Pre-emptive embolization of lumbars/IMA

Is it warranted?

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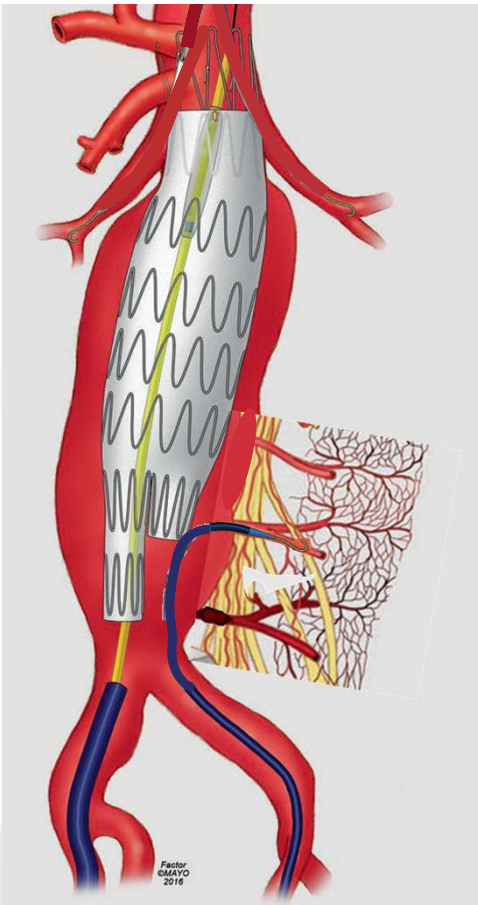
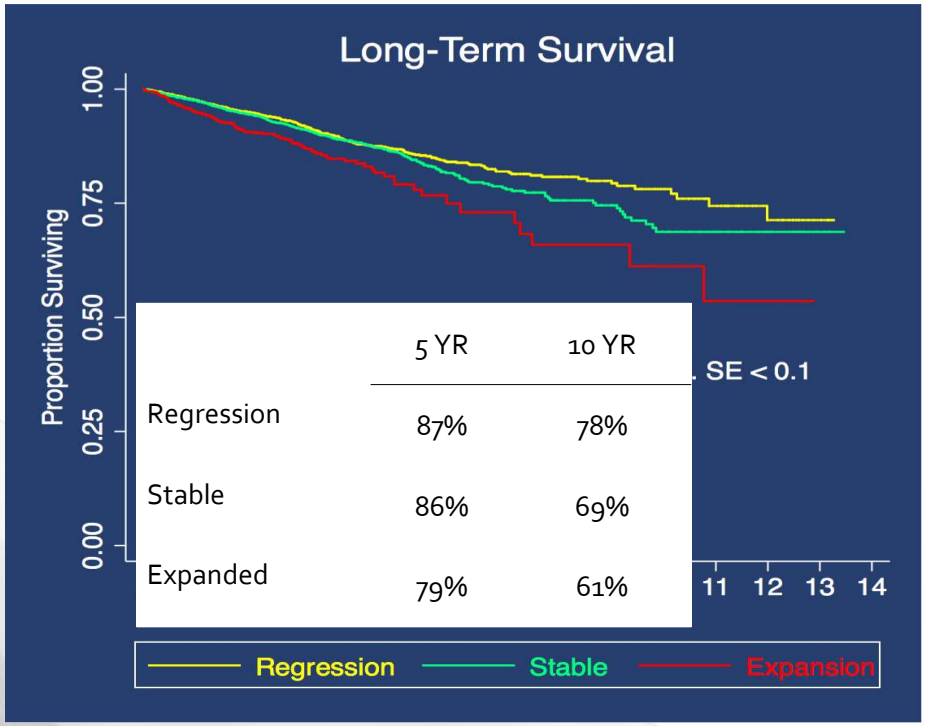


Disclosures

	Cook Medical	WL Gore	Getinge	ViTTA	Centerline Biomedical
Relationship	Research Support, Clinical Trials, Consulting	Clinical Trials, Consulting	Consulting	Clinical Trials, Consulting	Consulting
Received	Grants, Honoraria	Honoraria	Honoraria	Honoraria	Stock Options

Association of Aneurysm Sac Behavior with Long-Term Survival Following EVAR



	5 YR	10 YR
Regression	87%	78%
Stable	86%	69%
Expanded	79%	61%

All patients (n=14,827) undergoing EVAR the Vascular Quality Initiative (VQI), 2003 - 2017

- **1 year:**
  - Expansion 25%
  - Stable 35%
  - Regression 40%

- Even stable sacs associated with lower survival
- Sac behavior associated with new endoleaks, reintervention, and long-term mortality.
- Association between sac behavior and long-term mortality persisted in patients without endoleaks

O'Donnell et al.

