Technical Future

CO2 Angiography procedures in Endovascular Aortic Repair

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Disclosure

Speaker name: **Prof Mauro Gargiulo**

I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- **X Principal Invesigator European Registry EVAR and CO2 Angiography**
- ☐ I do not have any potential conflict of interest

CO2 Angiography in Endovascular Aortic Repair

Agenda

- EVAR and renal function
- CO2 Angiography
- Experience of Vascular Surgery-University of Bologna Italy about Endovascular Aortic Repair with CO2 Angiography
    - EVAR
    - F/BEVAR

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Results of standard suprarenal fixation endografts for abdominal aortic aneurysms with neck length ≤10 mm in high-risk patients unfit for open repair and fenestrated endograft

Enrico Gallitto, MD, Mauro Gargiulo, MD, Antonio Freyrie, MD, Claudio Bianchini Massoni, MD, Rodolfo Pini, MD, Chiara Mascoli, MD, Gianluca Faggioli, MD, and Andrea Stella, MD, *Bologna, Italy*

J Vasc Surg 2016

	No.	*%*
Cardiovascular risks factors and comorbidities		
Hypertension	58	97
Smoking	16	27
Hypercholesterolemia	31	52
CAD	29	48
COPD	42	70
CVD	17	28
Diabetes	16	27
Obesity	20	33
PAOD	9	15
CRF	18	30
Reasons for FEVAR ineligibility		
AAA maximum diameter >65 mm	26	43
Symptomatic AAA	4	7
AAA growth >5 mm/6 months	15	25
Proximal neck angles ≥60 degrees	19	32
Renal arteries unfit for FEVAR	5	8

CAD, Coronary artery disease; *COPD,* chronic obstructive pulmonary disease; *CRF,* chronic renal failure; *CVD,* cerebrovascular disease; *PAOD,* peripheral arterial obstructive disease.

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J Vasc Surg 2016

	No.	*%*	*Mean*	*Range*
Main body oversize, %	—	—	18	10-30
Proximal cuff placement	4	7	—	—
Iliac leg stenting	11	18	—	—
Contrast medium, mL	—	—	170	100-410
Fluoroscopy time, minutes	—	—	23	13-80
Procedure time, minutes	—	—	169	95-420
Intensive unit care, patients	13	22	—	—
Hospitalization, days	—	—	4.8	3-13

A systematic review & meta-analysis indicates **underreporting renal dysfunction** following EVAR

Karthikesalingam Aet al
Kidney Interventional Advance, 2015

- 1-year renal function deterioration: **18%**

- To discuss ***Measures that should be implemented*** to mitigate or minimize this effect on renal function

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Carbon dioxide (CO_2)

- ✓ Several studies have proposed the use of the carbon dioxide (CO_2) as an alternative contrast media for EVAR
- ✓ Non-nephrotoxic, non-allergenic gas

CO2 Angiography in Endovascular Aortic Repair

N	Author	Year	Journal	Title
1	Chao A et al	2007	J Vasc Surg	***Carbon dioxide*** *digital subtraction angiography-assisted endovascular aortic aneurysm repair in the azotemic patient .*
2	Criado E et al	2008	J Vasc Surg	*Catheter-less angiography for endovascular aortic aneurysm repair: a new application of* ***carbon dioxide*** *as a contrast agent.*
3	Criado E et al	2012	J Vasc Surg	*Endovascular aortic aneurysm repair with* ***carbon dioxide****-guided angiography in patients with renal insufficiency.*
4	Huang SG et al	2013	Ann Vasc Surg	*A prospective study of* ***carbon dioxide*** *digital subtraction versus standard contrast arteriography in the detection of endoleaks in endovascular abdominal aortic aneurysm repairs.*
5	Sueyoshi E et al	2015	J Vasc Surg	***Carbon dioxide*** *digital subtraction angiography as an option for detection of endoleaks in endovascular abdominal aortic aneurysm repair procedure.*
6	De Almeida Mendes C et al	2017	Ann Vasc Surg	***Carbon Dioxide*** *as Contrast Medium to Guide Endovascular Aortic Aneurysm Repair.*
7	De Angelis C et al	2017	Int J Cardiovasc Imaging.	***Carbon dioxide (CO2)*** *angiography as an option for endovascular abdominal aortic aneurysm repair (EVAR) in patients with chronic kidney disease (CKD).*

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2	Cri			*Catheter-less angiography for endovascular aortic aneurysm ... as a contrast*
3	Cri			***...rbon dioxide-*** *...ficiency.*
4	Hu			*...l subtraction ... detection of ...ic aneurysm*
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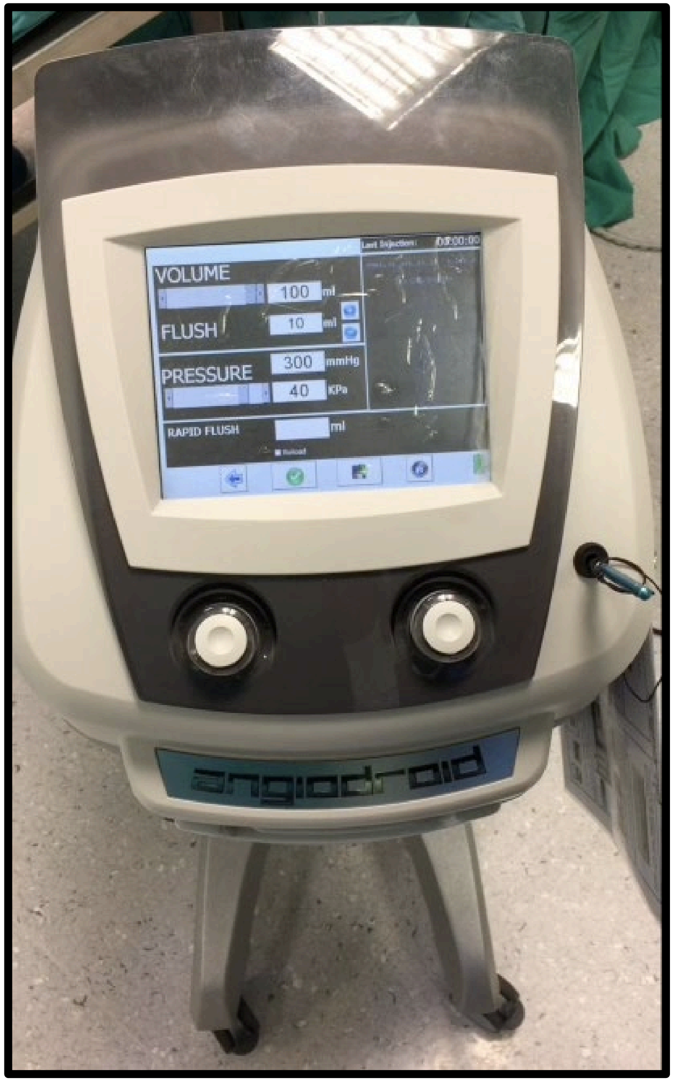
- ✓ Manual injection
- ✓ Not optimal control of the gas output

The use of CO_2 in EVAR procedure has not been standardised jet

EAR using Carbon Dioxide Injector DSA Angiography



Automated
carbon dioxide angiography system

No standardized protocol of automated injection for EVAR

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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

Ann Vasc Surg 51, 160-169, 2018

Aim

To report our preliminary experience with a new method of CO2 automated injection in EVAR procedures

Methods

- ✓ Consecutive patients undergoing EVAR for AAA
- ✓ All procedures performed with automated CO_2 injection and controlled with traditional iodinate contrast medium angiography

