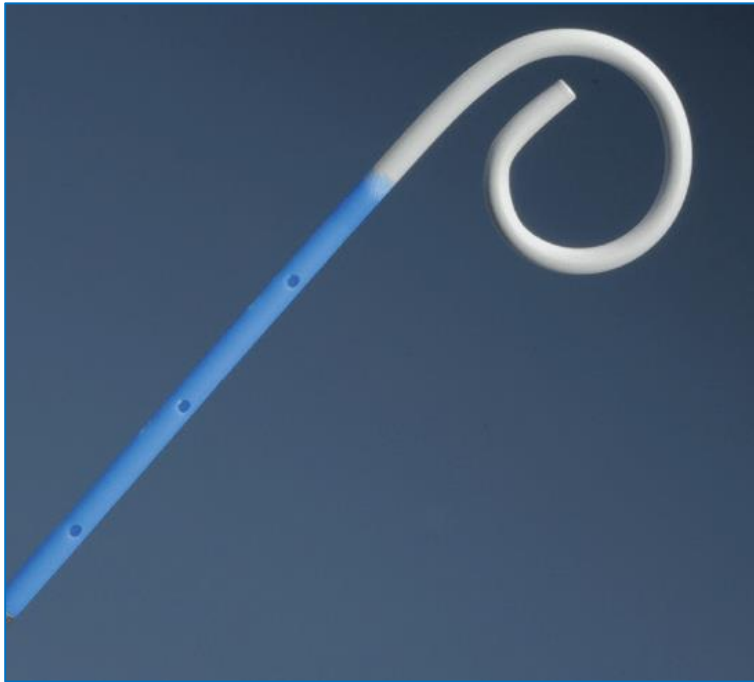
Anterior



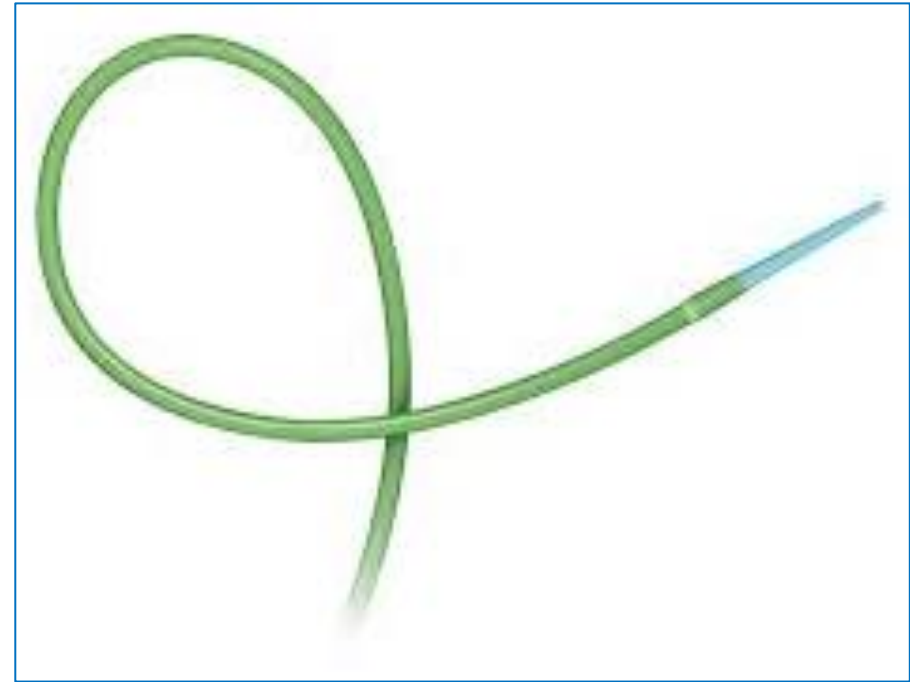
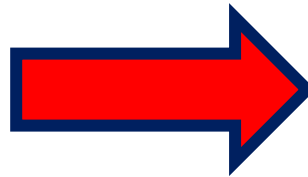
Posterior



# Renal arteries detection



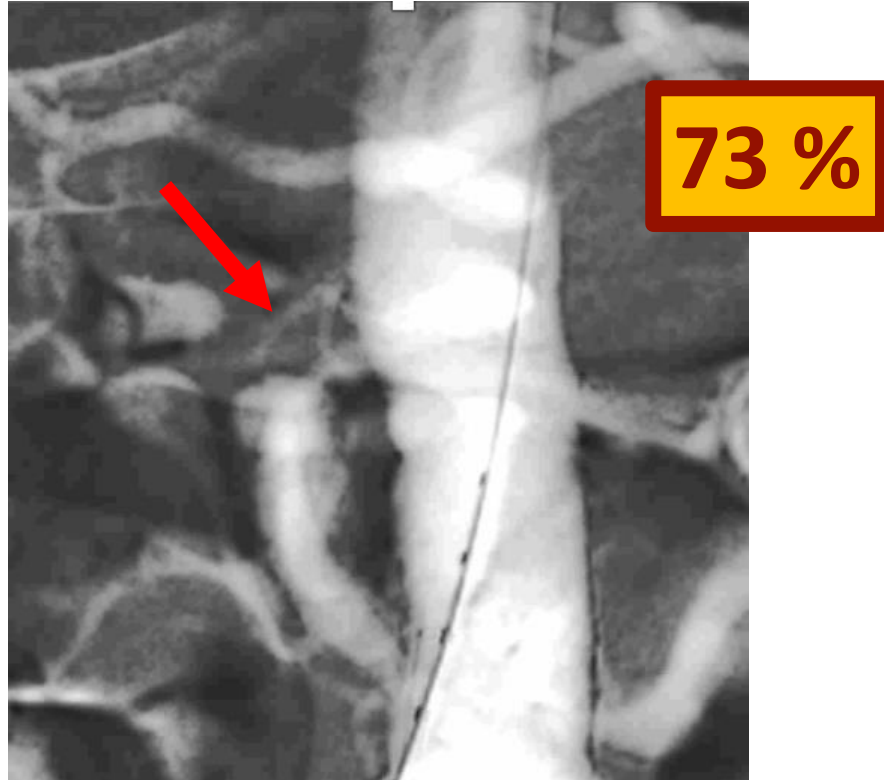
**Multi Holes** Pigtail catheter  
5F, 65 cm



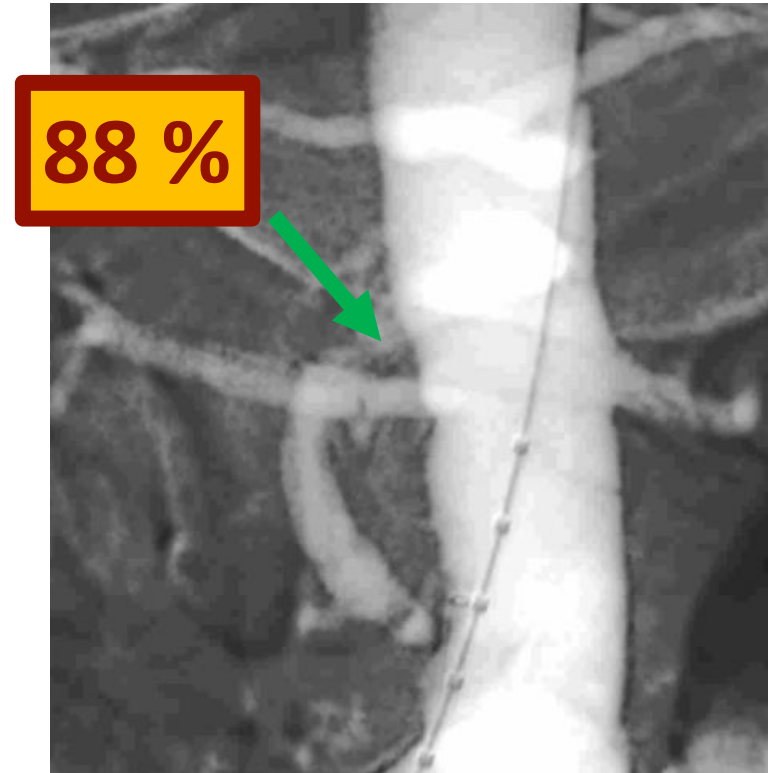
**Single Hole** Introducer  
5F, 45 - 55 cm