Aug 2019

One-year aneurysm-sac dynamics are associated with reinterventions and rupture following infrarenal endovascular aneurysm repair

Vinamr Rastogi, MD,[a,b] Thomas F. X. O'Donnell, MD,[c] Christina L. Marcaccio, MD, MPH,[a] Priya B. Patel, MD, MPH,[a,d] Rens R. B. Varkevisser, MD,[a,b] Sai Divya Yadavalli, MD,[a] Jorg L. de Bruin, MD, PhD,[b] Hence J. M. Verhagen, MD, PhD,[b] Virendra I. Patel, MD, MPH,[c] *and* Marc L. Schermerhorn, MD,[a] *Boston, MA; Rotterdam, The Netherlands; New York, NY; and New Brunswick, NJ*

- VQI EVAR database query 2003 - 2018 linked to Medicare long-term claims
- N = 31,185 (52% had 1 year imaging: n=16,102)

Feb 2024

One-year aneurysm-sac dynamics are associated with reinterventions and rupture following infrarenal endovascular aneurysm repair

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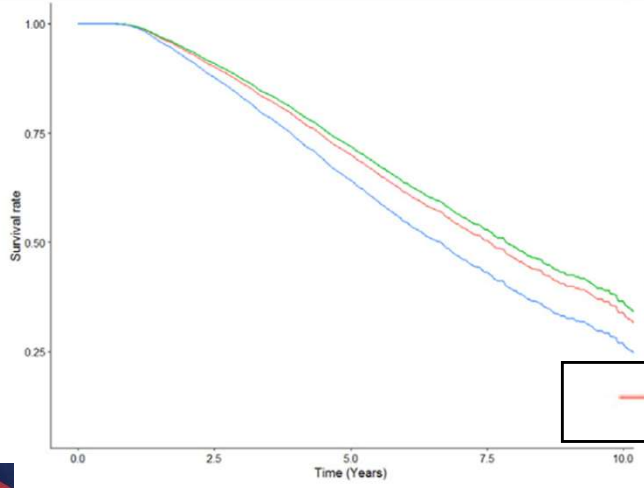
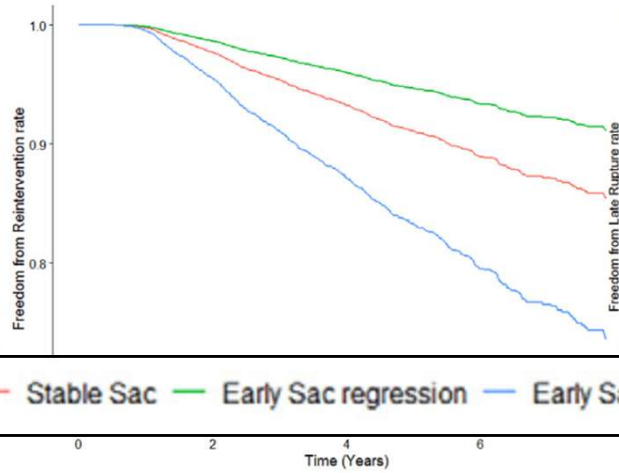
Survival



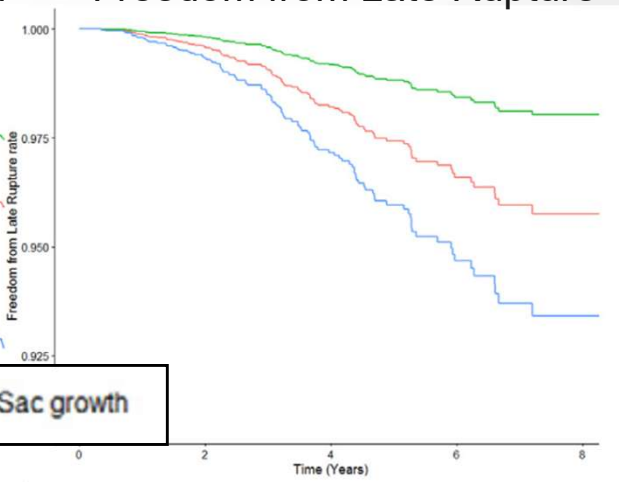
Survival	Hazard Ratio (HR)	95% CI	P-value
Ref: Stable Sac		-	-
Early Sac Regression	**0.92**	**0.85-0.99**	**.032**
Early Sac Expansion	**1.27**	**1.11-1.46**	**<.001**