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Automated CO_2 Angiography

Angiodroid System

- ✓ Pressure : 300 – 500 mmHg
- ✓ Volume : 80 – 100 mL

Methods

- ✓ **ICM** was delivered in the suprarenal aorta pigtail catheter using automatic injector
- ✓ **CO_2** was delivered through a brand new automatic injector connected to a 10F-sheath positioned in the external iliac artery

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Endpoints

1. Visualization of the renal arteries
2. Visualization of the internal iliac arteries
3. Detection of endoleaks
4. Safety of CO_2 standardized automated injection

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Results

- ✓ August - December 2016

- ✓ 31 consecutive patients underwent EVAR for AAA

- ✓ CO_2 automated injection and Iodinate contrast media (ICM)

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Results

DEMOGRAPHIC	**N**	**%**
Age (yrs)	76.8	7.4*
Sex (male)	31	100
HPT	29	93.5
COPD	10	32.2
CAD	6	19.3
Atrial fibrillation	4	12.9
Dyslipidemia	19	61.2
CRF (GFR< 60 mL/min/1.73 m^2)	**10**	**32.2**
Dialysis	3	9.6
Smoke	22	70.9
Obesity	4	12.9
Peripheral artery disease	3	9.6
HPT	29	93.5

INTRA-OPERATIVE DATA	**N**	**%**
Endograft		
Suprarenal fixation	16	51.6
Infrarenal fixation	15	48.3
General anesthesia (n°)	12	38.7
Spinal anestesia (n°)	19	61.3
AAA-sac embolization	14	45.1

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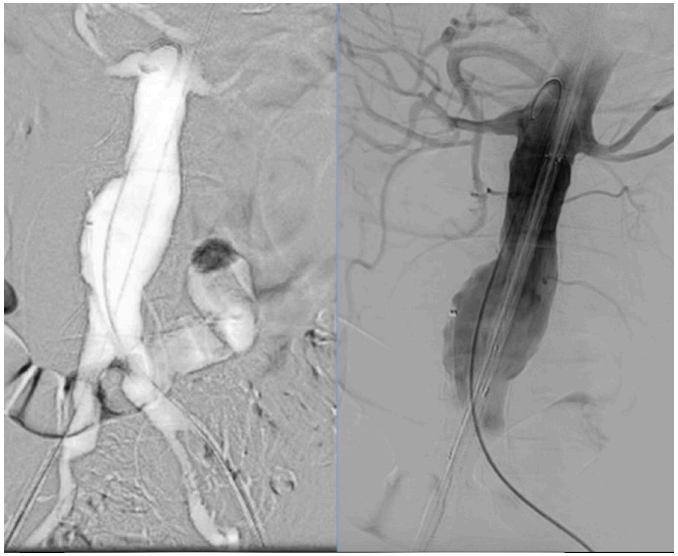
Results – CO2 DSA

	N	%
Patient	31	
Lowest renal artery (RA) visualization	**19**	**61**
Lowest RA not visualised (No RA)	12	39
Hypogastric artery visualization	**31**	**100**



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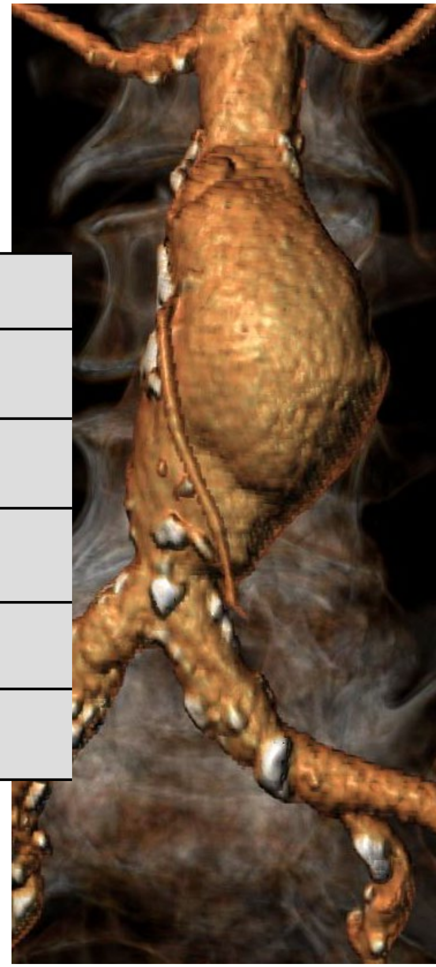
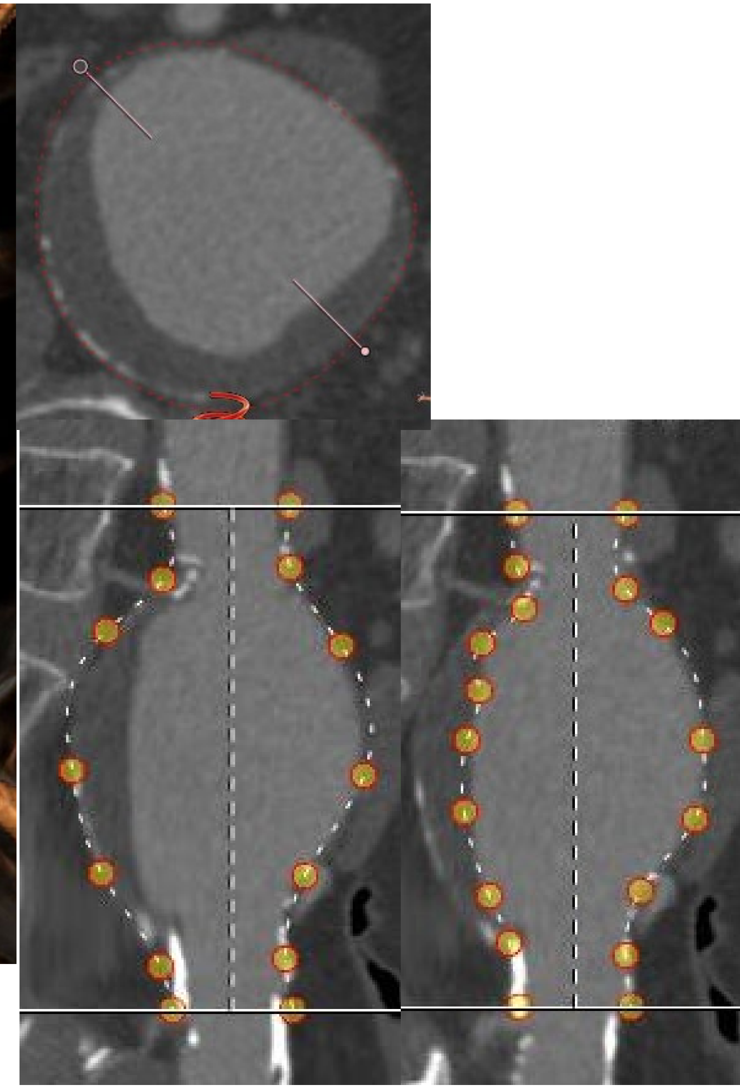
Bi/Tri-Dimensional morphological pre-operative characteristics

AAA diameter (mm)
AAA Total Volume (mm^3)
AAA Lumen Volume (mm^3)
Distance RA - Aortic bifurcation (mm)
Distance RA – Hypogastric Artery (mm)
Distance RA – apex of 10F sheet (mm)





