CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE
CONTROVERSIES & UPDATES IN VASCULAR SURGERY
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MARRIOTT RIVE GAUCHE & CONFERENCE CENTER
PARIS, FRANCE
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Pre emptive treatment of Type II endoleaks

Coil embolisation is the most efficient way

D. Fabre, C. Angel.

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CENTRE CHIRURGICAL

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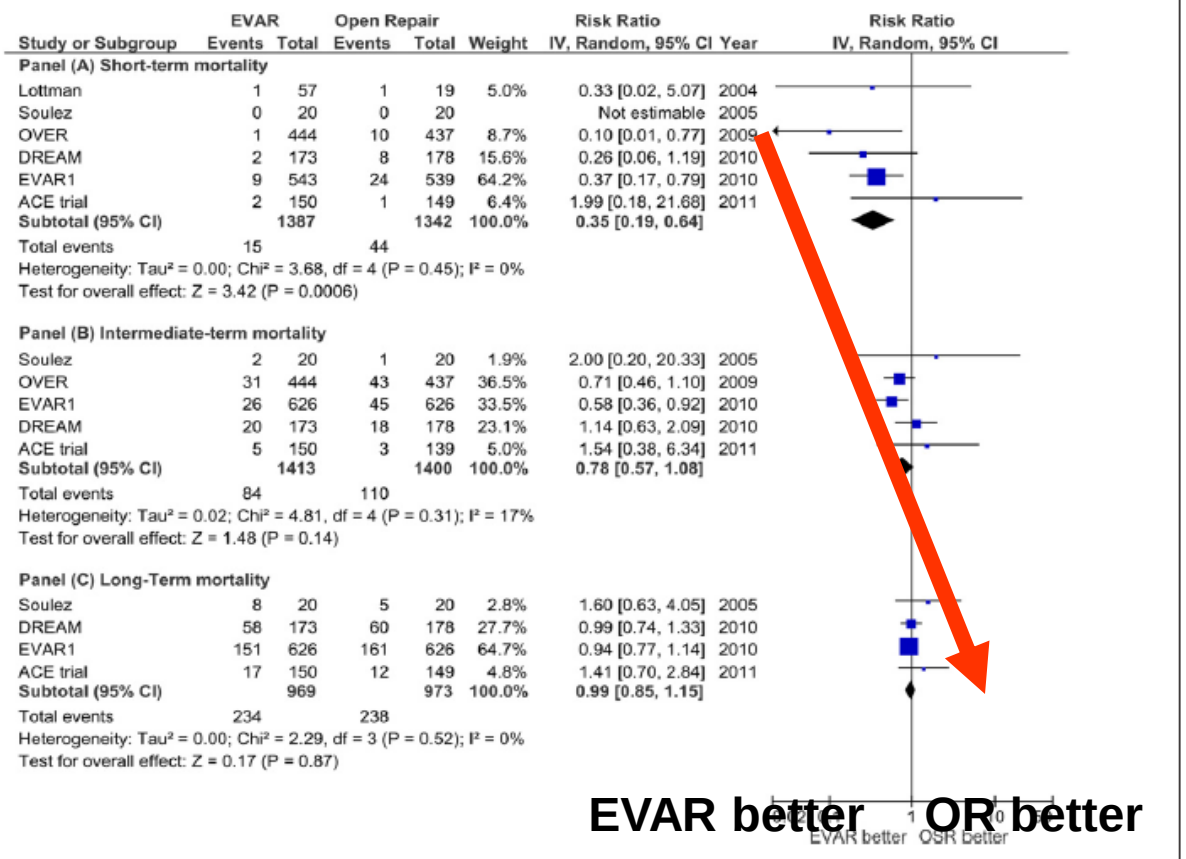
No disclosure

Background



Study or Subgroup	EVAR Events	EVAR Total	Open Repair Events	Open Repair Total	Weight	Risk Ratio IV, Random, 95% CI	Year
Panel (A) Short-term mortality							
Lottman	1	57	1	19	5.0%	0.33 [0.02, 5.07]	2004
Soulez	0	20	0	20		Not estimable	2005
OVER	1	444	10	437	8.7%	0.10 [0.01, 0.77]	2009
DREAM	2	173	8	178	15.6%	0.26 [0.06, 1.19]	2010
EVAR1	9	543	24	539	64.2%	0.37 [0.17, 0.79]	2010
ACE trial	2	150	1	149	6.4%	1.99 [0.18, 21.68]	2011
Subtotal (95% CI)		**1387**		**1342**	**100.0%**	**0.35 [0.19, 0.64]**	
Total events	15		44				
Heterogeneity: Tau² = 0.00; Chi² = 3.68, df = 4 (P = 0.45); I² = 0%							
Test for overall effect: Z = 3.42 (P = 0.0006)							
Panel (B) Intermediate-term mortality							
Soulez	2	20	1	20	1.9%	2.00 [0.20, 20.33]	2005
OVER	31	444	43	437	36.5%	0.71 [0.46, 1.10]	2009
EVAR1	26	626	45	626	33.5%	0.58 [0.36, 0.92]	2010
DREAM	20	173	18	178	23.1%	1.14 [0.63, 2.09]	2010
ACE trial	5	150	3	139	5.0%	1.54 [0.38, 6.34]	2011
Subtotal (95% CI)		**1413**		**1400**	**100.0%**	**0.78 [0.57, 1.08]**	
Total events	84		110				
Heterogeneity: Tau² = 0.02; Chi² = 4.81, df = 4 (P = 0.31); I² = 17%							
Test for overall effect: Z = 1.48 (P = 0.14)							
Panel (C) Long-Term mortality							
Soulez	8	20	5	20	2.8%	1.60 [0.63, 4.05]	2005
DREAM	58	173	60	178	27.7%	0.99 [0.74, 1.33]	2010
EVAR1	151	626	161	626	64.7%	0.94 [0.77, 1.14]	2010
ACE trial	17	150	12	149	4.8%	1.41 [0.70, 2.84]	2011
Subtotal (95% CI)		**969**		**973**	**100.0%**	**0.99 [0.85, 1.15]**	
Total events	234		238				
Heterogeneity: Tau² = 0.00; Chi² = 2.29, df = 3 (P = 0.52); I² = 0%							
Test for overall effect: Z = 0.17 (P = 0.87)							

Figure 2. All-Cause Mortality

(A) Pooled mortality rates reported at 30-day post-procedure follow-up. **(B)** Cumulative outcomes reported at intermediate follow-up (up to 2 years after procedure). **(C)** Cumulative outcomes reported at follow-up of at least 3 years after procedure. CI = confidence interval(s); IV = intravenous; OSR = open surgical repair; other abbreviations as in Figure 1.