# Renal arteries detection

ClinicalTrials.gov ID: NCT05304026

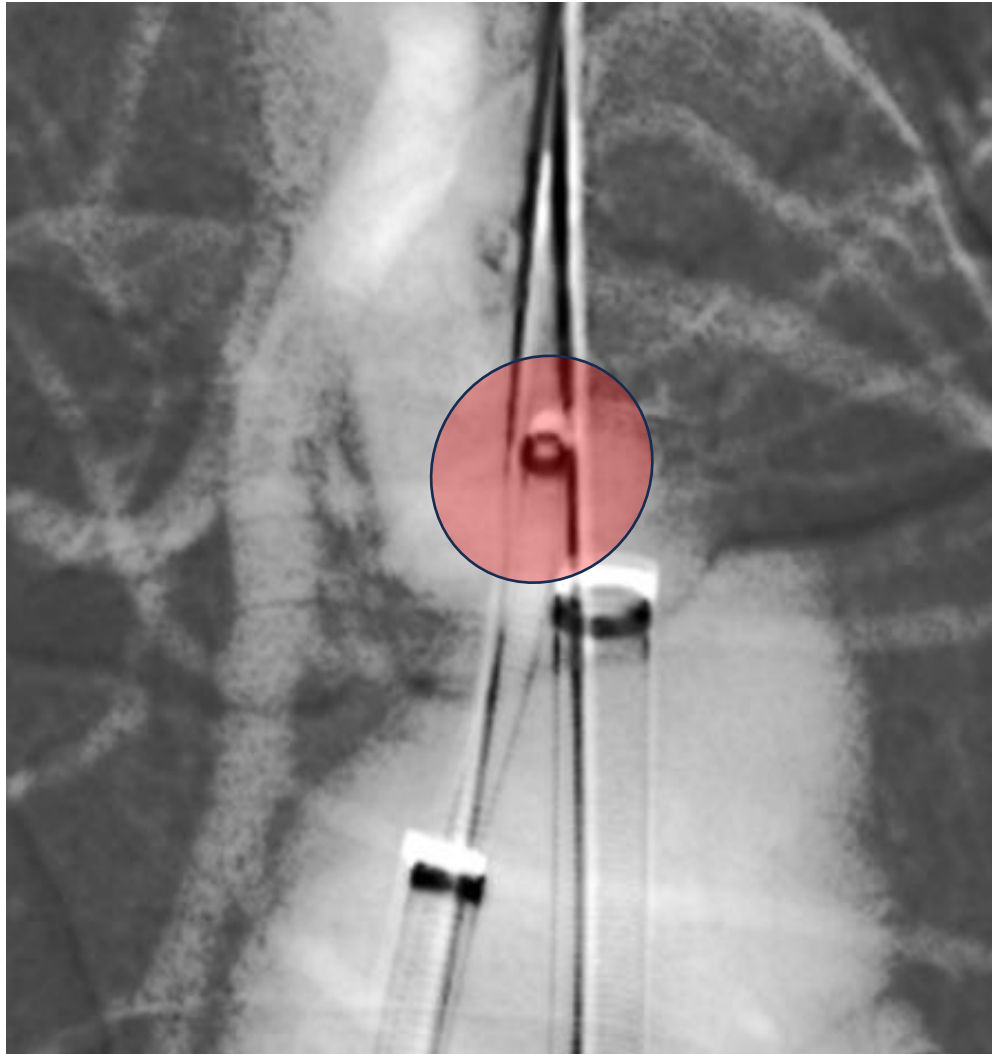


**Multi Holes** Pigtail catheter  
5F, 65 cm



**Single Hole** Introducer  
5F, 45 - 55 cm

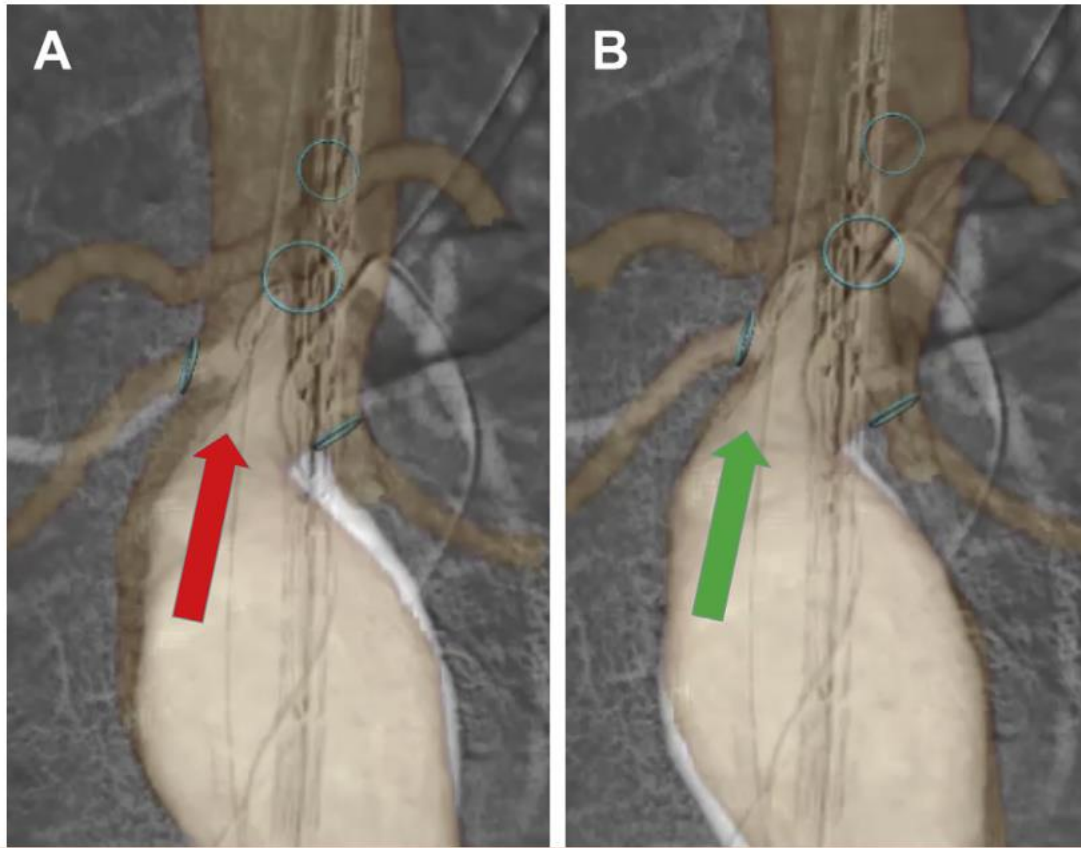
# Renal arteries detection - 5 F, 45cm introducer