Bi/Tri-Dimensional morphological pre-operative characteristics

	RA mean	No RA mean	p *
AAA diameter (mm)	55.1 (6.4)	58.7 (10.8)	0.09
AAA Total Volume (mm^3)	160.0 (61.9)	181.5 (107.9)	0.09
AAA Lumen Volume (mm^3)	57.0 (10,2)	95.9 (25.2)	**0.03**
Distance RA- Aortic Biforcation (mm)	105.5 (13,2)	113.6 (14,1)	0.98
Distance RA - Right Hypogastric artery (mm)	174.0 (22.3)	177.4 (17,6)	0.29
Distance LRA - Left Hypogastric artery (mm)	176.2 (27.9)	178.7 (14.3)	0.11
Distance LRA - 10F sheet apex (mm)	189.5 (22,5)	192.0 (17,8)	0.53

* T-student Test

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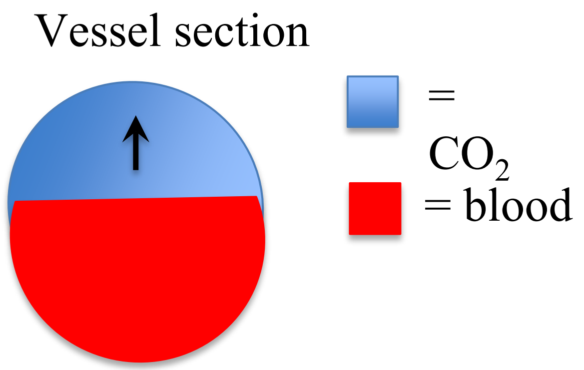
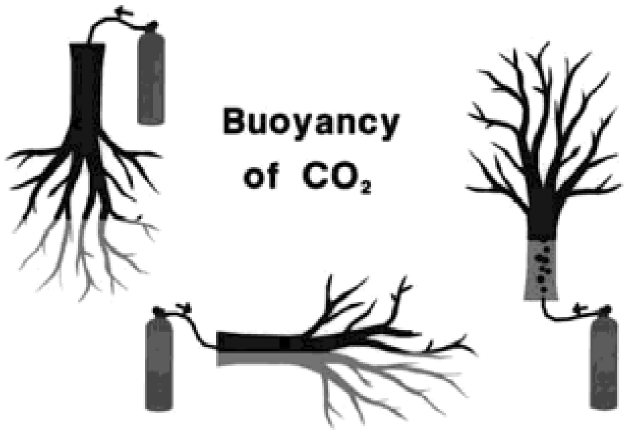
VISUALIZATION OF THE RENAL ARTERIES





CO_2 FLOATS

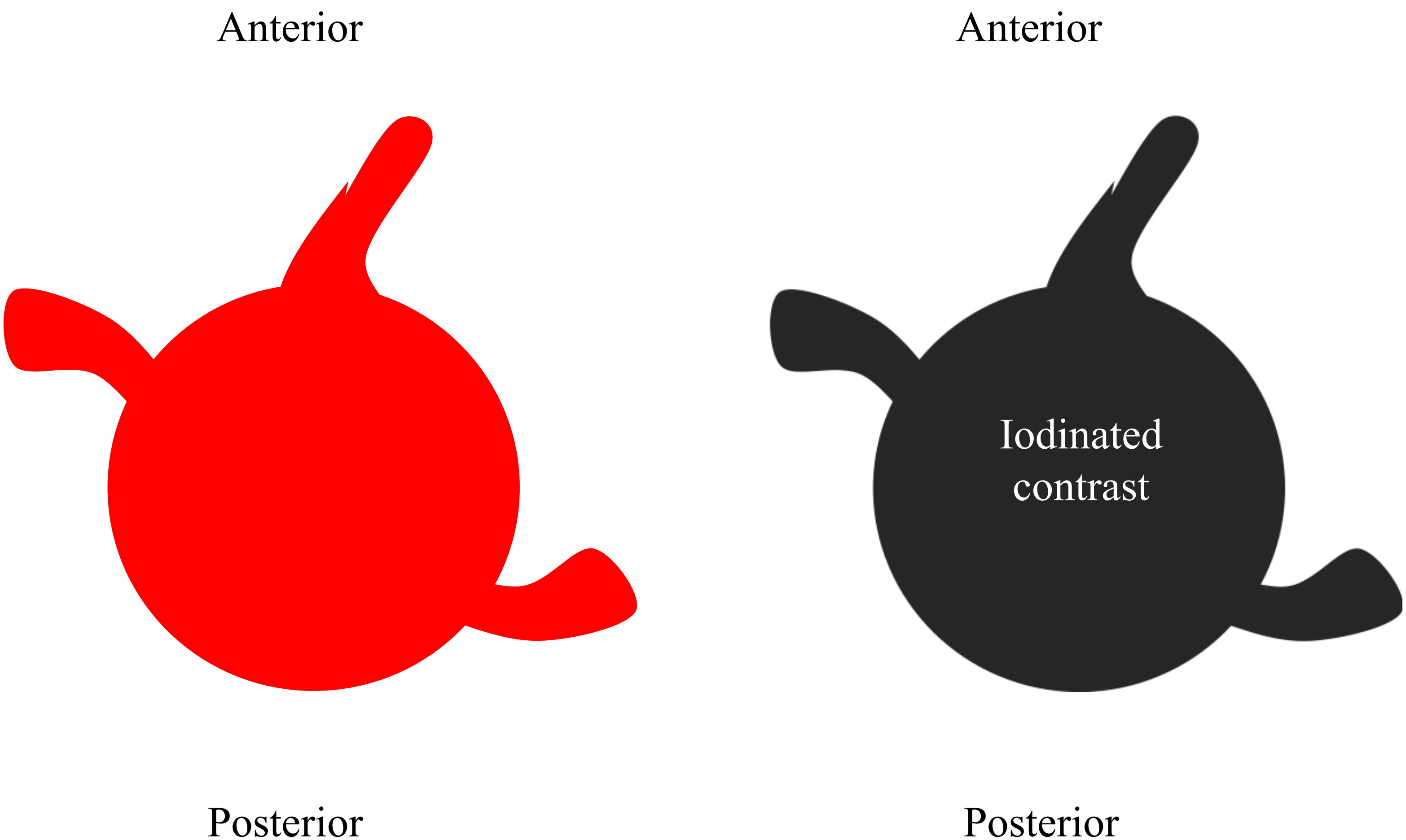
↓

CO_2 FILLS SUPERFICIAL VESSELS

↓

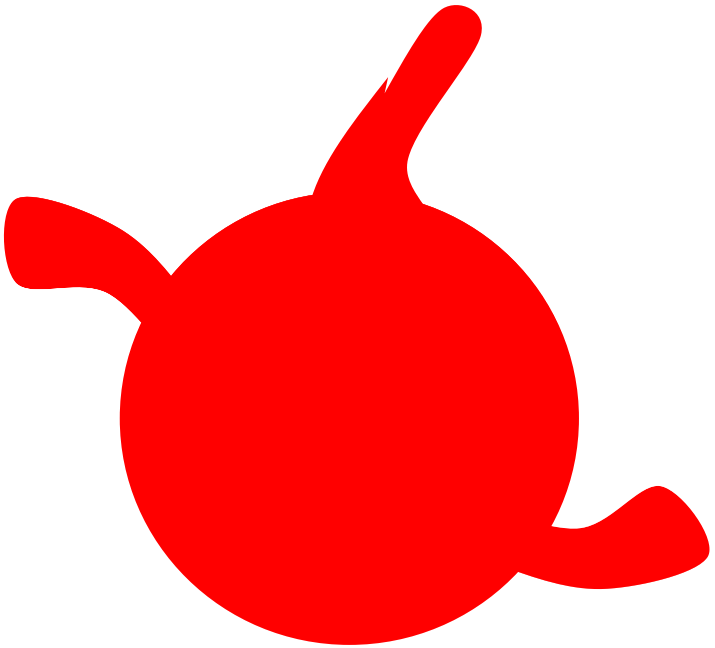
IF RENAL ARTERY IS IN A POSTERIOR POSITION FROM SAGITTAL PLANE POINT OF VIEW IT WILL BE DIFFICULT TO COMPLETELY FILL IT WITH CO_2