30 days

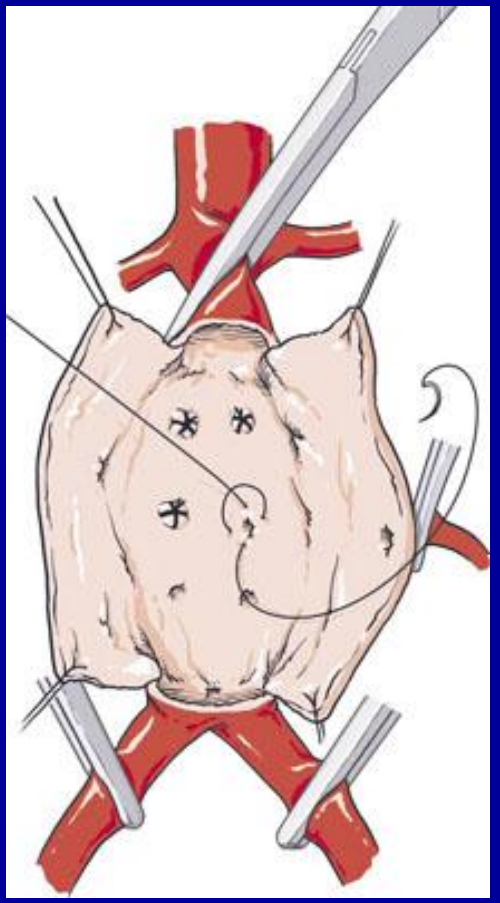
2 years

> 3 years

EVAR / Open Metanalysis *JACC* 2012

Background

- Open repair (OR) is the reference treatment for AAA
- Two step procedure
  - aneurysm opening (lumbar arteries ligation)
  - aortic graft replacement
- Definitive treatment
- No need for a close follow-up

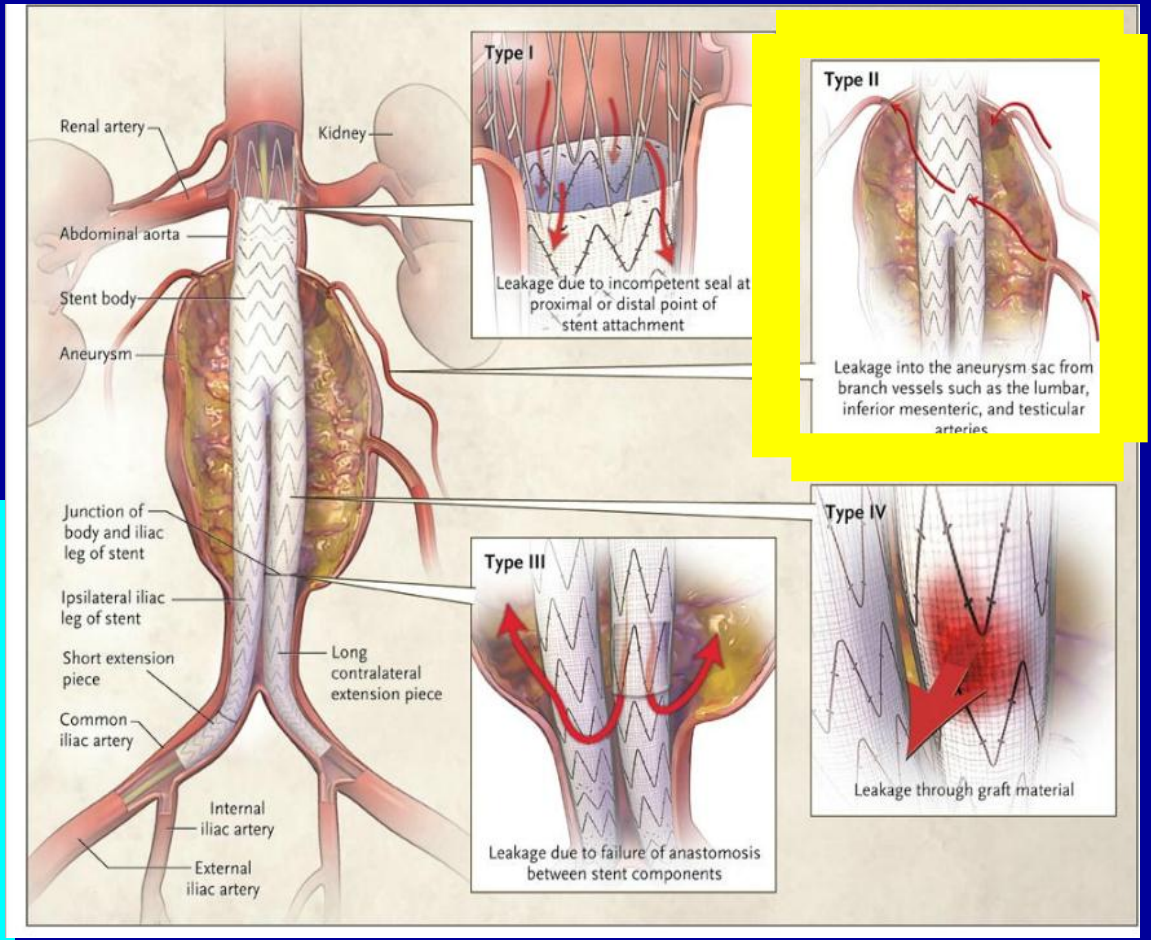


Aneurysm opening is the main difference between EVAR or OR

Type II Endoleak

- Actual level: 8% to 28% at one year
- Eurostar register: 22.2% (1818 / 8165)
- Treatment recommanded if aneurysm enlargement

- Solutions:
  - Preoperative embolization
  - Operative procedure
  - Post-operative procedure



Background

Why should we prevent type II Endoleak?

Vascular Medicine

Predictors of Abdominal Aortic Aneurysm Sac Enlargement After Endovascular Repair

Andres Schanzer, MD; Roy K. Greenberg, MD; Nathanael Hevelone, MPH; William P. Robinson, MD; Mohammad H. Eslami, MD; Robert J. Goldberg, PhD; Louis Messina, MD

Background—The majority of infrarenal abdominal aortic aneurysm (AAA) repairs in the United States are performed with endovascular methods. Baseline aortoiliac arterial anatomic characteristics are fundamental criteria for appropriate patient selection for endovascular aortic repair (EVAR) and key determinants of long-term success. We evaluated compliance with anatomic guidelines for EVAR and the relationship between baseline aortoiliac arterial anatomy and post-EVAR AAA sac enlargement.