Freedom from Reintervention



8-year Reintervention	Hazard Ratio (HR)	95% CI	P-value
Ref: Stable Sac		-	-
Early Sac Regression	**0.58**	**0.50-0.68**	**<.001**
Early Sac Growth	**1.98**	**1.57-2.51**	**<.001**

Freedom from Late Rupture



8-year Rupture	Hazard Ratio (HR)	95% CI	P-value
Ref: Stable Sac		-	-
Early Sac Regression	**0.45**	**0.29-0.69**	**<.001**
Early Sac Growth	1.61	0.88-2.96	.12

Stable Sac — Early Sac regression — Early Sac growth

One-year aneurysm-sac dynamics are associated with reinterventions and rupture following infrarenal endovascular aneurysm repair

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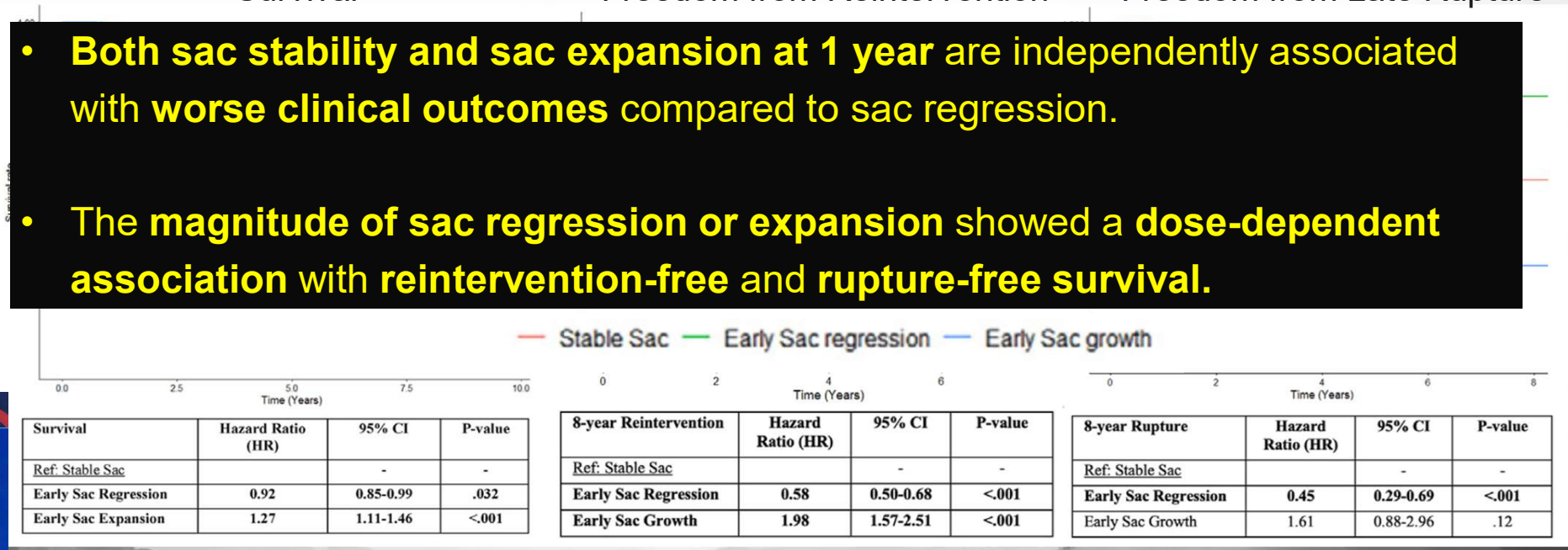
Survival | Freedom from Reintervention | Freedom from Late Rupture

- **Both sac stability and sac expansion at 1 year** are independently associated with **worse clinical outcomes** compared to sac regression.
- The **magnitude of sac regression or expansion** showed a **dose-dependent association** with **reintervention-free** and **rupture-free survival.**