Target visceral vessels visualization

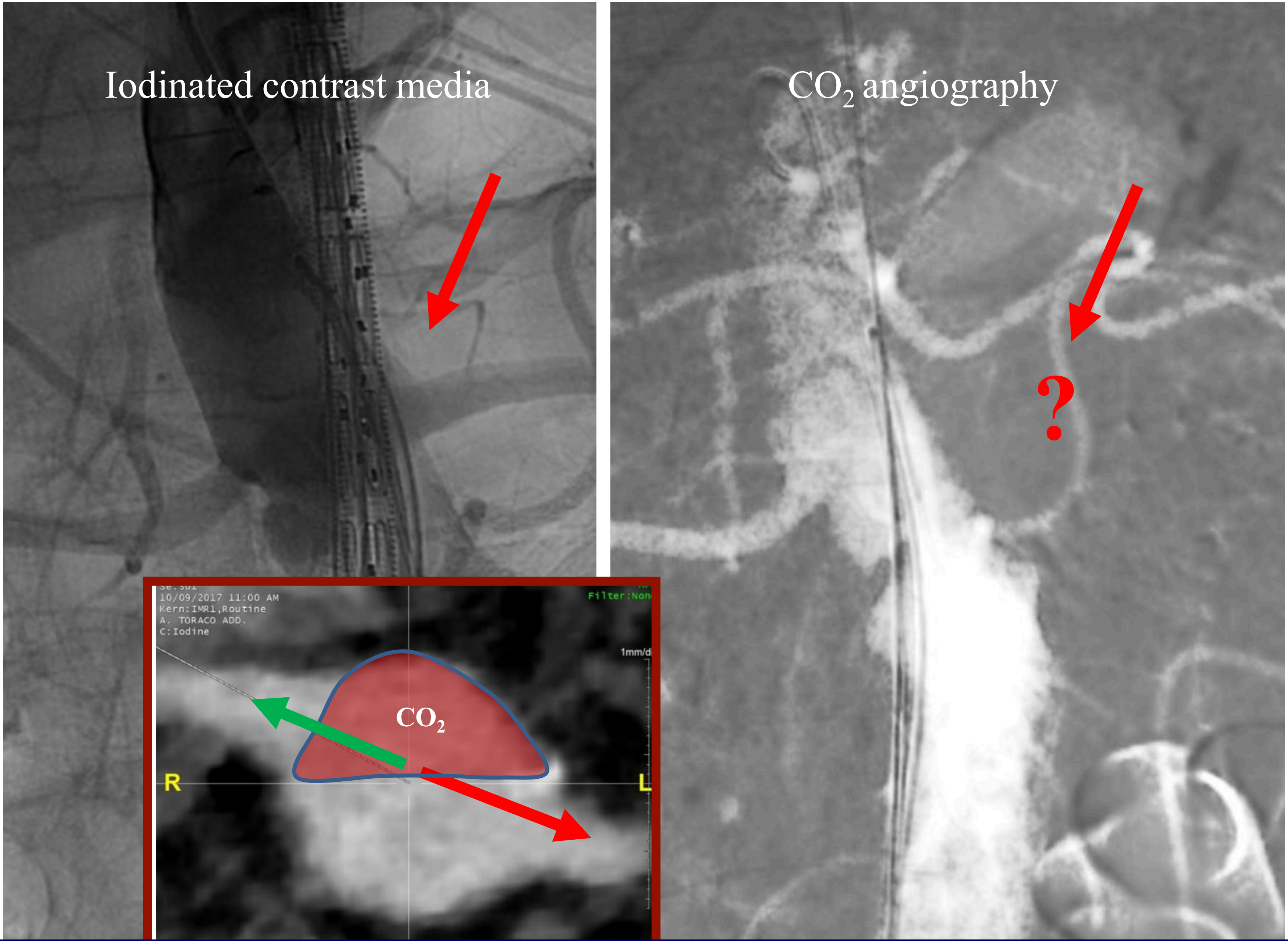


Target visceral vessels visualization

Anterior Anterior



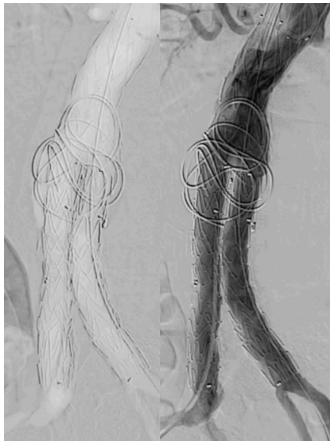
Posterior Posterior



Iodinated contrast media
CO2 angiography
?
10/09/2017 11:00 AM
Kern:IMR1,Routine
A. TORACO ADD.
C:Iodine
Filter:Non
1mm/d
R
L
CO2

Results – CO_2 DSA

	N	%
Patient	31	
Hypogastric artery visualization	**31**	**100**
Endoleak I/III	0	-
Endoleak II	**10**	**32**



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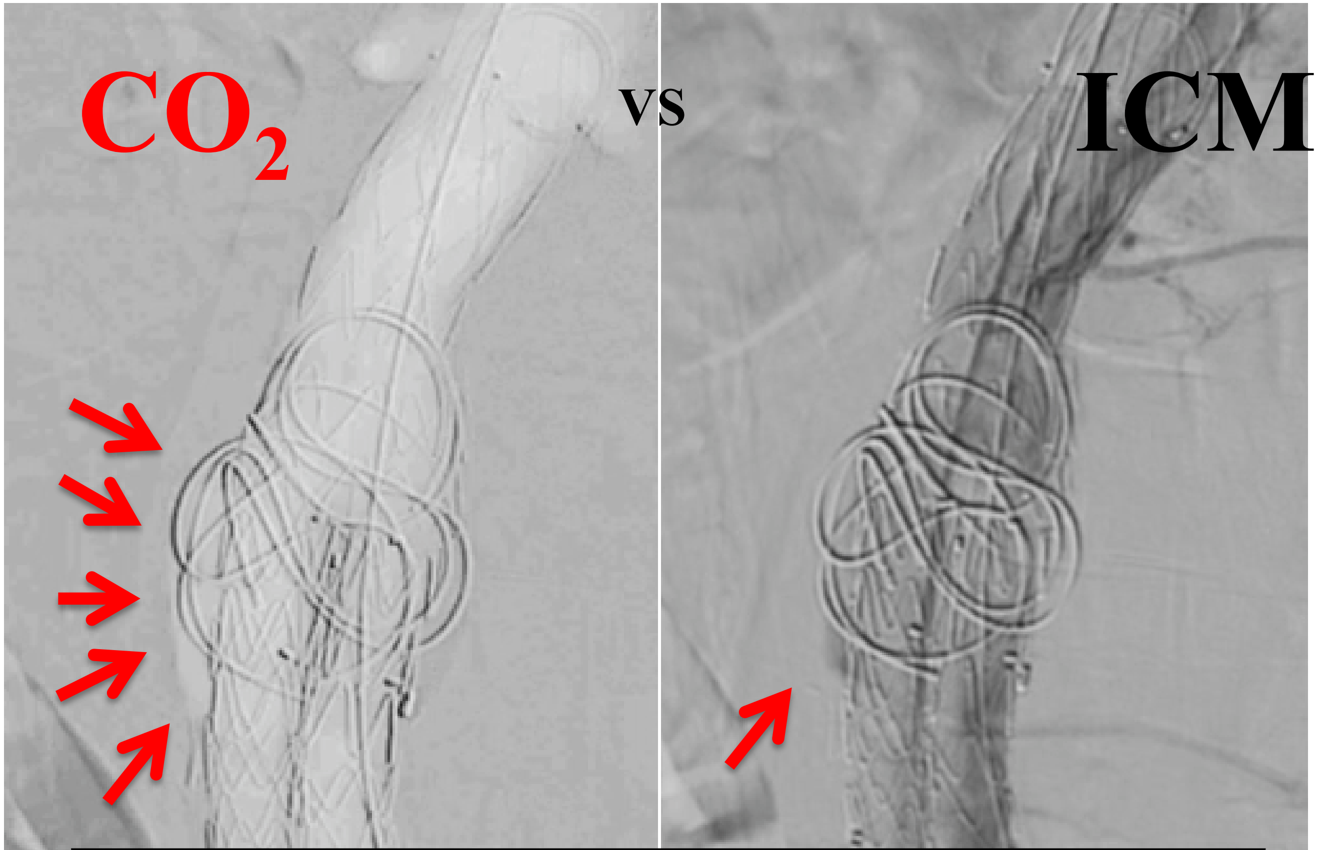
CO2 Angiography and Endoleak type II