Methods and Results—Patients with pre-EVAR and at least 1 post-EVAR computed tomography scan were identified from the M2S, Inc. imaging database (1999 to 2008). Preoperative baseline aortoiliac anatomic characteristics were reviewed for each patient. Data relating to the specific AAA endovascular device implanted were not available. Therefore, morphological measurements were compared with the most liberal and the most conservative published anatomic guidelines as stated in each manufacturer's instructions for use. The primary study outcome was post-EVAR AAA sac enlargement (>5-mm diameter increase). In 10 228 patients undergoing EVAR, 59% had a maximum AAA diameter below the 55-mm threshold at which intervention is recommended over surveillance. Only 42% of patients had anatomy that met the most conservative definition of device instructions for use; 69% met the most liberal definition of device instructions for use. The 5-year post-EVAR rate of AAA sac enlargement was 41%. Independent predictors of AAA sac enlargement included endoleak, age ≥80 years, aortic neck diameter ≥28 mm, aortic neck angle >60°, and common iliac artery diameter >20 mm.

Conclusion—In this multicenter observational study, compliance with EVAR device guidelines was low and post-EVAR aneurysm sac enlargement was high, raising concern for long-term risk of aneurysm rupture. (***Circulation*. 2011;123:2848-2855.**)

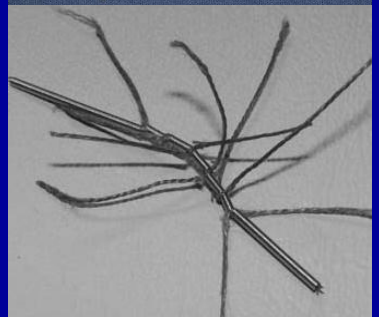
Key Words: abdominal aortic aneurysm ■ endovascular procedures ■ graft

Schanzer Circulation 2011

Endoleak = Independant factor for aneurysm Enlargement

How could we replace aneurysm opening and lumbar arteries ligation?

- Complete thrombosis of the aneurysm sac could replace the opening of the aneurysm
- Thrombosis should be definitive
- Material used could be:
  - Glue
  - Coils
  - Thrombogenic material
  - Thrombin
  - Gelatin Sponge
  - Polyurethane foam
  - Onyx (ethylene-vinyl alcohol copolymer)
  - Amplatzer
  - Plugs…



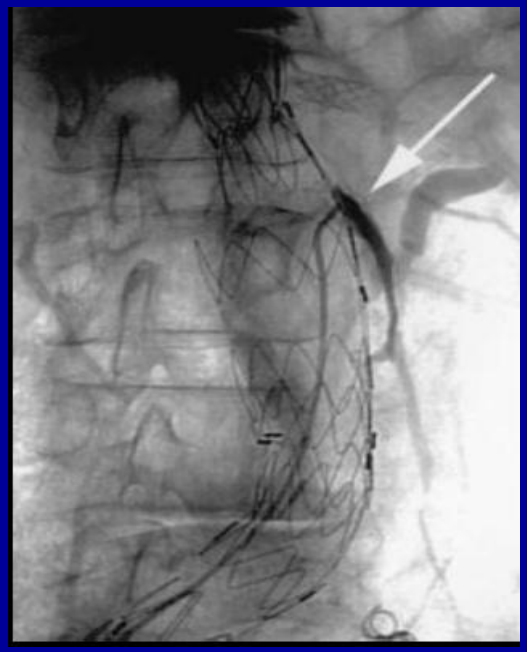
SAFE AND SAFE

Long-term postplacement cost after endovascular aneurysm repair

- hospital cost associated with EVAR is approximately : $20,000
- cumulative 5-year postplacement cost per patient was: $11,351

The 5-year cost for patients with endoleak $26,739

The 5-year cost for patients without endoleak $5706



4.7-fold increase, P < .05

Noll *JVS* 2007

Preoperative embolization

Clinical Studies

Inferior Mesenteric Artery Embolization before Endovascular Repair of an Abdominal Aortic Aneurysm: Effect on Type II Endoleak and Aneurysm Shrinkage

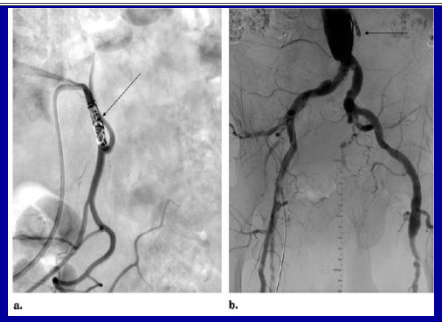
Terhi Nevala, MD, Fausto Biancari, MD, PhD, Hannu Manninen, MD, PhD, Pekka Matsi, MD, PhD, Kimmo Mäkinen, MD, PhD, Kari Ylönen, MD, and Jukka Perälä, MD, PhD

PURPOSE: To evaluate the value of preoperative embolization of the inferior mesenteric artery (IMA) before endovascular repair of an abdominal aortic aneurysm.

MATERIALS AND METHODS: From January 2000 to October 2006, 79 patients (mean age, 72.3 years; 69 men) scheduled for endovascular aneurysm repair (EVAR) were found to have a patent IMA at computed tomography. Coil embolization of the patent IMA was performed in 40 patients at Kuopio University Hospital, and their outcome was compared with that of 39 patients with a patent IMA who underwent EVAR at Oulu University Hospital without preoperative IMA embolization (control group). All patients were treated with a Zenith stent-graft. The mean follow-up time was 3.4 years ± 1.7 (median, 3.1 years; range, 0–7.6 years).

RESULTS: There were significantly fewer type II endoleaks in the IMA embolization group than in the control group (25% vs 59%, respectively; $P = .002$). Preoperative IMA embolization did not correlate with aneurysm size change. The overall linearized aneurysm shrinkage rate per year was 1.4 mm per year ± 3.8 in the IMA embolization group and 1.7 mm per year ± 2.4 in the control group ($P = .72$).

CONCLUSIONS: Preoperative coil embolization of the IMA reduced the frequency of type II endoleaks after EVAR, but the authors failed to show any influence on late postoperative aneurysm shrinkage.