## The benefit of combined carbon dioxide automated angiography and fusion imaging in preserving perioperative renal function in fenestrated endografting

Enrico Gallitto, MD, PhD, Gianluca Faggioli, MD, Andrea Vacirca, MD, Rodolfo Pini, MD, PhD, Chiara Mascoli, MD, Cecilia Fenelli, MD, Antonino Loggiacco, MD, Mohammad Abualhin, MD, and Mauro Gargiulo, MD, *Bologna, Italy*

*JVS, 2020*

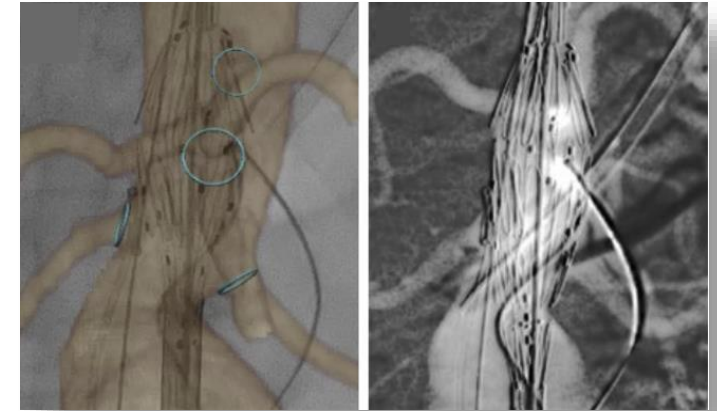


**F/B-EVAR** combining  
Vessel Navigator + CO<sub>2</sub> angiography

# The benefit of combined carbon dioxide automated angiography and fusion imaging in preserving perioperative renal function in fenestrated endografting

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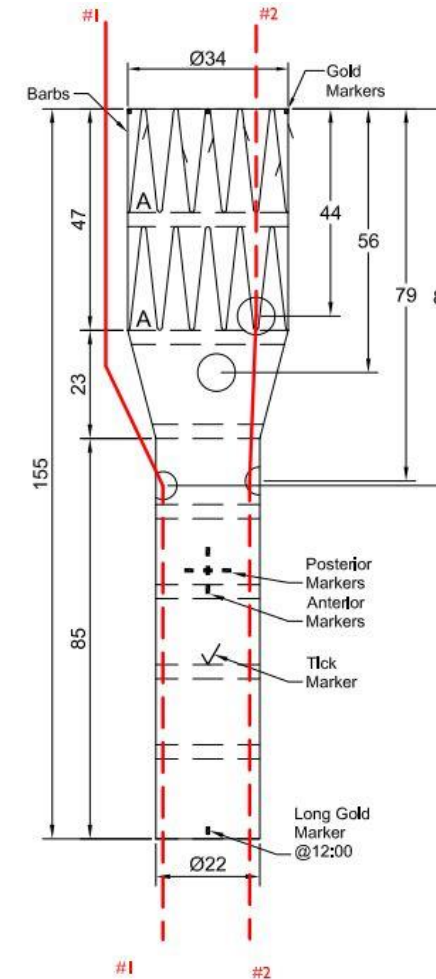
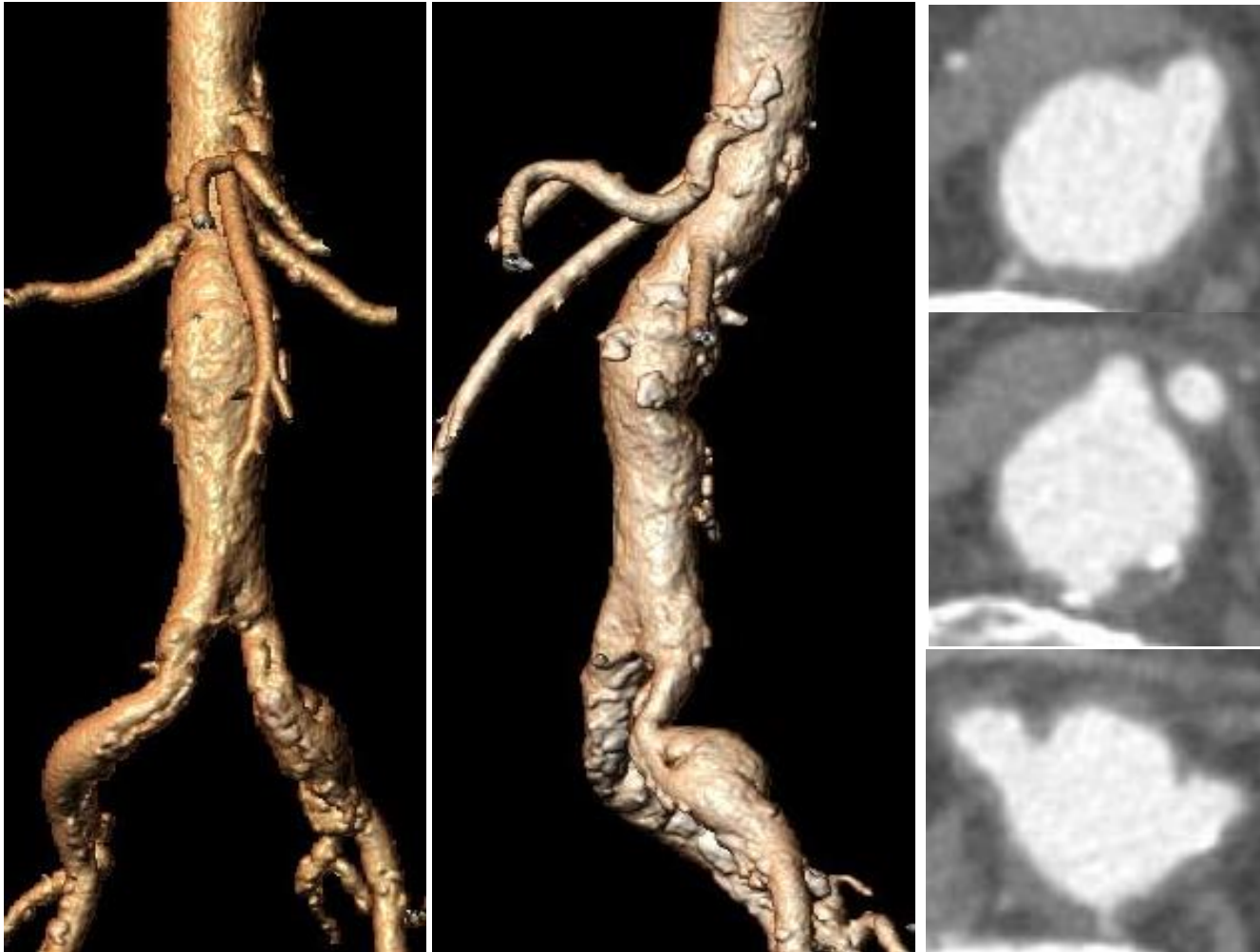
*JVS, 2020*