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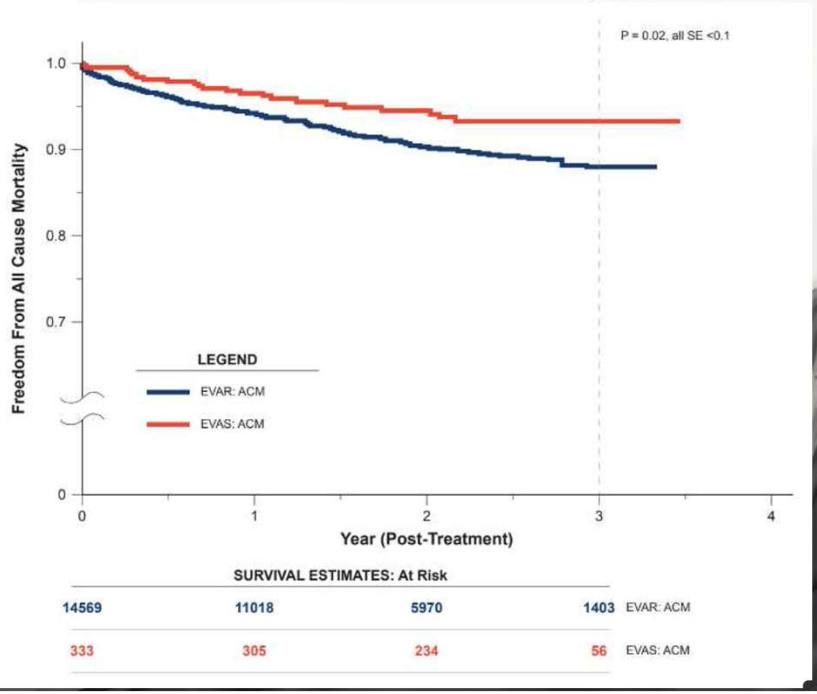
Why is there so much interest in Type II?

Endovascular Aneurysm Sealing is Associated with Higher Medium-Term Survival than Traditional EVAR

Thomas F.X. O'Donnell, MD[1,2], Jeffrey P. Carpenter, MD[3], John S. Lane III, MD[4,5], Jose Trani, MD[3], Sajjad Hussain, MD[6], Christopher Healey, MD[7], Mahmoud B. Malas, MD[8], Marc L. Schermerhorn, MD[1]

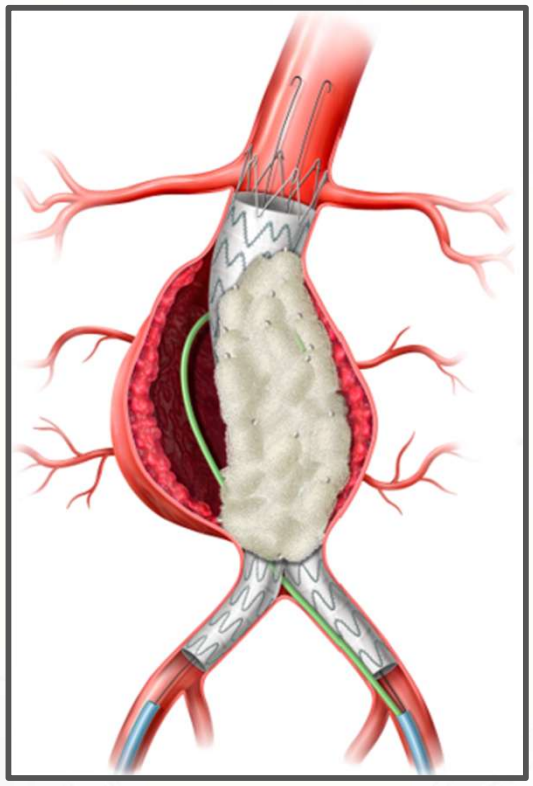
- Reduced Type II endoleaks
- Reduced post-implant syndrome
- EVAS versus VQI control: 3-year survival
- 93% versus 88%