IMA

No influence on late postoperative shrinkage

J ENDOVASC THER
2003;10:227–232

◆ CLINICAL INVESTIGATION

Preoperative Embolization of Collateral Side Branches: A Valid Means to Reduce Type II Endoleaks After Endovascular AAA Repair

Robert Bonvini, MD[1]; Mario Alerci, MD[2]; Francesco Antonucci, MD[2]; Paolo Tutta, MD[1]; Rolf Wyttenbach, MD[4]; Marcel Bogen, MD[3]; Angelo Pelloni, MD[3]; Ludwig von Segesser, MD[5]; and Augusto Gallino, MD[1]

Departments of [1]Vascular Medicine, [2]Interventional Radiology, [3]Surgery, and [4]Radiology, Ospedale Regionale Bellinzona e Valli, Bellinzona, Switzerland; and [5]Division of Cardiovascular Surgery, CHUV, Lausanne, Switzerland

Purpose: To report the results of preprocedural embolization of collateral branches arising from abdominal aortic aneurysms (AAA) scheduled for endovascular repair.
Methods: Twenty-three consecutive AAA patients (all men; mean age 73 years, range 56–82) had coil embolization of patent lumbar and inferior mesenteric arteries (IMA) in a staged procedure prior to endovascular repair. Embolization with microcoils was attempted in 37 of the 52 identified lumbar arteries and 14 of 15 inferior mesenteric arteries. Follow-up included biplanar abdominal radiography, spiral computed tomography, and duplex ultrasonography at 1, 30, 90, and 180 days after the stent-graft procedure and at 6-month intervals thereafter.
Results: Successful embolization was obtained in 24 (65%) of lumbar arteries, while all 14 (100%) IMAs were occluded with coils. No complication was associated with embolotherapy. Over a mean 17-month follow-up of 22 patients (1 intraoperative death), there was only 1 (4.5%) type II endoleak from a patent lumbar artery, with no sac expansion after 2 years. There were 4 (18%) type I and 1 (4.5%) type III endoleaks.
Conclusions: The embolization of side branches arising from an infrarenal aortic aneurysm before endovascular repair is feasible, with a high success rate; this maneuver may play a relevant role in reducing the rate of type II endoleak, improving long-term outcome.
J Endovasc Ther 2003;10:227–232

Key words: abdominal aortic aneurysm, endovascular repair, stent-graft, complication, endoleak, lumbar artery, inferior mesenteric artery, coil embolization

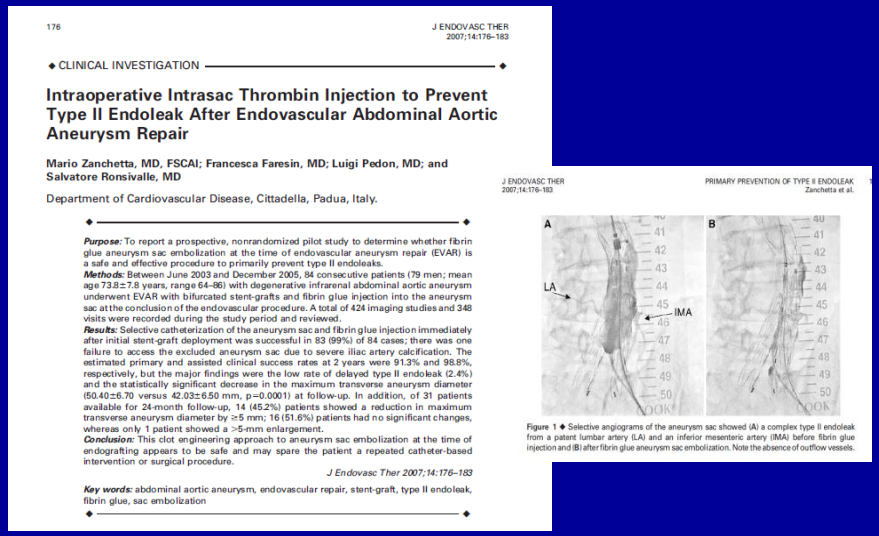
Collateral Side Branches

- Safe procedure
- No sac extension

- Persistent endoleak in 4.5%

Intraoperative embolization

Thrombin



176 J ENDOVASC THER 2007;14:176–183

◆ CLINICAL INVESTIGATION ◆

Intraoperative Intrasac Thrombin Injection to Prevent Type II Endoleak After Endovascular Abdominal Aortic Aneurysm Repair

Mario Zanchetta, MD, FSCAI; Francesca Faresin, MD; Luigi Pedon, MD; and Salvatore Ronsivalle, MD

Department of Cardiovascular Disease, Cittadella, Padua, Italy.

Purpose: To report a prospective, nonrandomized pilot study to determine whether fibrin glue aneurysm sac embolization at the time of endovascular aneurysm repair (EVAR) is a safe and effective procedure to primarily prevent type II endoleaks.

Methods: Between June 2003 and December 2005, 84 consecutive patients (79 men; mean age 73.8±7.8 years, range 64–86) with degenerative infrarenal abdominal aortic aneurysm underwent EVAR with bifurcated stent-grafts and fibrin glue injection into the aneurysm sac at the conclusion of the endovascular procedure. A total of 424 imaging studies and 348 visits were recorded during the study period and reviewed.

Results: Selective catheterization of the aneurysm sac and fibrin glue injection immediately after initial stent-graft deployment was successful in 83 (99%) of 84 cases; there was one failure to access the excluded aneurysm sac due to severe iliac artery calcification. The estimated primary and assisted clinical success rates at 2 years were 91.3% and 98.8%, respectively, but the major findings were the low rate of delayed type II endoleak (2.4%) and the statistically significant decrease in the maximum transverse aneurysm diameter (50.40±6.70 versus 42.03±6.50 mm, p=0.0001) at follow-up. In addition, of 31 patients available for 24-month follow-up, 14 (45.2%) patients showed a reduction in maximum transverse aneurysm diameter by ≥5 mm; 16 (51.6%) patients had no significant changes, whereas only 1 patient showed a >5-mm enlargement.

Conclusion: This clot engineering approach to aneurysm sac embolization at the time of endografting appears to be safe and may spare the patient a repeated catheter-based intervention or surgical procedure.

J Endovasc Ther 2007;14:176–183

Key words: abdominal aortic aneurysm, endovascular repair, stent-graft, type II endoleak, fibrin glue, sac embolization

J ENDOVASC THER 2007;14:176–183 PRIMARY PREVENTION OF TYPE II ENDOLEAK Zanchetta et al.

Figure 1 ◆ Selective angiograms of the aneurysm sac showed (A) a complex type II endoleak from a patent lumbar artery (LA) and an inferior mesenteric artery (IMA) before fibrin glue injection and (B) after fibrin glue aneurysm sac embolization. Note the absence of outflow vessels.

- Decrease of type II endoleak to 2.4%
- No AAA size regression

Gelatin Sponge

Prevention of lumbar artery endoleaks following EVAR with the selective use of absorbable gelatin sponge.