	<b>CO<sub>2</sub> + FI, median (IQR)</b>	<b>ICM + FI, median (IQR)</b>	<b>P</b>
Procedure time, minutes	290 (135)	348 (111)	.07
Fluoroscopy time, minutes	60 (33)	75 (17)	.25
Total DAP, mGy·cm <sup>2</sup>	1,201,117 (571,310)	892,108 (834,558)	.27
ICM, mL	41 (26)	139 (88)	.001

	<b>CO<sub>2</sub> + FI, median (IQR)</b>	<b>ICM + FI, median (IQR)</b>	<b>P</b>
Creatinine increase (mg/dL)	0.09 (0.03)	0.3 (0.4)	.049
Hospitalization (days)	5 (1)	7.5 (4)	.002

# FEVARs with no Contrast ?



## Catheter Pathway

### REINFORCED LARGE FENESTRATION #1

**\*Preloaded Catheter\*** access from above (#2)  
**\*\*Strut Free\*\***  
 DIAMETER: 8mm  
 DIST FROM PROX EDGE: 44mm  
 CLOCK: 1:30  
 IVD: 27mm

### REINFORCED LARGE FENESTRATION #2

**\*\*Strut Free\*\***  
 DIAMETER: 8mm  
 DIST FROM PROX EDGE: 56mm  
 CLOCK: 12:15  
 IVD: 27mm

### REINFORCED SMALL FENESTRATION #1

**\*Preloaded Catheter\*** access from below (#2)  
 DIAMETER: 6mm  
 DIST FROM PROX EDGE: 79mm  
 CLOCK: 3:15  
 IVD: 21mm

### REINFORCED SMALL FENESTRATION #2

**\*Preloaded Catheter\*** access from below (#1)  
 DIAMETER: 6mm  
 DIST FROM PROX EDGE: 80mm  
 CLOCK: 10:00  
 IVD: 21mm

- SINGLE DIAMETER REDUCING TIES
- LOW PROFILE FABRIC

**\*\*\*MODIFIED PRELOADED DELIVERY SYSTEM\*\*\***  
 (Biport handle and preloaded catheters)

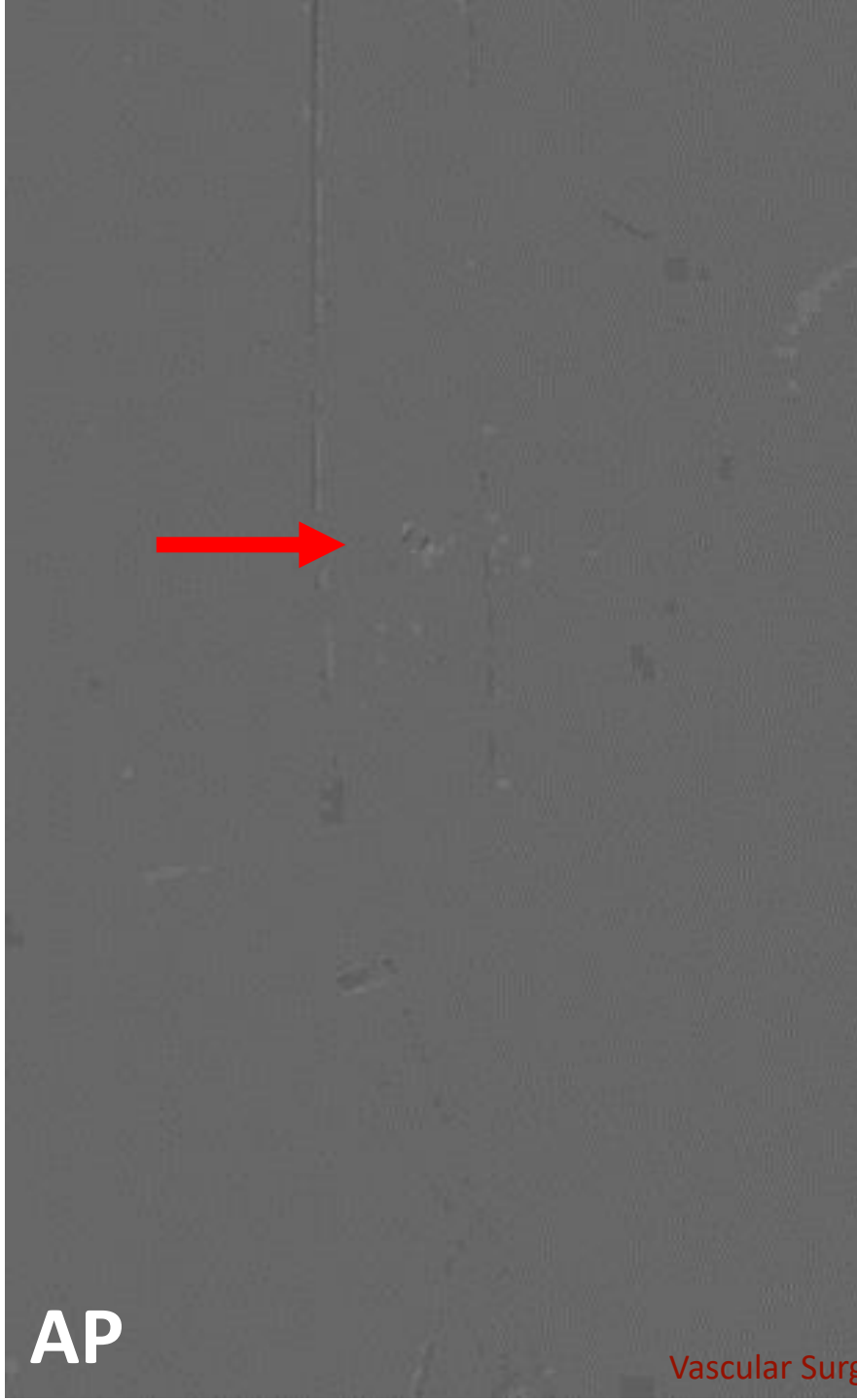
Plus:

**G32595 - AAA-BIFURCATED-GRAFT**  
 (As per ZFEN-D-12-45-76)

Ipsilateral Leg Extension  
**ZISL-16-93**

Contralateral Leg Extension  
**ZBIS-12-61-41**

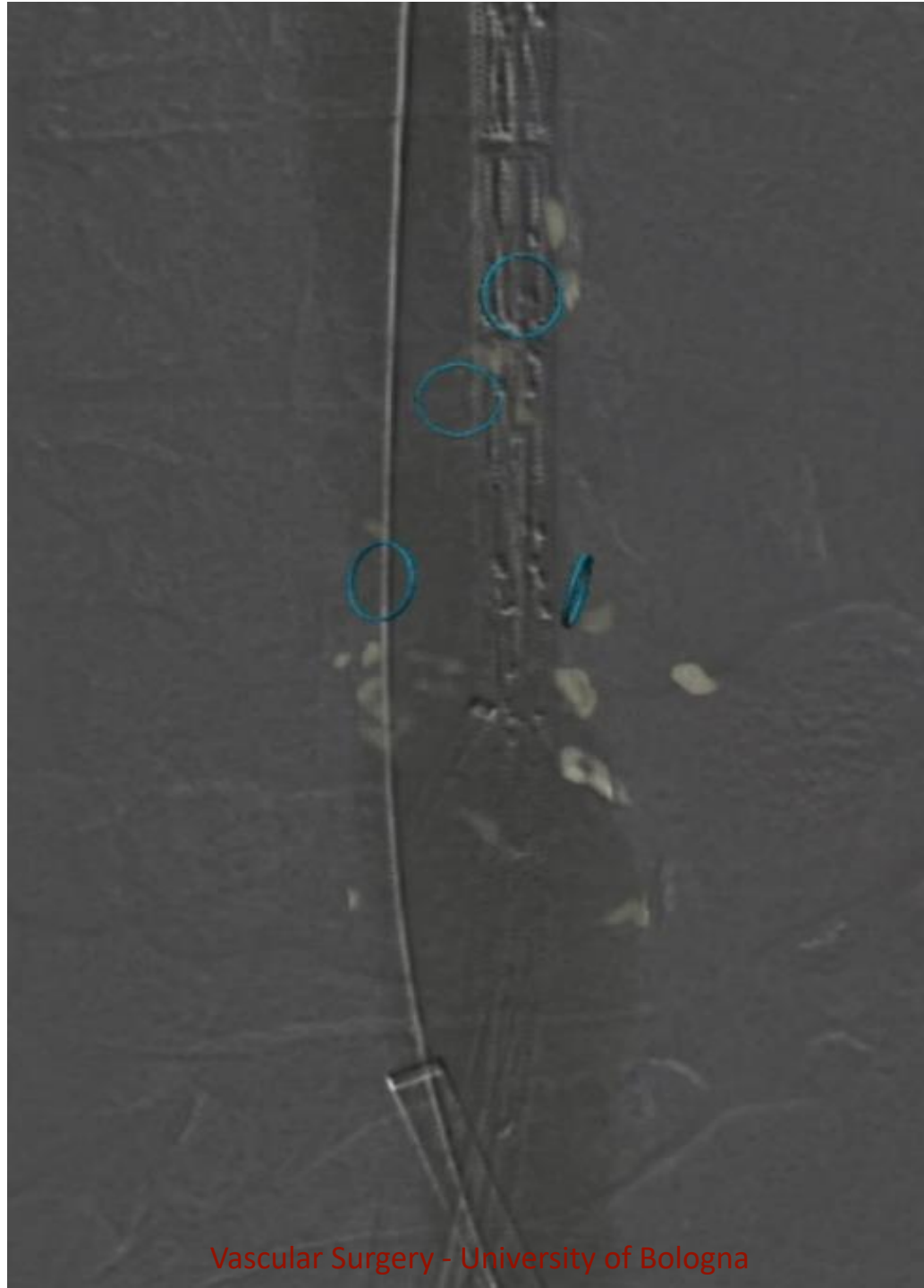
Bridging limb  
**ZISL-16-59**



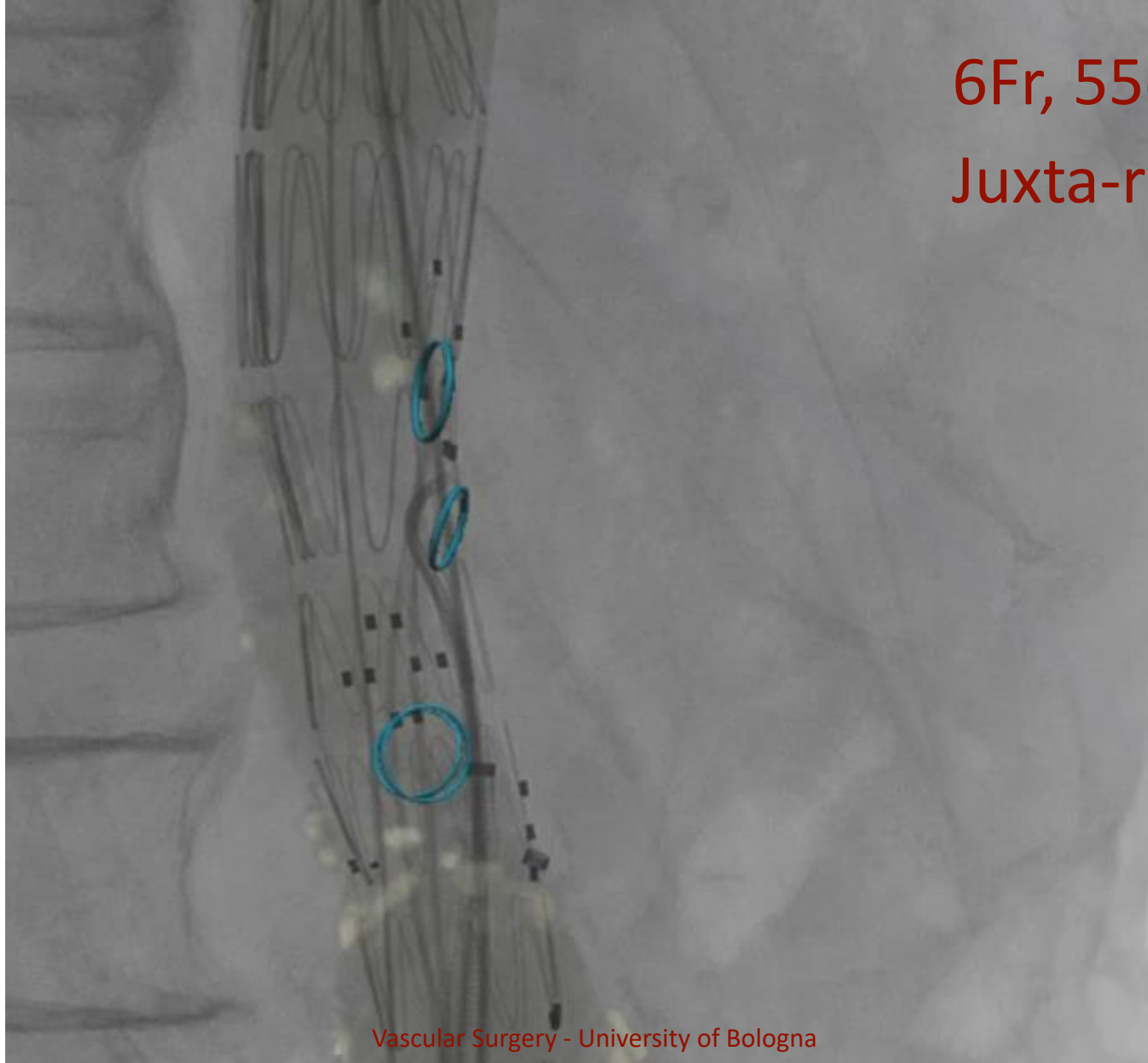
- ✓ 6Fr, 55cm Flexor  
Juxta-renal aorta
- ✓ Volume 100 mL
- ✓ Pressure 650 mmHg
- ✓ DSA 6 - 3 fps