	CO2	ICM
ELII	10 - 32%	2 - 6%

CO2 Angiography and Endoleak type II

Endoleak type II

ID PATIENT	CO_2	ICM	CEUS
5	✔	–	✔
9	✔	–	–
14	✔	–	✔
16	✔	–	–
17	✔	✔	✔
18	✔	–	–
21	✔	–	✔
23	✔	✔	✔
28	✔	–	✔
29	✔	–	–
Tot.	**10**	**2**	**5**

✔ : Detected
– : Undetected

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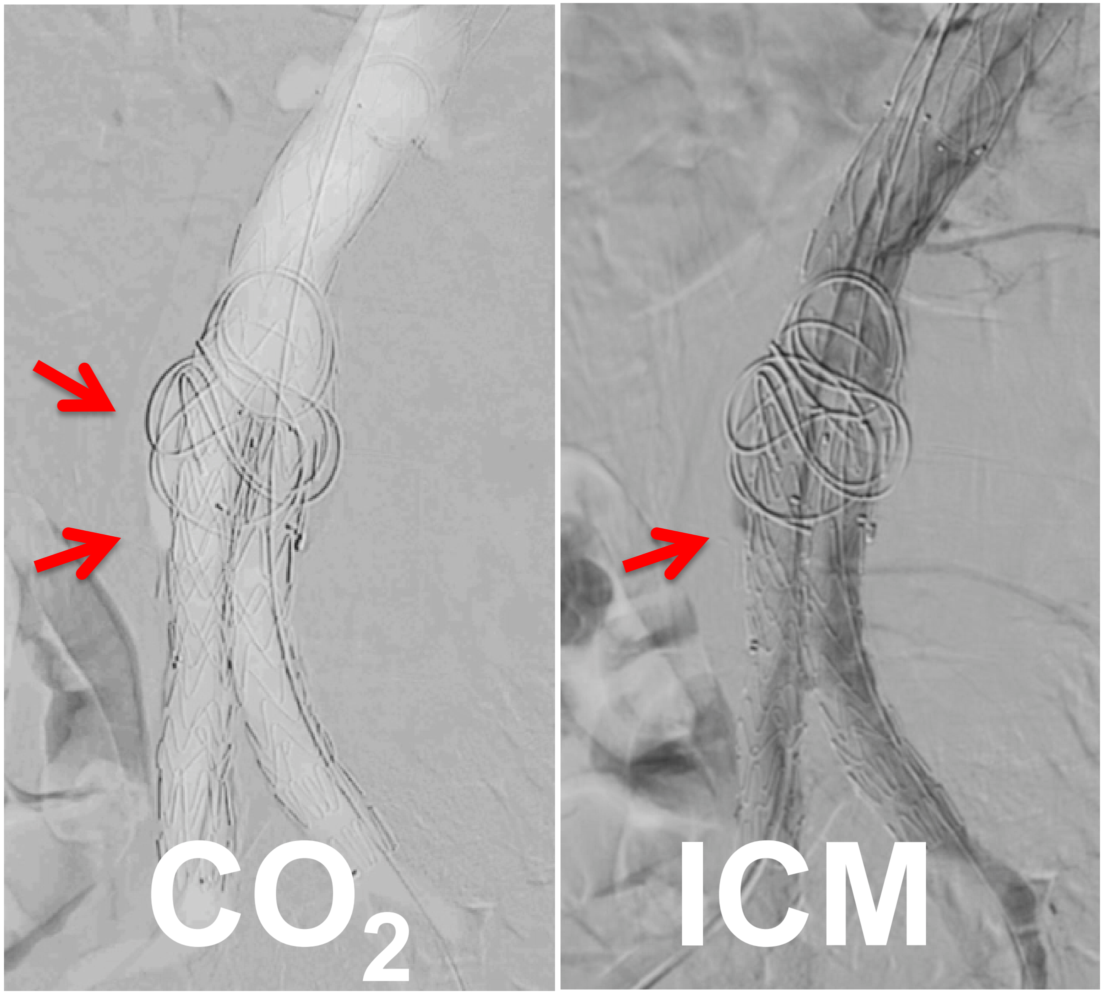
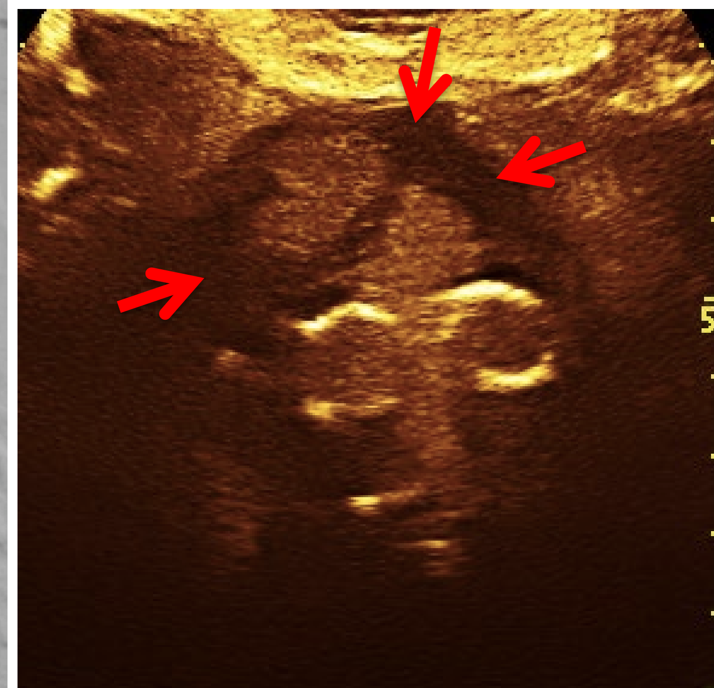
CO2 Angiography and Endoleak type II



Post-operative CEUS



Endoleak type II

ID PATIENT	CO_2	ICM	CEUS
5	✓	–	✓
9	✓	–	–
14	✓	–	✓
28	✓	–	✓
29	✓	–	–
Tot.	**10**	**2**	**5**

✓ : Detected
– : Undetected

ELII detection

- CEUS and ICM showed a poor agreement *(Cohen's K:0.35)*
- CEUS and CO_2 showed a substantial agreement *(Cohen's K:0.65)*

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Carbon dioxide digital subtraction angiography as an option for detection of endoleaks in endovascular abdominal aortic aneurysm repair procedure

Eijun Sueyoshi, MD, Hiroki Nagayama, MD, Ichiro Sakamoto, MD, and **Masataka Uetani, MD,** *Nagasaki, Japan*