S. R. Walker, J. Macierewicz, B. R. Hopkinson
BJS 2002

Low cost
No long term results

Intraoperative intrasac Coil and Fibrin glue injection during EVAR

doi:10.1510/icvts.2009.231167

INTERACTIVE CARDIOVASCULAR AND THORACIC SURGERY

Interactive CardioVascular and Thoracic Surgery 11 (2010) 78-82

www.icvts.org

ESCVS article - Aortic and aneurysmal

Intrasac fibrin glue injection after platinum coils placement: the efficacy of a simple intraoperative procedure in preventing type II endoleak after endovascular aneurysm repair☆

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Operative Unit of Vascular and Endovascular Surgery, San Bortolo Hospital, Vicenza, Italy

Received 14 December 2009; received in revised form 17 March 2010; accepted 21 March 2010

Abstract

Objectives: To verify in our experience if fibrin glue injection into the aneurysm sac, made at the end of endovascular aneurysm repair (EVAR), can reduce type II endoleak rates. **Methods:** Between January 2005 and February 2008, 38 patients underwent EVAR for an unruptured abdominal aortic aneurysm. The first 20 consecutive patients (Group A) had standard EVAR while the last 18 patients (Group B) had EVAR with fibrin glue injection into the sac, regardless of type II endoleak's presence. **Results:** There was no statistically significant difference between the two groups concerning the surgical time and the time of X-ray exposure ($P=0.30$ and 0.54, respectively). Type II endoleak rate was significantly higher in Group A compared to Group B (6 cases, 30% vs. 1 case, 5.5%, respectively, $P=0.05$). Primary short-term clinical success was 95% and 100%, respectively. At 12 months, selective lumbar embolization was performed in two patients in Group A and in one patient in Group B. Patients in Group A had less computed tomography (CT) studies than patients in Group B (2.0 vs. 1.2, respectively, $P=0.024$). **Conclusions:** Fibrin glue injection is a safe procedure and seems to reduce type II endoleak rates. Patients who received this procedure had fewer CT examinations, with reduced health-care costs.

Keywords: Abdominal aortic aneurysm; Endovascular repair; Type II endoleak; Fibrin glue; Sac embolization

Safe and feasible procedure

Statistically significant decrease in type II endoleak rates.

Essential in preventing this complication at the end of EVAR.

Midterm outcomes after treatment of type II endoleaks associated with aneurysm sac expansion

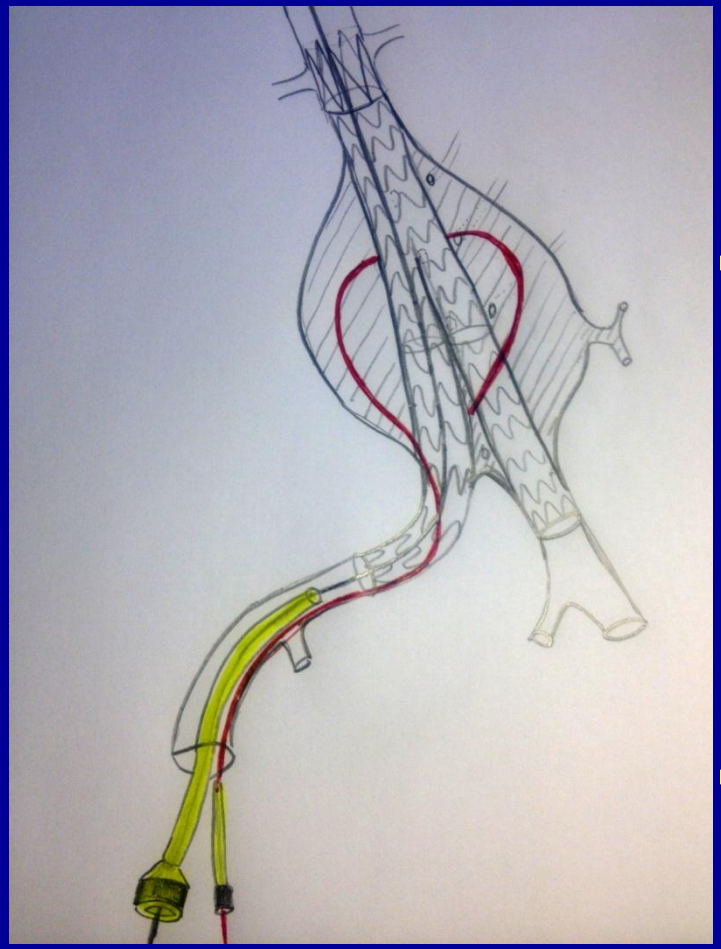
- Independent predictors of type II endoleak:
  - mural thrombus ($p<0.001$),
  - patent lumbar arteries ($p = 0.004$),
  - aneurysm length ($p = 0.011$)
  - iliac artery length ($p = 0.004$).

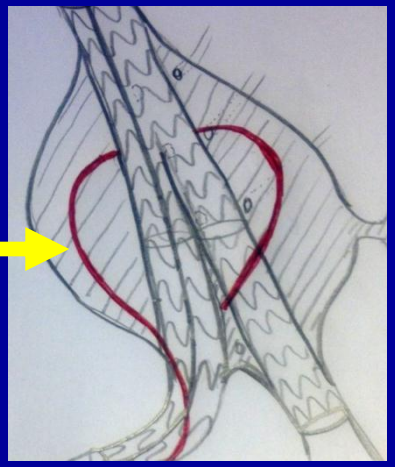
•Gallagher KA *J Endovasc Ther.* 2012

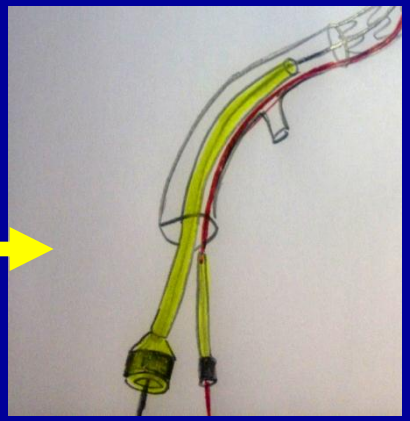
Marie Lannelongue's Procedure Intraoperative coils embolization during EVAR

- Limited to Patients with risk for type II endoleak
- No circumferential thrombus
- IFU guidelines