AP



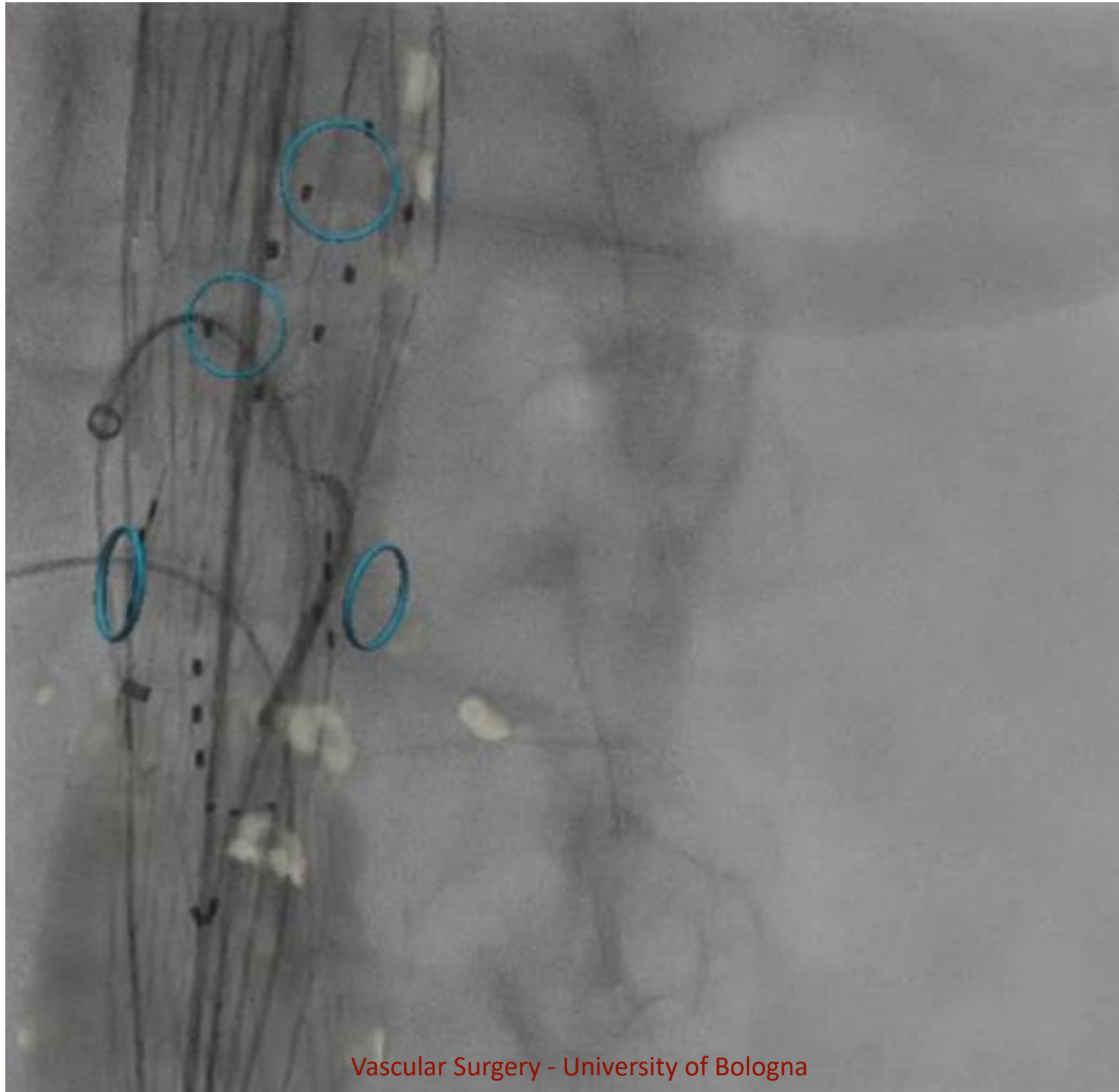


6Fr, 55cm Flexor  
Juxta-renal aorta

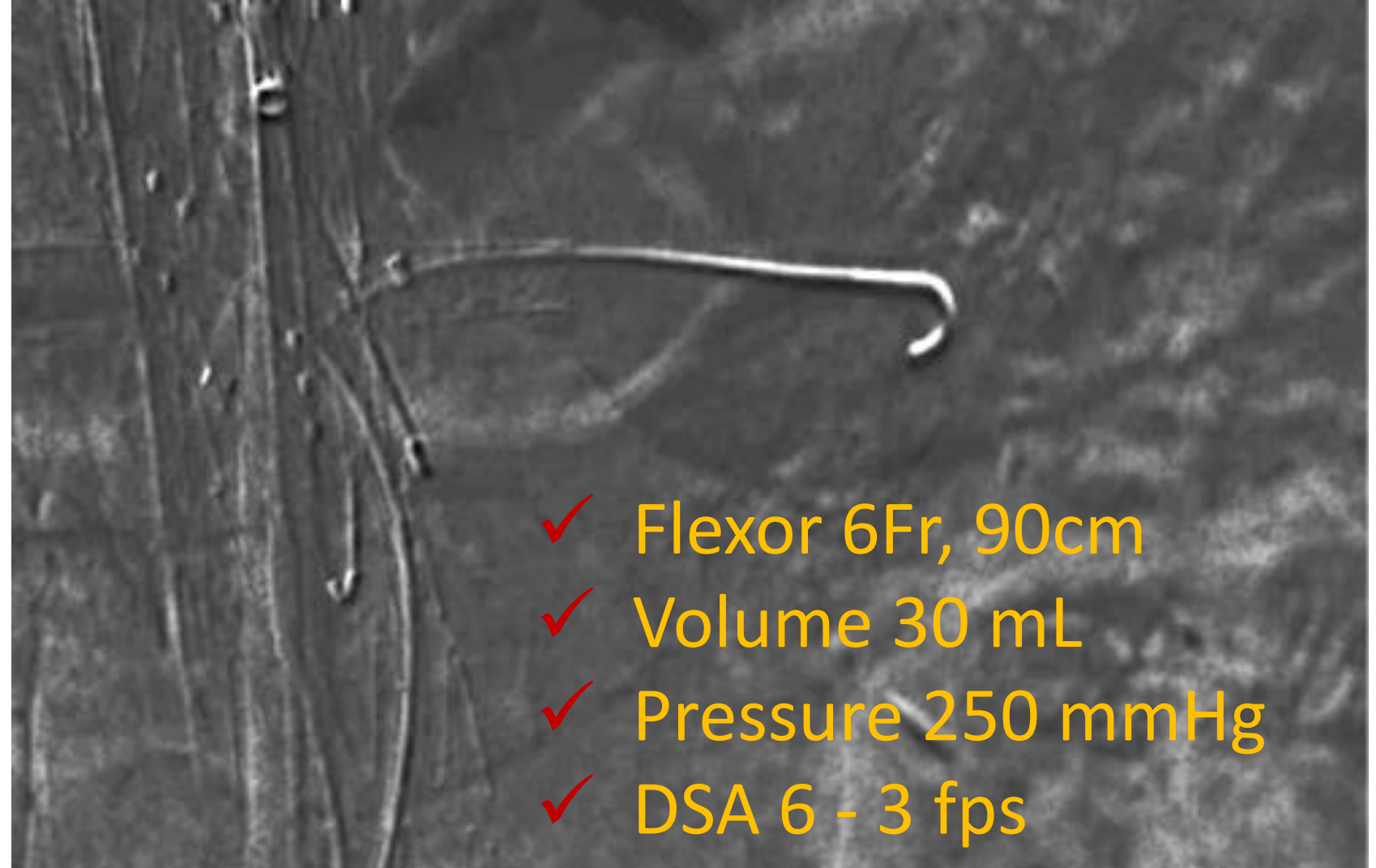
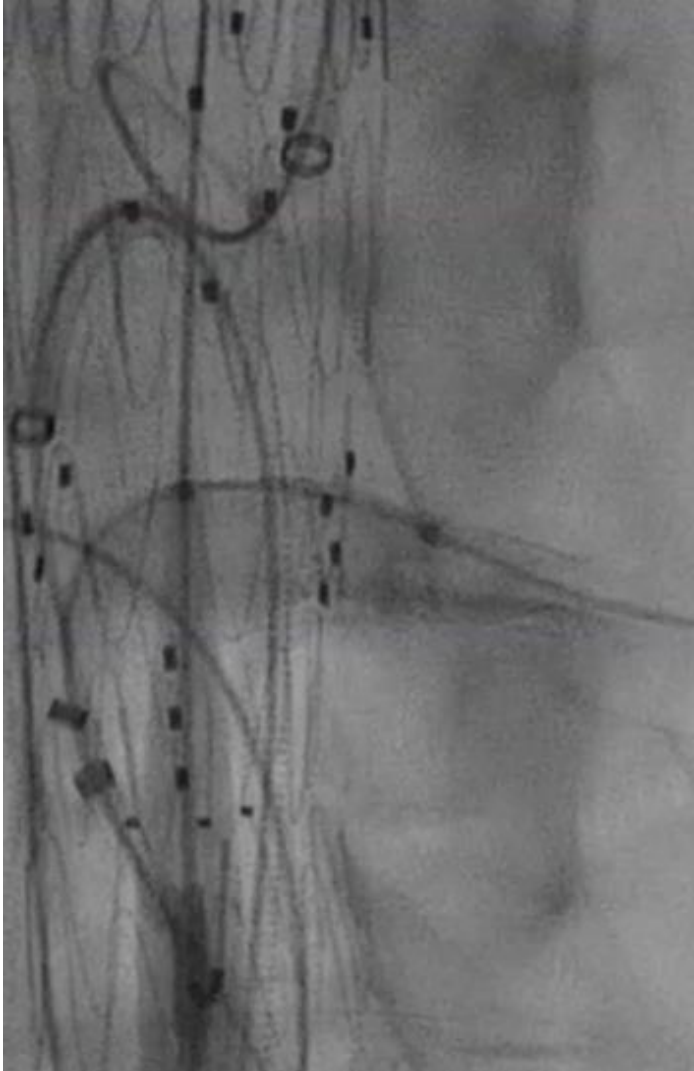