Objective: **The purpose of this study was to evaluate carbon dioxide digital subtraction angiography (CO_2-DSA) as an option for the detection of endoleaks (ELs) in the endovascular abdominal aortic aneurysm repair (EVAR) procedure.**

Methods: **Forty patients with abdominal aortic aneurysm who were scheduled to undergo EVAR were enrolled in the study. There were 35 men and five women (mean age, 77.9 years). All patients had both iodinated contrast conventional DSA (C-DSA) and CO_2-DSA immediately after EVAR. The sensitivity and specificity were calculated for the ability of CO_2-DSA to detect ELs. We also correlated with computed tomography findings 6 months after EVAR.**

Results: **C-DSA showed that 27 of the 40 patients (68%) had 28 ELs (type I, four; type II, 20; type III, three; type IV, one). CO_2-DSA showed that 16 of the 40 patients (40%) had 17 ELs (type I, four; type II, 10; type III, three; type IV, none). For the prediction of direct ELs (type I and type III) with use of C-DSA as the criterion standard, CO_2-DSA has a sensitivity of 1.0 and a specificity of 1.0. For the detection of persistent type II ELs (n = 11) with use of computed tomography findings 6 months from EVAR as the criterion standard, CO_2-DSA has a sensitivity of 0.87 and a specificity of 0.97. C-DSA has a sensitivity of 0.82 and a specificity of 0.64.**

Conclusions: **CO_2-DSA is reliable for the detection of direct ELs and persistent type II ELs in EVAR. CO_2-DSA can be an option to detect ELs in the EVAR procedure. (J Vasc Surg 2015;61:298-303.)**

J Vasc Surg. 2015

Results - CO2 adverse event

- ✓ **Severe hypotension** during the procedure: **3 patients**
- ✓ **Nausea and vomiting** just before the onset of the hypotension: **2 patients**
- ✓ All the symptoms solved spontaneously

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Conclusion

CO_2 DSA

- ✓ Safe
- ✓ Excellent hypogastric artery visualization
- ✓ Excellent type II endoleak detection
- ✓ Renal arteries visualization to be improved

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EVAR and CO_2 DSA
European Multicenter, Prospective Study

Bologna – Italy (PI - Prof. Mauro Gargiulo)

Muenster (St. Franziskus + University Hospital) - Germany

Malmo - Sweden

Athens - Grece

Bordeaux - France

Aalst - Belgium

Ourense - Spain

Patients: 160

Objectives

- To improve Renal Arteries Visualization
- To standardize a CO_2 EVAR Protocol
- To achieve a zero contrast EVAR

Endpoints

- **Primary Endpoint:**
  Technical success (renal and hypogastric arteries assessment)

- **Secondary Endpoints:**
  - Image quality
  - Type I-IV Endoleak Detection
  - Amount of CO_2 at each deployment stage
  - Aneurysm Exclusion without type I-III EL

Endpoints

- Safety Endpoints:

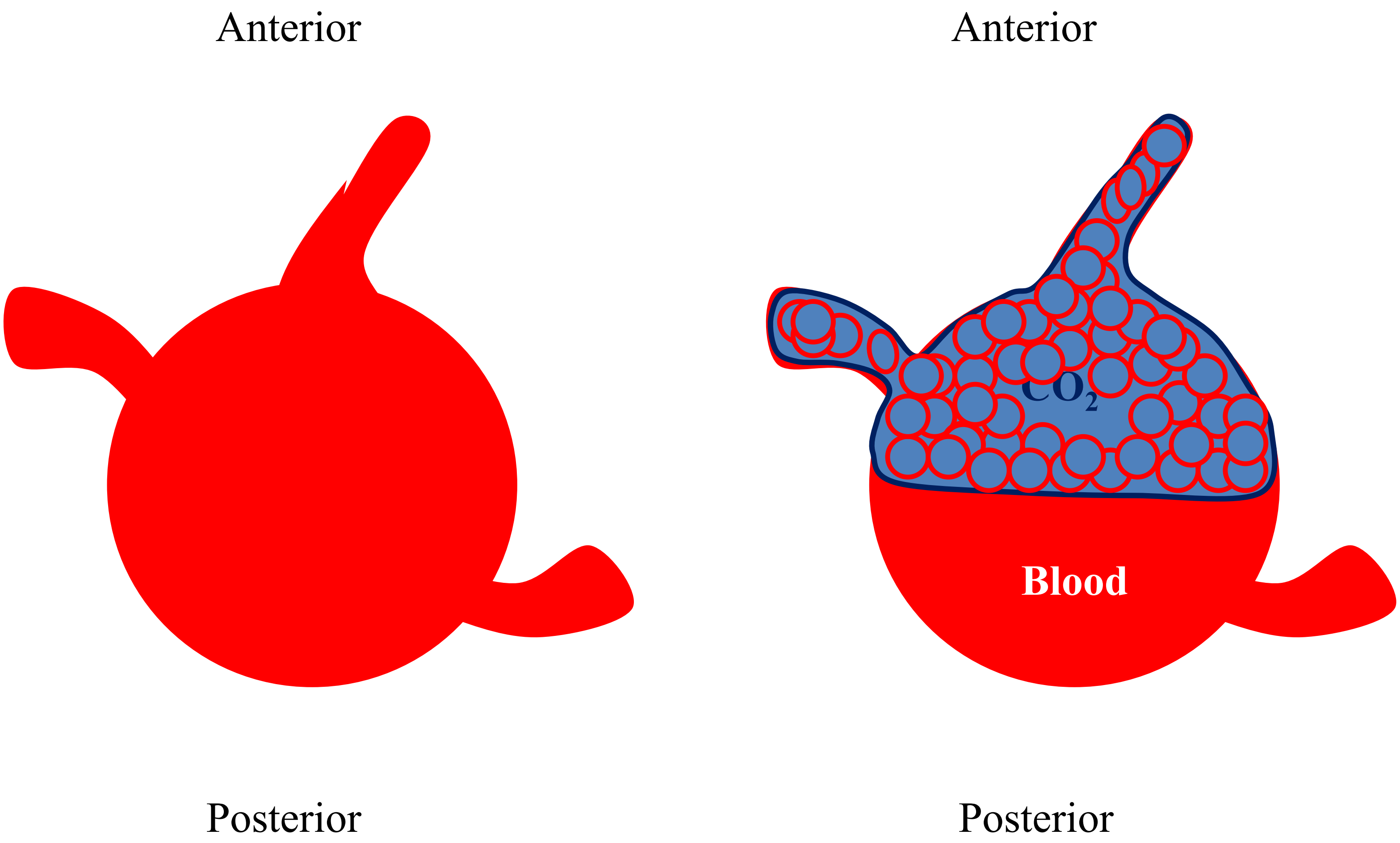
  - Intraoperative adverse events

    Severe Hypotension
    Pain
    Vomit
    Diarrhea

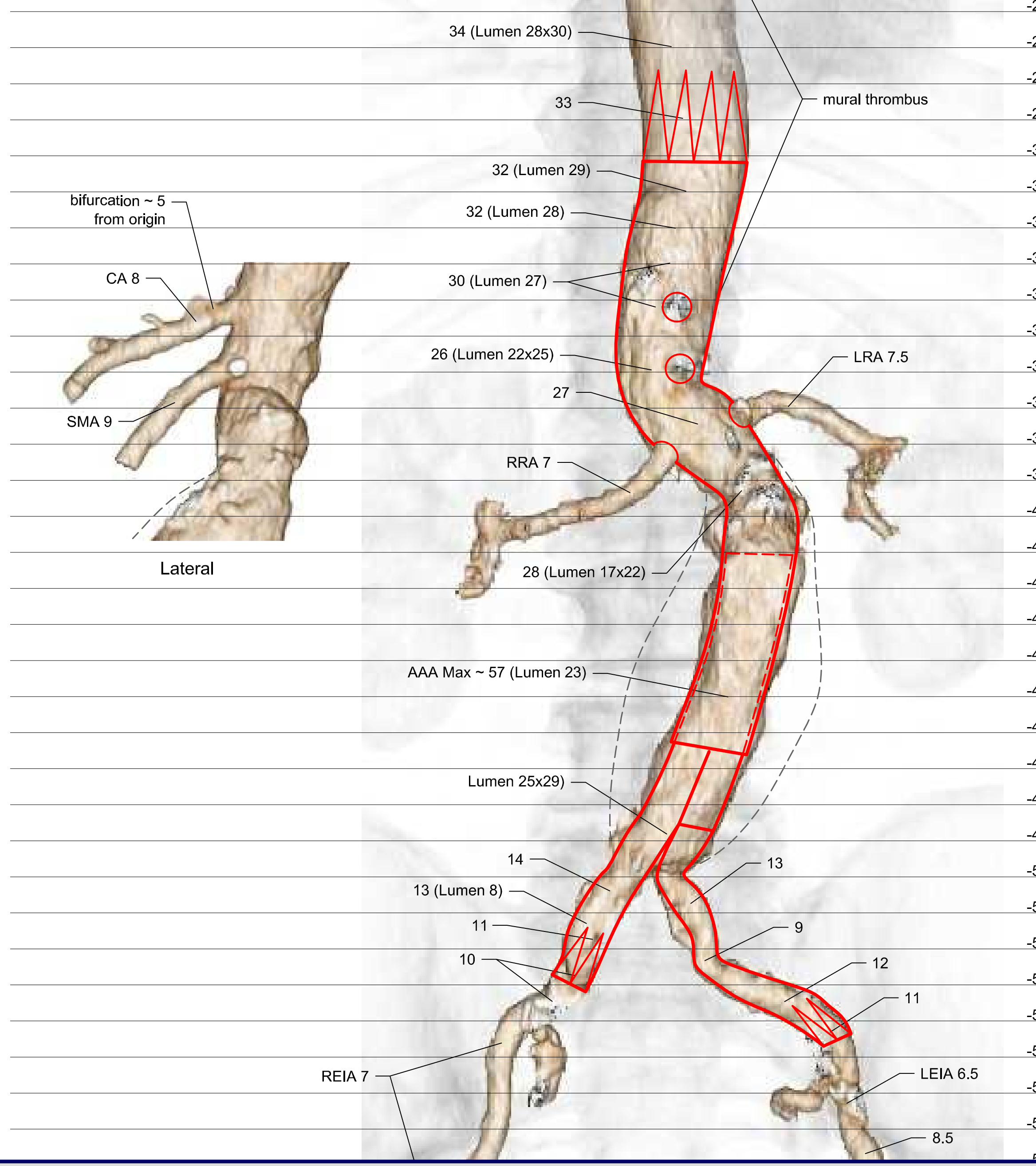
  - Postoperative adverse events (Creatinine, GFR, pCO_2, TCO_2)

    Severe Hypotension
    Pain
    Vomit
    Diarrhea
    Acute Renal Failure
    Allergic Reaction