COIL EMBOLIZATION / First step



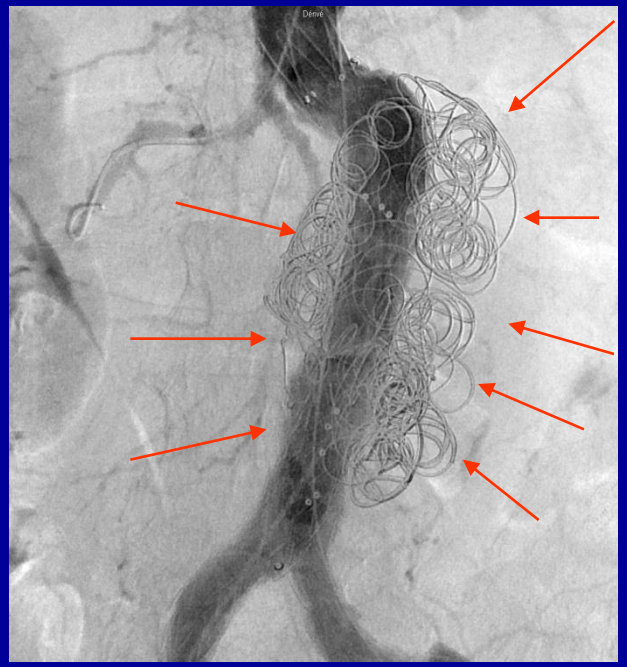




TERUMO GUIDE IN ANEURYSM SAC BEFORE CONTROLATERAL ILIAC LEG DEPLOYMENT

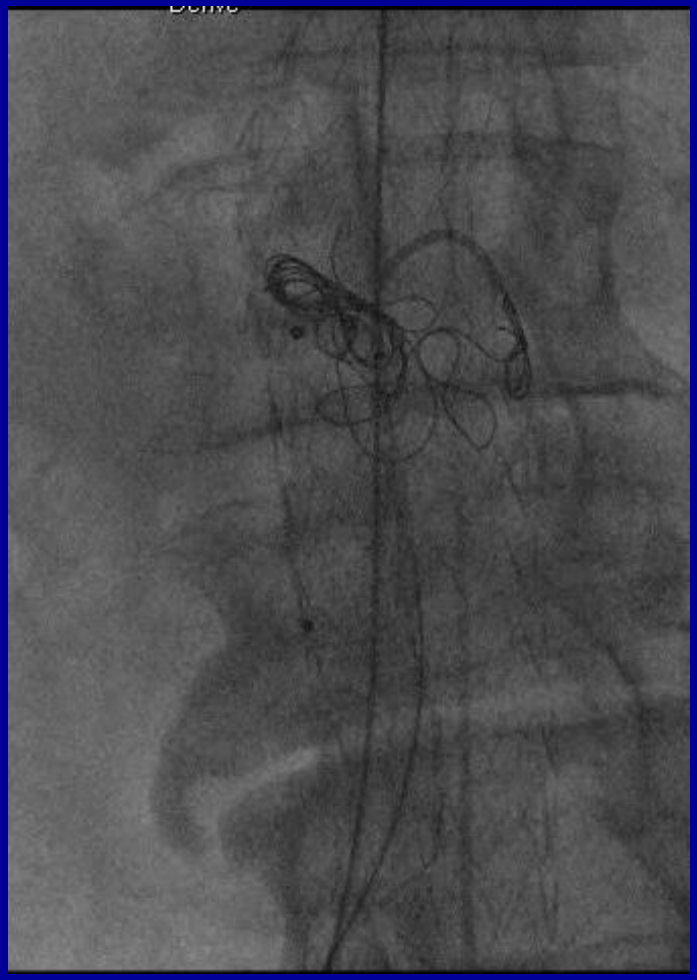
4Fr Introduceur

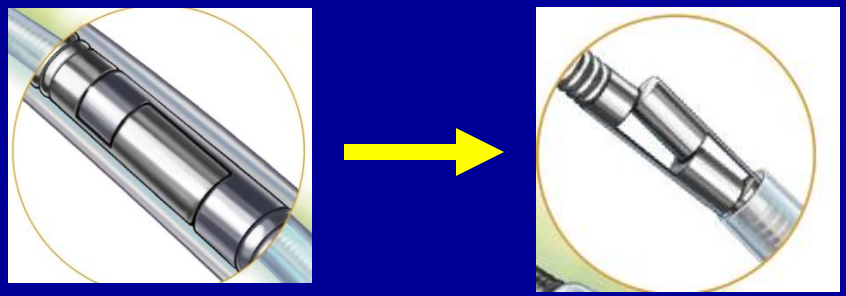
COIL EMBOLIZATION / Second step



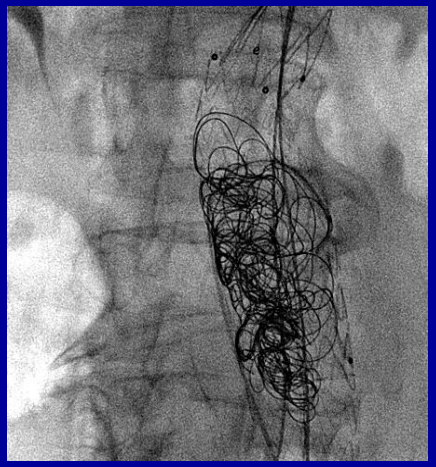
AFTER CONTROLATERAL ILIAC LEG DEPLOYMENT
USING MICROCATHETER / 10 TO 18 COILS (30 cm lenght)