Feb 2020

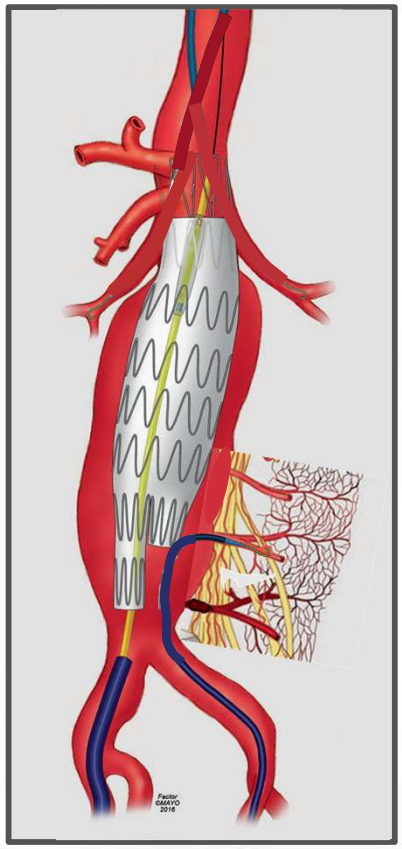


Options for Sac Management

EVAS - Endovascular Aneurysm Sealing



Sac Embolization

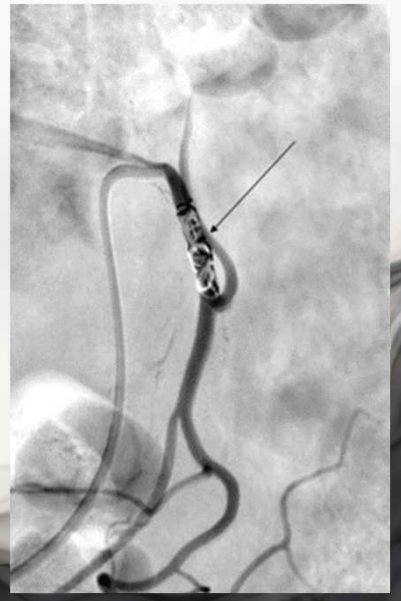


Side-branch Embolization

Five-year follow-up of randomized clinical trial for pre-emptive inferior mesenteric artery embolization during endovascular aneurysm repair

Yuriko Takeuchi, MD, Noriyasu Morikage, MD, Makoto Samura, MD, Ryunosuke Sakamoto, MD, Soichi Ike, MD, Takahiro Mizoguchi, MD, Takasuke Harada, MD, Hiroshi Kurazumi, MD, Ryo Suzuki, MD, Kotaro Suehiro, MD, *and* Kimikazu Hamano, MD, *Ube, Japan*

- Single-center, randomized trial
- High-risk for Type II endoleak
  - Patent IMA
    - IMA $\geq$ 3mm
    - Lumbar arteries $\geq$ 2 mm
    - AI aneurysm
- IMA embolized @ time of EVAR



Sept 2024

5-year RCT for IMA embolization

Outcome variables	IMA embolization	Non-embolization	*P* value IMA-embolization vs non-embolization	T2EL low risk
ITT analysis	n = 53	n = 53		n = 155
T2EL	15 (28.3)	29 (54.7)	.006	26 (16.8)
Sac diameter change, mm	−4.5 ± 9.8	−0.42 ± 12.9	.035	−4.1 ± 11.0
Reintervention	5 (9.4)	6 (11.3)	.51	14 (9.0)
T2EL-related reintervention	0	1 (1.9)	.32	1 (0.65)
Follow-up period, months	56.0 ± 27.1	61.0 ± 29.0	.36	49.8 ± 26.8
PP analysis	n = 46	n = 52		n = 154
T2EL	11 (23.9)	28 (53.8)	.003	25 (16.2)
Sac diameter change, mm	−5.1 ± 10.2	−0.42 ± 13.0	.026	−4.1 ± 11.1
Reintervention	5 (10.9)	6 (11.5)	.75	14 (9.1)
T2EL-related reintervention	0	1 (1.9)	.32	1 (0.65)
Follow-up period, months	57.6 ± 26.0	62.2 ± 28.1	.41	50.1 ± 26.6

ITT, Intention-to-treat; *PP*, per-protocol.
Data are presented as number (%) or mean ± standard deviation.

Sept 2024

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Intention-to-treat; *PP*, per-protocol.
a are presented as number (%) or mean ± standard deviation.

- **Significant difference in sac shrinkage ≥ 5mm (54.2% vs 33.6%)**
- **Significant difference in the presence of T2EL (28.3% versus 54.7%)**
- **Freedom from T2EL related sac enlargement (≥ 10 mm) was similar**