6Fr, 55cm



# Selective Renal Artery angiography

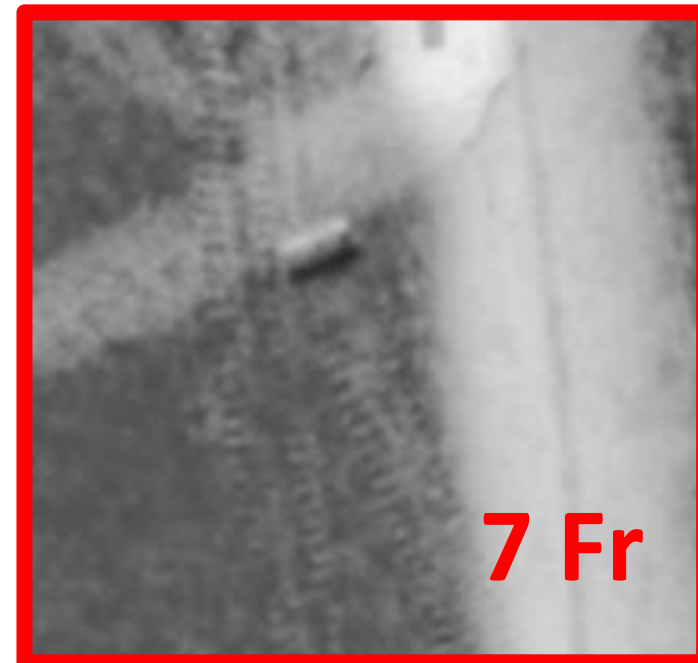


- ✓ Flexor 6Fr, 90cm
- ✓ Volume 30 mL
- ✓ Pressure 250 mmHg
- ✓ DSA 6 - 3 fps

# SMA angiography from the aorta

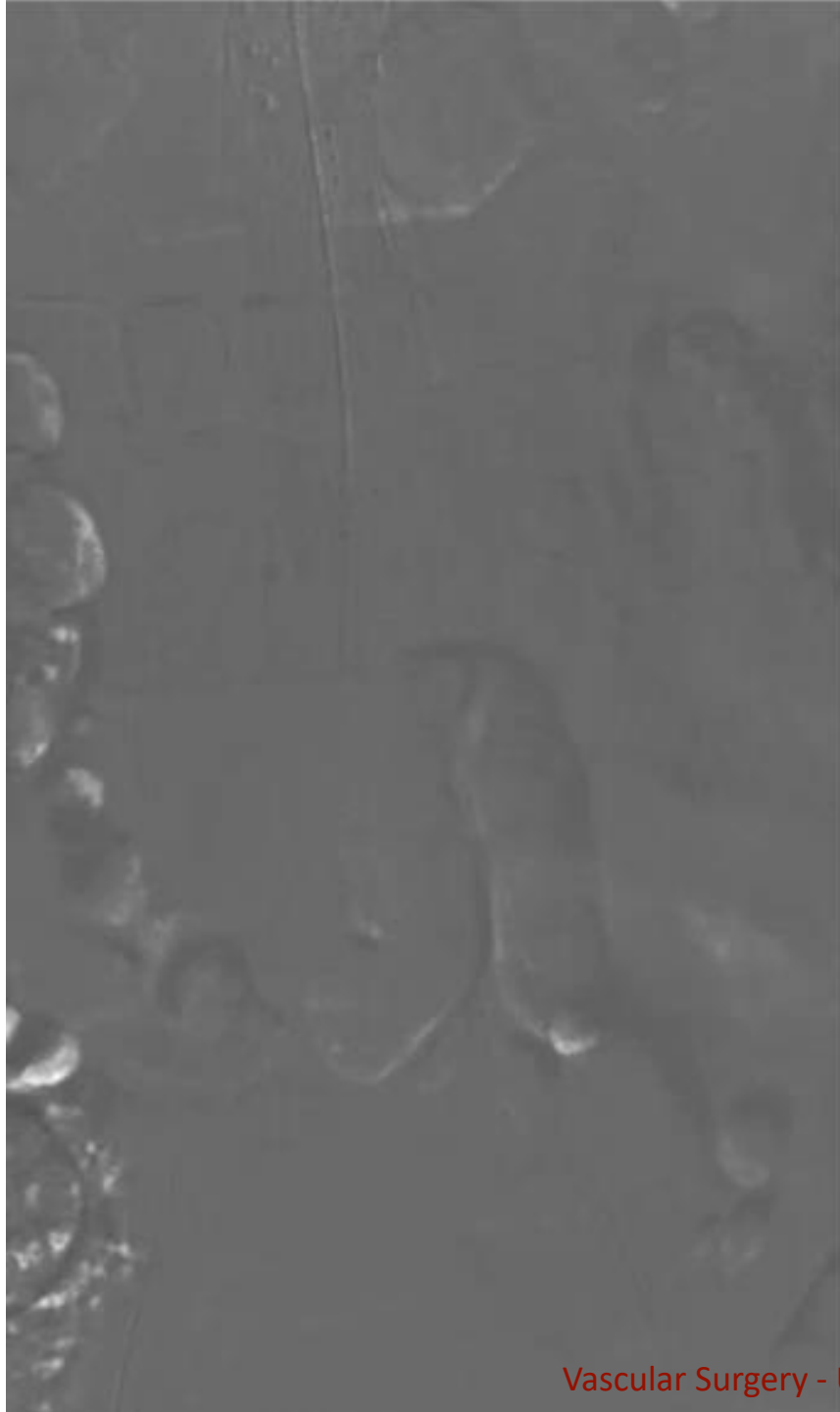


- ✓ Volume 100 mL
- ✓ Pressure 650 mmHg





Completion angiography  
8 Fr from above



## Completion angiography from femoral introducer

4 FEN + ZBIS	
Fluoroscopy time	46 min
DAP	869.730 mGy/cm <sup>2</sup>
CO <sub>2</sub>	2180 mL



# No contrast FEVAR Prospective Study

*ClinicalTrials.gov ID: NCT05304026*

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- ✓ FEVAR for j/p-AAAs
- ✓ November 2023 - December 2024
- ✓ Philips Hybrid Room
- ✓ Fusion Imaging
- ✓ Angiodroid CO<sub>2</sub> Injector

Aortography

100 mL, 650 mmHg

Selective TVVs angiography

30 mL, 250mmHg

- ✓ DSA 3 f / s

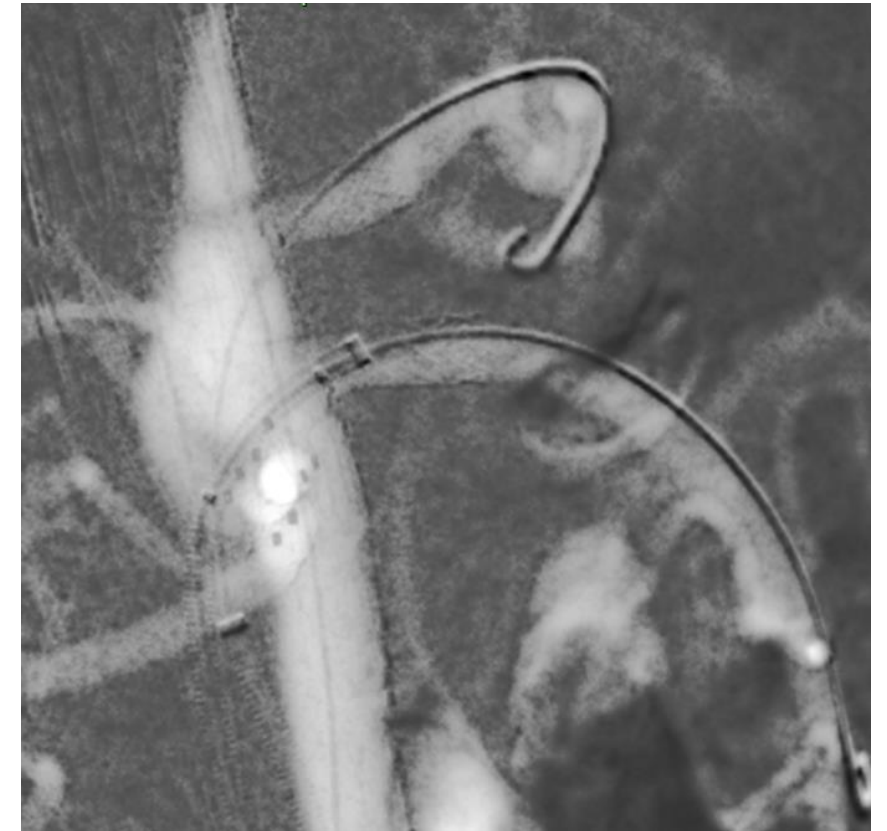
# No contrast FEVAR Prospective Study

ClinicalTrials.gov ID: NCT05304026

✓ Cases enrolled @ February 2024      17

	n	%
Technical Success	17	100
AKI	1	6
Reintervention @ 30-day	0	-

	median	IQR
Iodinated Contrast media (mL)	15	5 - 24



# CO<sub>2</sub> reduces the postoperative renal impairment

CO<sub>2</sub> Automated Angiography in Endovascular Aortic Repair Preserves Renal Function to a Greater Extent Compared with Iodinated Contrast Medium. Analysis of Technical and Anatomical Details

Andrea Vacirca, Gianluca Faggioli, Chiara Mascoli, Enrico Gallitto, Rodolfo Pini, Paolo Spath, Antonino Loggiacco, Sergio Palermo, and Mauro Gargiulo, Italy

AVS, 2022

	Tot N = 321 N (percent) or mean ± SD	CO <sub>2</sub> -EVAR = 72 N (percent) or mean ± SD	ICM-EVAR = 249 N (percent) or mean ± SD	P value
Death	4 (1.2%)	0	4 (1.6%)	0.93