Very safe procedure





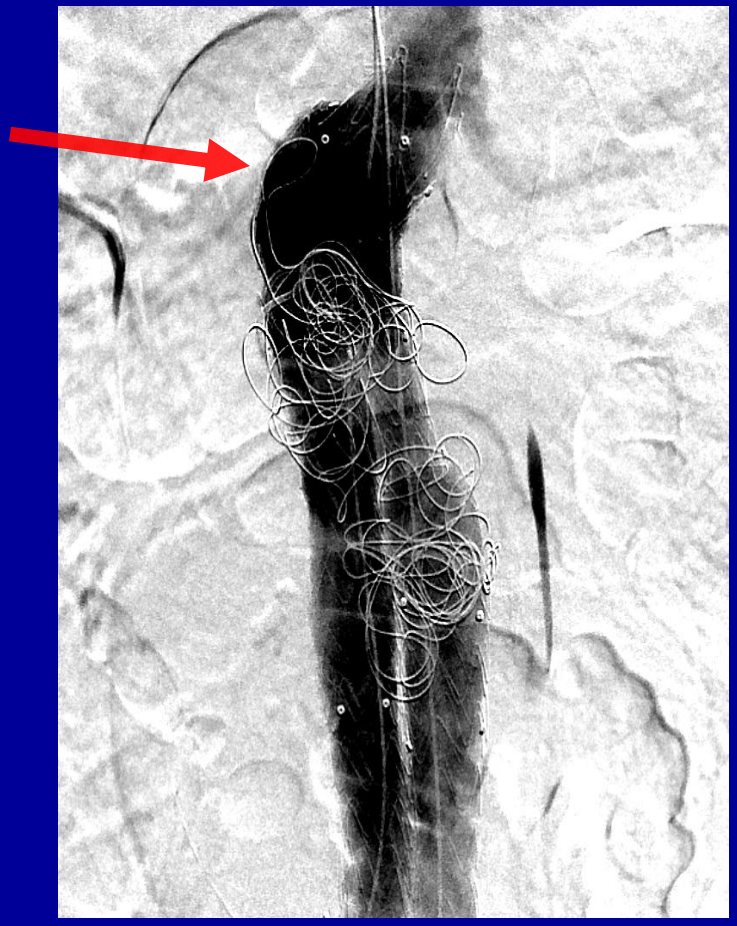
COIL EMBOLIZATION / Third step



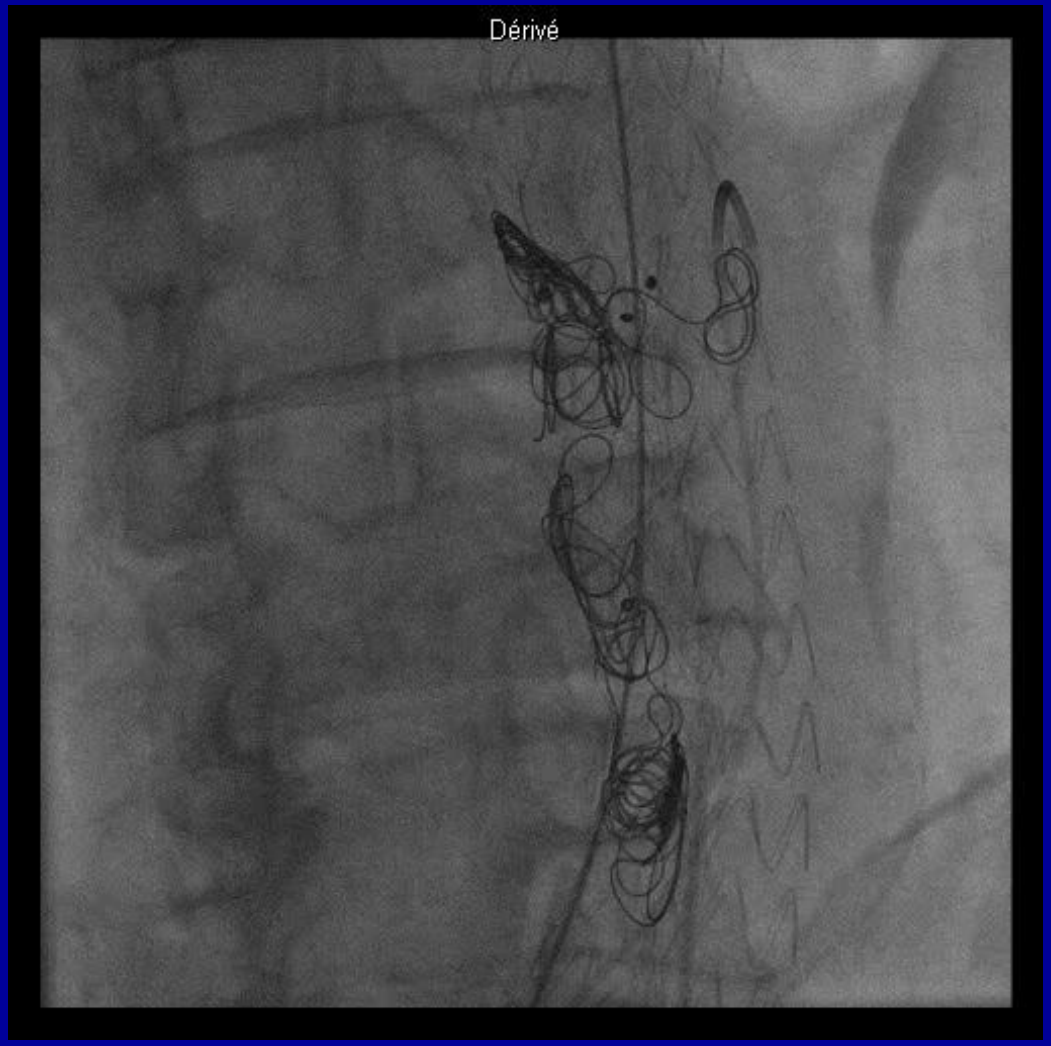
Ballooning, angiographic control and microcatheter withdrawal

Coils just under angulated neck
to avoid type I endoleak

Coils just under short neck
to avoid type I endoleak



Controlled release around the prosthesis



Marie Lannelongue's Experience 10/2009 to 11/2012

119 EVAR

Patient at risk for Type II Endoleak (Ref)

66 Pts / 55%

Patient with low risk for Type II Endoleak

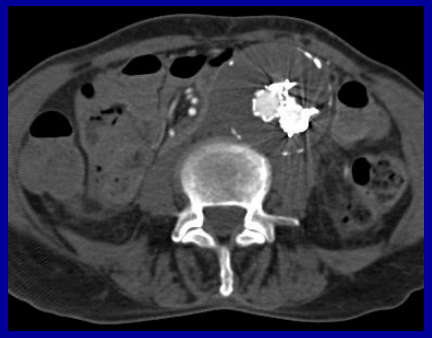
53 Pts / 45%

Midterm outcomes after treatment of type II endoleaks associated with aneurysm sac expansion
Gallagher KA *J Endovasc Ther.* 2012

Procedure / stentgraft 2009 - 2012

- Mean length of the aortic neck: 17 mm (range 9-35 mm).
- Mean maximal aneurysmal diameter: 56.8 mm (range 48.5-92mm)

- Procedure:
  - 65 aorto bi-iliac EVAR
  - 1 aorto uni-iliac EVAR with controlateral iliac occlusion
- Stentgraft:
  - Talent 6
  - Zenith 3
  - Gore 2
  - Vascutek 1
  - Endurant 54