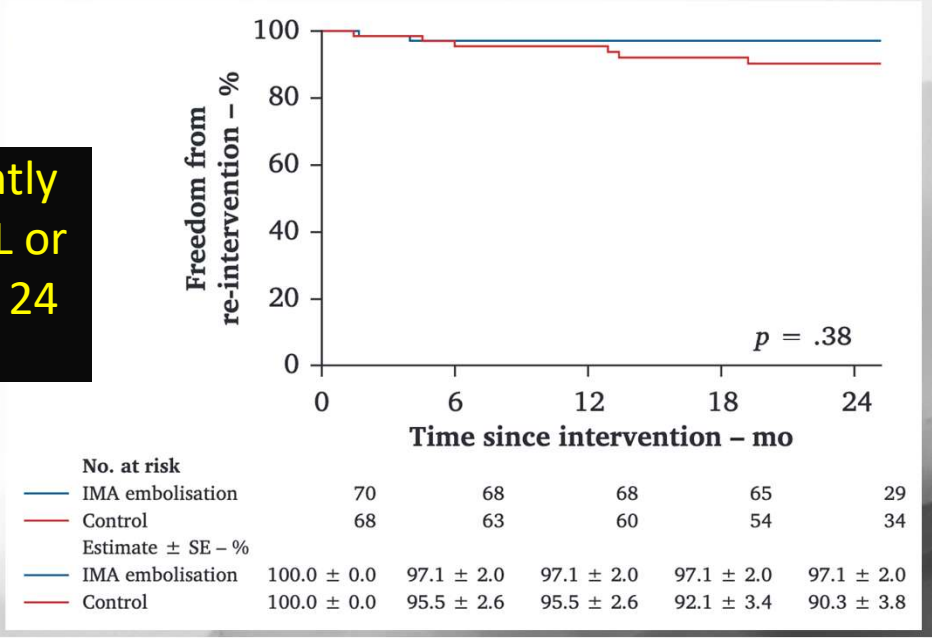
Sept 2024

Editor's Choice – **Multicentre Randomised Controlled Trial to Evaluate the Efficacy of Pre-emptive Inferior Mesenteric Artery Embolisation during Endovascular Aortic Aneurysm Repair on Aneurysm Sac Change**

Shigeo Ichihashi [a,*], Mitsuyoshi Takahara [b], Naoki Fujimura [c], Hiroshi Banno [d], Seiji Onitsuka [e], Masami Shingaki [f], Terutoshi Yamaoka [g], Makoto Sumi [h], Osamu Iida [i], Shinichi Iwakoshi [a], Stephan Haulon [j], Kimihiko Kichikawa [a], on behalf of the CLARIFY IMA Investigators [†]

- 24 Center in Europe
- 138 patients randomized to IMA embolization for (>2.5 mm)
  - Treatment: IMA embo + EVAR - 70
  - Control: EVAR - 681-Year Outcomes

Pre-emptive IMA embolisation did not significantly impact the change in aneurysm sac volume, T2EL or re-intervention rates compared with controls at 24 month follow-up.



Apr 2025

An updated systematic review and meta-analysis of pre-emptive aortic side branch embolization to prevent type II endoleaks after endovascular aneurysm repair

Hok Yee Harry Yu, MBBS, FRCS (Edin), FHKAM (Surg), David Lindström, MD, PhD, FEBVS, Anders Wanhainen, MD, PhD, Gustaf Tegler, MD, Giuseppe Asciutto, MD, PhD, *and* Kevin Mani, MD, PhD, FEBVS, *Uppsala, Sweden*

- Analysis between January 2019 and May 2022
- 17 studies identified
- Technical success 81.6% for embolization
- 424 patients
  - 2.4% of patients reported abdominal pain - resolved with medical mgmt
  - 1 death related to embolization

June 2023

An updated systematic review and meta-analysis of pre-emptive aortic side branch embolization to prevent type II endoleaks after endovascular aneurysm repair

- 16 studies
- T2EL 19.7% versus 37.4%

Favors embolization

June 2023

Incidence of Type II Endoleaks

Study or Subgroup	Embolization Events	Embolization Total	Control Events	Control Total	Weight	Odds ratio M-H, Fixed, 95% CI
Gould 2001	4	20	10	43	1.9%	0.82 [0.22 , 3.04]
Parry 2002	0	14	8	22	2.4%	0.06 [0.00 , 1.12]
Axelrod 2004	5	30	30	72	5.5%	0.28 [0.10 , 0.81]
Muthu 2007	7	65	10	67	3.3%	0.69 [0.24 , 1.93]
Nevala 2010	10	40	23	39	6.5%	0.23 [0.09 , 0.60]
Ward 2013	37	108	78	158	15.5%	0.53 [0.32 , 0.89]
Burbelko 2014	0	33	9	38	3.3%	0.05 [0.00 , 0.83]
Müller-Willie 2014	6	31	14	43	3.5%	0.50 [0.17 , 1.49]
Aoki 2017	1	24	33	56	7.1%	0.03 [0.00 , 0.24]
Fukuda 2017	22	143	61	189	16.6%	0.38 [0.22 , 0.66]
Hiraoka 2017	10	58	60	226	7.6%	0.58 [0.27 , 1.21]
Lokík 2017	1	15	8	15	2.8%	0.06 [0.01 , 0.60]
Manunga 2017	4	12	11	12	2.7%	0.05 [0.00 , 0.49]
Vaillant 2019	10	37	32	45	7.9%	0.15 [0.06 , 0.40]
Samura 2020	13	53	26	53	7.3%	0.34 [0.15 , 0.77]
Petit 2021	15	52	43	142	6.1%	0.93 [0.46 , 1.88]
Total (95% CI)		**735**		**1220**	**100.0%**	**0.38 [0.30 , 0.47]**
Total events:	145		456			