Postoperative creatinine (mg/dL)	1.16 ± 0.7	1.2 ± 0.9	1.15 ± 0.6	0.53
Postoperative eGFR (mL/min)	67.8 ± 7.1	69.2 ± 7.8	67.2 ± 6.7	0.47
Creatinine increase (mg/dL)	0.15 ± 0.08	0.08 ± 0.04	0.17 ± 0.09	0.01 <sup>a</sup>
eGFR decrease (mL/min)	8.8 ± 4.9	2.3 ± 1.1	10.6 ± 5.3	<0.001 <sup>a</sup>
Renal function worsening requiring hemodialysis	2 (0.6%)	0	2 (0.8%)	1
Post-OP hospital stay (days)	4.8 ± 3.1	4 ± 2.3	5 ± 3.5	0.27

# CO<sub>2</sub> increases radiation exposure

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Urgent cases	25 (7.7%)	4 (5.5%)	21 (8.4%)	0.42
Suprarenal fixation graft	175 (54.5%)	41 (57%)	134 (53.8%)	0.9
ICM amount (mL)	80.9 ± 8.5	52.8 ± 6.1	88.1 ± 9.2	<0.001 <sup>a</sup>
Fluoroscopy radiation dose DAP (mGy/cm <sup>2</sup> )	150,159.2 ± 129,219.1	142,109.5 ± 113,534.4	156,439.2 ± 132,303.8	0.33
DSA radiation dose DAP (mGy/cm <sup>2</sup> )	265,270.9 ± 247,845.7	366,901.1 ± 307,701.3	175,862.6 ± 126,061.3	<0.001 <sup>a</sup>
Total radiation dose DAP (mGy/cm <sup>2</sup> )	414,635.3 ± 320,944.8	500,550.8 ± 377,394.6	332,301.8 ± 230,139.3	0.001 <sup>a</sup>
Anesthesia type:				0.48
General	135 (42.3%)	28 (38.9%)	107 (43.3%)	
Spinal	181 (56.7%)	44 (61.1%)	137 (55.5%)	
Local	3 (0.9%)	0	3 (1.2%)	

# CO<sub>2</sub> increases radiation exposure

- Set up of Hybrid rooms (2 f/s)
- Procedural protocols optimization

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# EVAR & F/B-EVAR with no contrast

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1. AKI post EVAR & F/B-EVAR
  - occurs up to 20%
  - mL ICM
  - impacts on patient 'survival
2. CO<sub>2</sub> automated angiography
  - effective in EVAR & F/B-EVAR
  - reduces postoperative and 1-year renal impairment
  - may increase radiation exposure