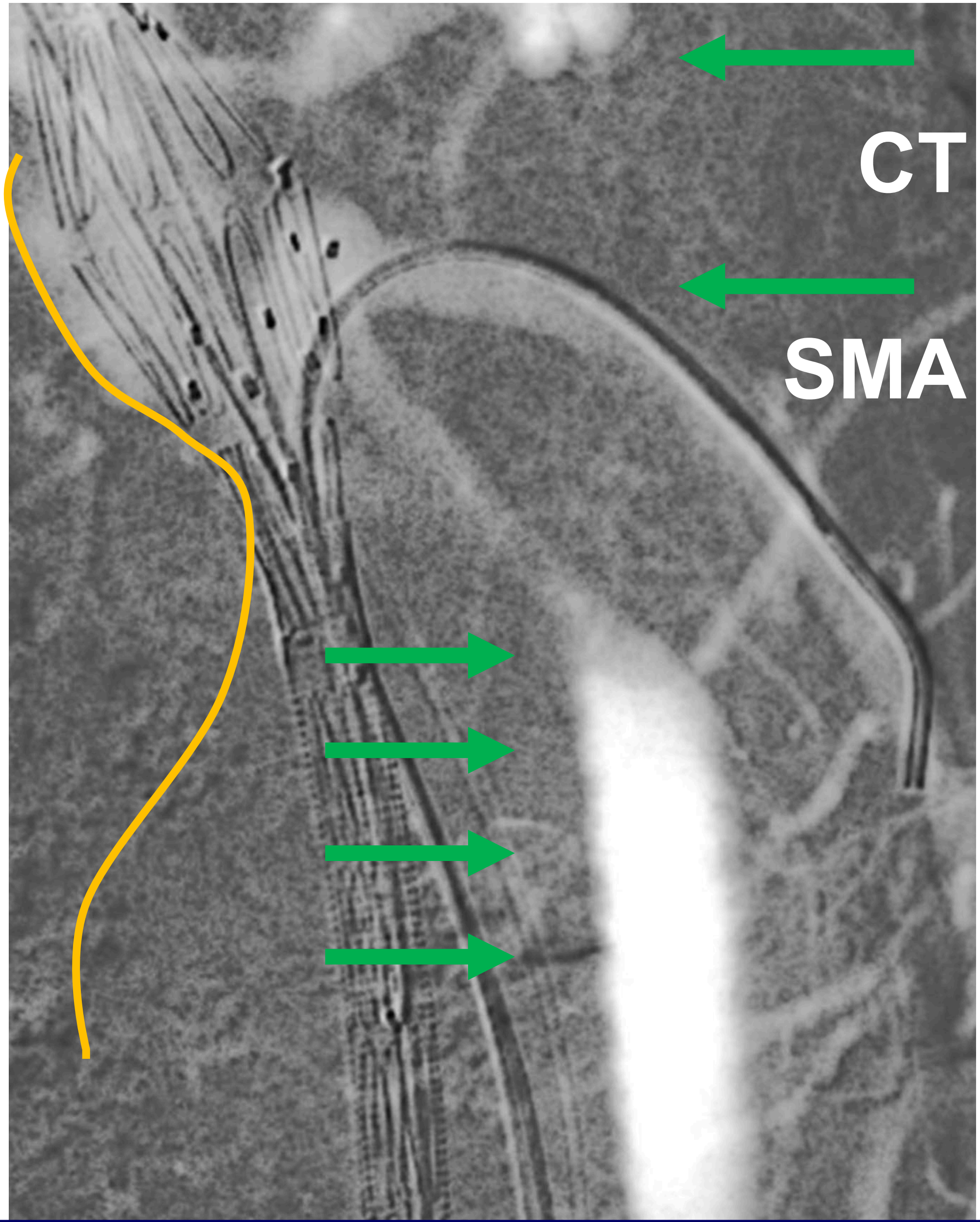
Target visceral vessels visualization

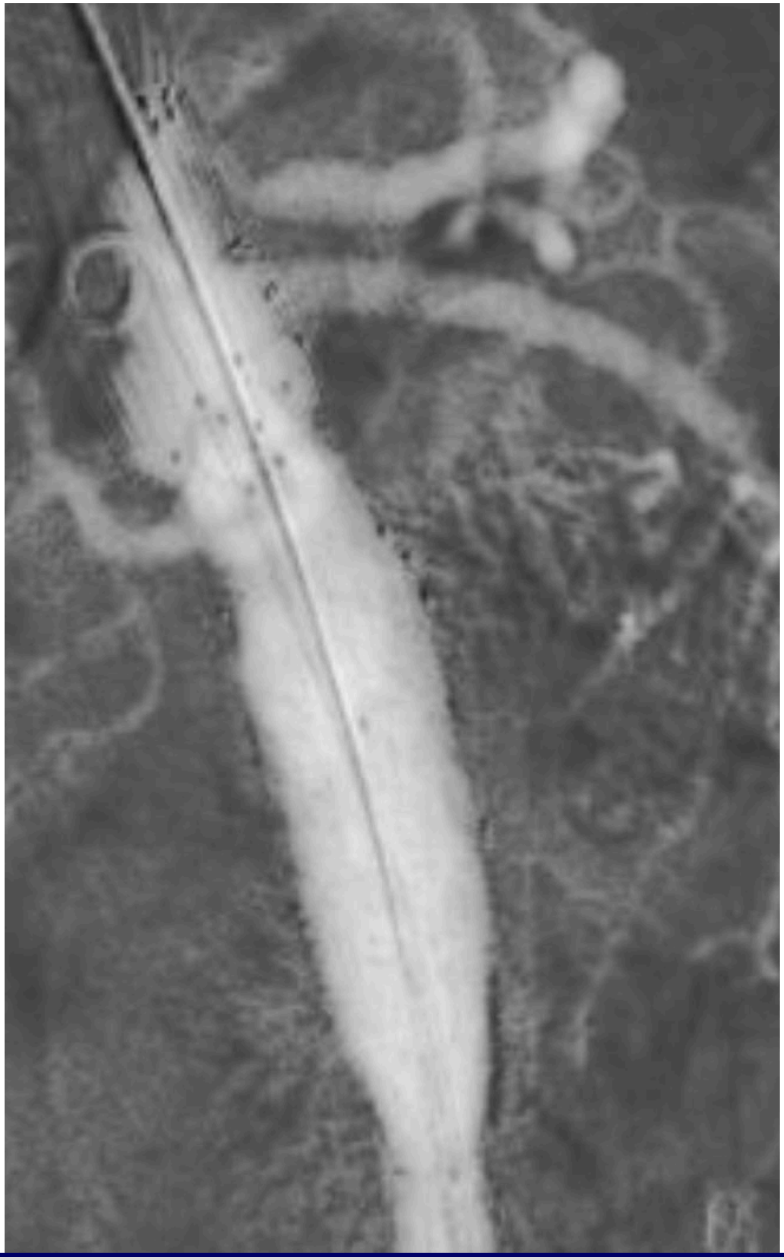


1 j-AAA



34 (Lumen 28x30)
33
mural thrombus
32 (Lumen 29)
bifurcation ~ 5
from origin
32 (Lumen 28)
CA 8
30 (Lumen 27)
26 (Lumen 22x25)
LRA 7.5
27
SMA 9
RRA 7
28 (Lumen 17x22)
Lateral
AAA Max ~ 57 (Lumen 23)
Lumen 25x29)
14
13
13 (Lumen 8)
11
9
10
12
11
REIA 7
LEIA 6.5
8.5


CT
SMA



The benefit of combined CO2 automated angiography and fusion imaging in preserving perioperative renal function in fenestrated endografting

Gallitto E et al
Submitted to JVS 2019

AIM: To compare results of 3 / 4 FEN performed by:

- ✓ CO_2 automated angiography + Vessels Navigator

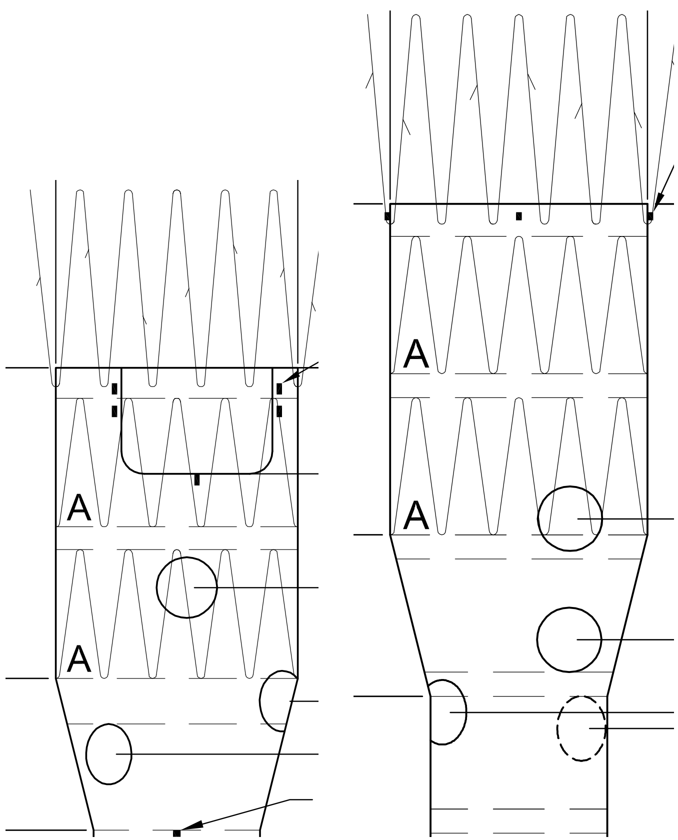
vs

- ✓ Iodinated contrast angiography + Vessel Navigator

Study design

- 2 groups
  - Prospective collection: January – April 2018
    CO2 angiography + Vessels Navigator
  - Retrospective collection: June – December 2017
    Iodinated contrast angiography + Vessels Navigator
- J/P-AAA or type IV TAAA
- 3 / 4 FEN endograft

Results - Endograft configuration



6 – 13%   39 – 87%

	CO_2 angiography %	Iodinated contrast media %	p
3 Fen	13	13	1
4 Fen	87	87	1

Results - Procedural data

	CO_2 angiography Median - IQR	**Iodinated contrast media** Median IQR	**p**
Time (min)	290 (135)	347.5 (111)	.07
Fluoroscopy Time (min)	60 (33)	75.5 (57)	.25
Total DAP (mGy/cm[2])	1201117 (571310)	892108.5 (834558)	.27
Iodinated contrast (mL)	**41 (26)**	**138.5 (88)**	**.001**

	CO_2 angiography %	**Iodinated contrast media** %	**p**
Technical Success	100	100	1
EL I – III *	7	7	1
EL II	27	20	.70

* 2 Endoleaks from bridging stent, intraoperatively detected and sealed

Results - TVVs visualization by CO_2

Before introduction	n	%
CT	15	100
SMA	15	100
RAs	19	63

Graft Introduction	n	%
CT	15	100
SMA	15	100
RAs	22	73

2 Stent deployed	n	%
CT	15	100
SMA	15	100
RAs	25	83

Results - @ 30-day

	CO_2 angiography %	Iodinated contrast media %	p
Death	0	0	-
SCI	0	0	-
Cardiac Morbidity	0	3	1
Pulmonary Morbidity	7	0	1
Renal function Worsening*	7	23	.45
Hemodialysis	0	0	-

	CO_2 angiography Median - IQR	Iodinated contrast media Median IQR	p
Creatinine increase (mg/dL)	0.09 (0.03)	0.3 (0.4)	.049
Hospitalization (days)	5 (1)	7.5 (4)	.002

* > 30% of baseline GFR

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Conclusion

1. Preliminary experience
2. Safe & effective
3. TS, procedure time, radiation dose are comparable with standard technique
4. Lower iodinated contrast, hospitalization, 30-day renal impairment
5. No difference in terms of 6-month reinterventions