Heterogeneity: Chi² = 31.97, df = 15 (P = 0.007); I² = 53%
Test for overall effect: Z = 8.53 (P < 0.00001)
Test for subgroup differences: Not applicable

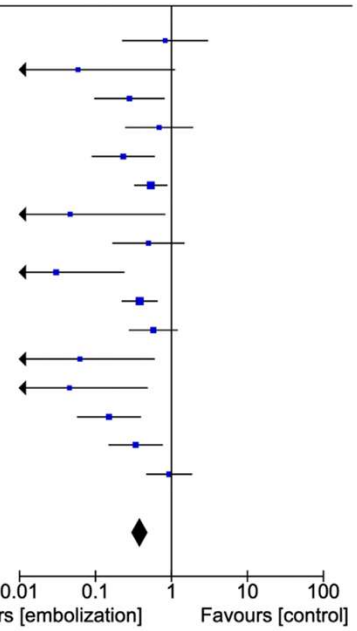


Fig 2. Forest plot on incidence of type II endoleaks. *CI*, Confidence interval.

An updated systematic review and meta-analysis of pre-emptive aortic side branch embolization to prevent type II endoleaks after endovascular aneurysm repair

Incidence of Sac Enlargement

- 10 Studies
- Mean f/u 21.9 months
- Sac enlargement (≥5 mm)
  4.3% versus 6.8%

Favors Embolization

June 2023

Study or Subgroup	Embolizaiton Events	Total	Control Events	Total	Weight	Odds ratio M-H, Fixed, 95% CI
Gould 2001	0	20	11	43	6.3%	0.07 [0.00 , 1.23]
Parry 2002	0	14	3	22	2.3%	0.19 [0.01 , 4.02]
Ward 2013	13	108	21	158	13.1%	0.89 [0.43 , 1.87]
Burbelko 2014	0	33	9	38	7.6%	0.05 [0.00 , 0.83]
Fukuda 2017	1	143	18	189	13.5%	0.07 [0.01 , 0.51]
Lokík 2017	1	15	6	15	4.9%	0.11 [0.01 , 1.04]
Vaillant 2019	1	37	15	45	11.5%	0.06 [0.01 , 0.45]
Samura 2020	1	53	9	53	7.7%	0.09 [0.01 , 0.77]
Petit 2021	5	52	9	142	3.8%	1.57 [0.50 , 4.93]
Rokosh 2021	10	272	960	14788	29.2%	0.55 [0.29 , 1.04]
Total (95% CI)		**747**		**15493**	**100.0%**	**0.38 [0.26 , 0.55]**
Total events:	32		1061			

Heterogeneity: $Chi^2 = 24.99$, $df = 9$ ($P = 0.003$); $I^2 = 64\%$
Test for overall effect: $Z = 5.08$ ($P < 0.00001$)
Test for subgroup differences: Not applicable

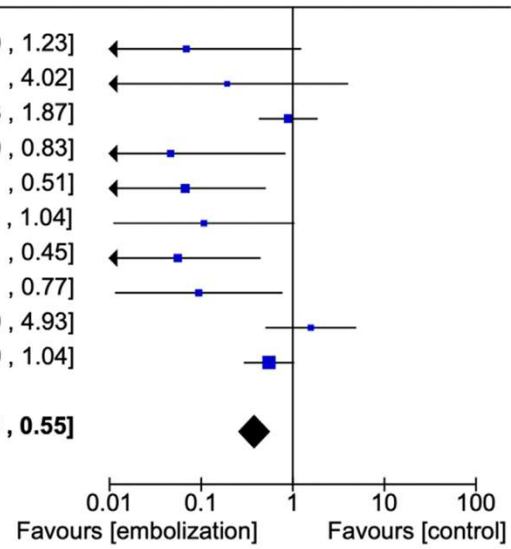


Fig 1. Forest plot on incidence of sac size enlargement. *CI*, Confidence interval.