Results
66 Patients

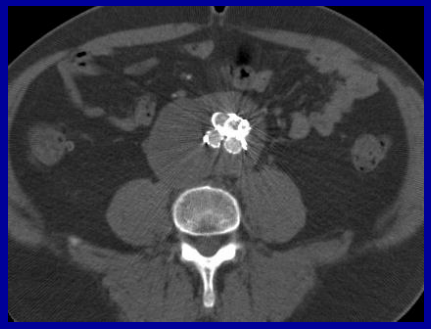
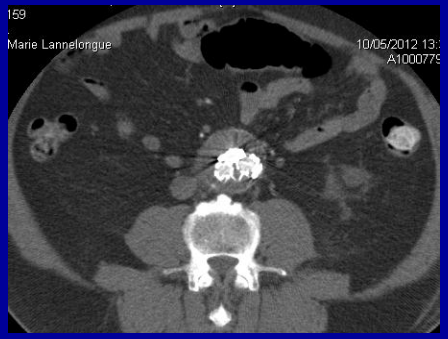
- No complication related to coils embolization
- In hospital mortality 0%
- O type II Endoleak

- 7% of type I Endoleak
  - (3 proximal and 2 distal)
  - Treatment with proximal extension or CP stent for proximal leak in 2 cases during hospitalisation and 1 case at 3 months
  - Treatment with covered stent extension for distal leak

  In 2 cases at 6 months and 1 year

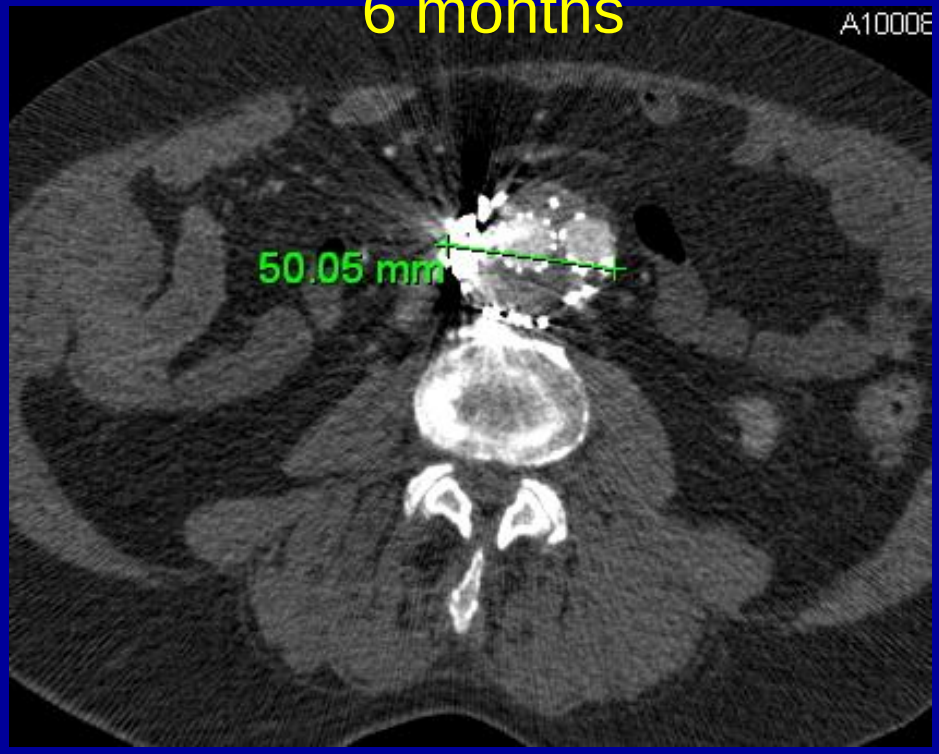
Results

Statistical regression of aneurysm size at 6 months

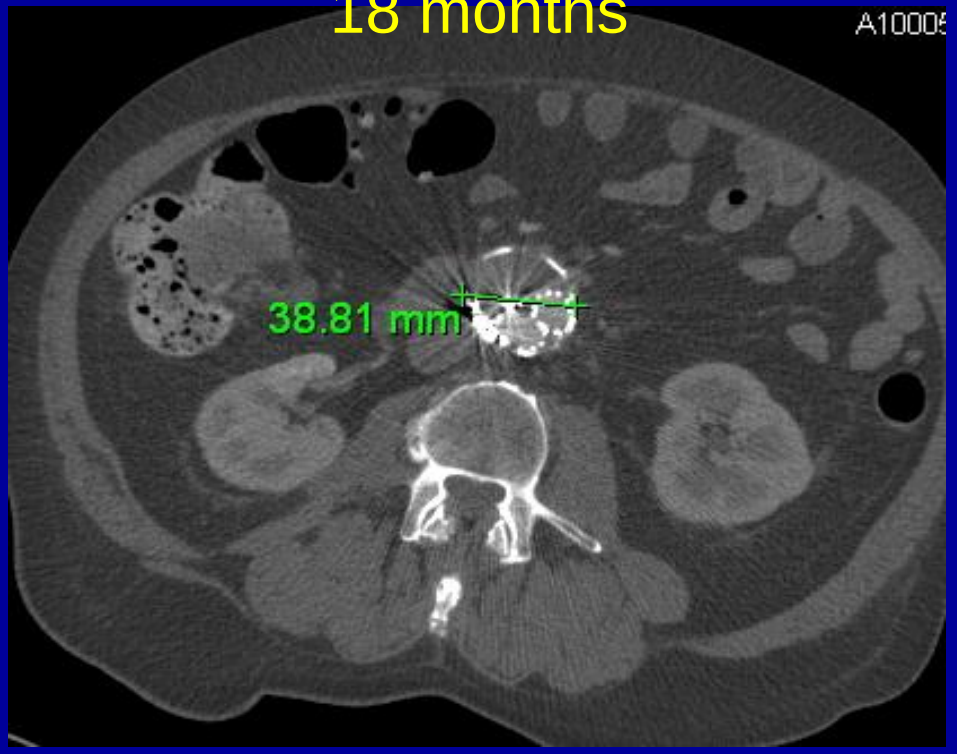
	1 Month	6 Months
Patient 1		
Patient 2		

Artifacts from coiled aneurysms

6 months



18 months



Theses results should be weighted by the difficulty
to detect small endoleaks

Conclusion

We have optimal release control during the embolization procedure.
Systematic coil embolization of the aneurysm sac during EVAR is technically feasible and clinically effective in preventing type II endoleak, with no complications.
Long term follow-up is required to confirm our results.
This technique reliably achieves complete thrombosis of the aneurysm sac, even in patients with numerous patent aortic side branches, drastically reducing the rate of all endoleaks.

We plan on conducting a prospective trial called SCOPE 1 where both group of patients with and without embolization could be compared head to head.

TAKE HOME MESSAGE

This complementary procedure could be considered as the first step of an OR procedure.

It could be systematically performed to improve outcomes of EVAR for patient @ risk for T2 EL

ANSM (AFSSAPS) gives us the authorization for this practice in our future clinical investigation.