An updated systematic review and meta-analysis of pre-emptive aortic side branch embolization to prevent type II endoleaks after endovascular aneurysm repair

Incidence of ReIntervention for T2EL

- 12 Studies
- Mean f/u 24.1 months
- Re-intervention
- 1.2% versus 11.2%

Favors Embolization

Study or Subgroup	Embolization Events	Embolization Total	Control Events	Control Total	Weight	Odds ratio M-H, Fixed, 95% CI
Gould 2001	0	20	2	43	2.1%	0.40 [0.02 , 8.83]
Parry 2002	0	14	6	22	6.6%	0.09 [0.00 , 1.69]
Axelrod 2004	0	30	4	72	3.5%	0.25 [0.01 , 4.78]
Muthu 2007	2	65	10	67	12.8%	0.18 [0.04 , 0.86]
Nevala 2010	1	40	11	39	14.6%	0.07 [0.01 , 0.54]
Ward 2013	1	108	12	158	12.9%	0.11 [0.01 , 0.89]
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Fukuda 2017	1	143	18	189	20.6%	0.07 [0.01 , 0.51]
Lokík 2017	1	15	5	15	6.3%	0.14 [0.01 , 1.42]
Manunga 2017	1	12	2	12	2.5%	0.45 [0.04 , 5.81]
Vaillant 2019	0	37	10	45	12.6%	0.05 [0.00 , 0.80]
Samura 2020	0	53	0	53		Not estimable
Total (95% CI)		**570**		**753**	**100.0%**	**0.12 [0.06 , 0.23]**
Total events:	7		84			

Heterogeneity: Chi² = 3.35, df = 10 (P = 0.97); I² = 0%
Test for overall effect: Z = 6.10 (P < 0.00001)
Test for subgroup differences: Not applicable

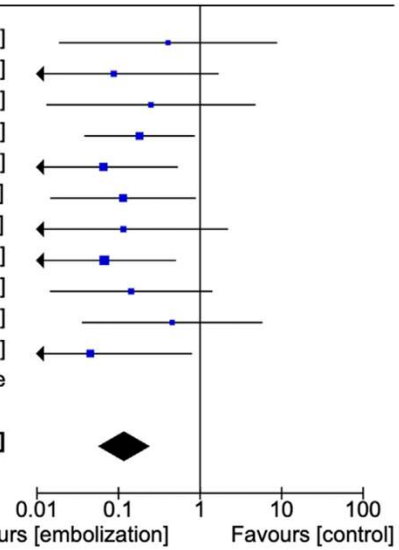


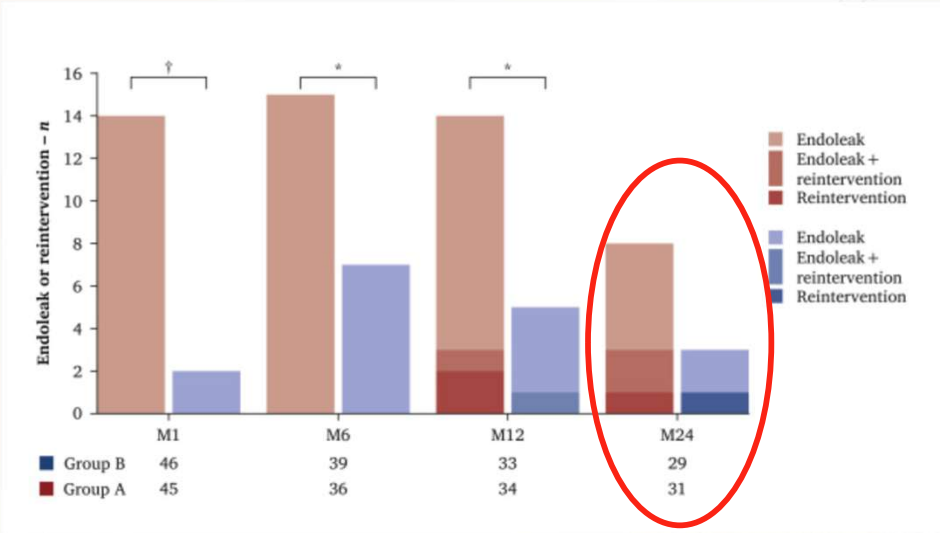
Fig 3. Forest plot on incidence of reintervention for type II endoleaks. *CI*, Confidence interval.

June 2023

Prospective, Randomised Two Centre Trial of Endovascular Repair of Abdominal Aortic Aneurysm With or Without Sac Embolisation

Dominique Fabre [a,*], Justine Mougin [a], Delphine Mitilian [a], Frederic Cochennec [b], Carlos Garcia Alonso [a], Jean-Pierre Becquemin [b], Pascal Desgranges [b], Eric Allaire [b], Sarah Hamdi [a], Philippe Brenot [a], Riyad Bourkaib [a], Stephan Haulon [a]

- 94 patients randomized to embolization/control
- High risk for Type II
  - IMA > 3mm
  - 3 pairs of lumbars
  - 2 pairs + acc renal or median sacral
- Rates of endoleak during follow-up
- Re-intervention for Type II EL
- Volume/Diameter changes



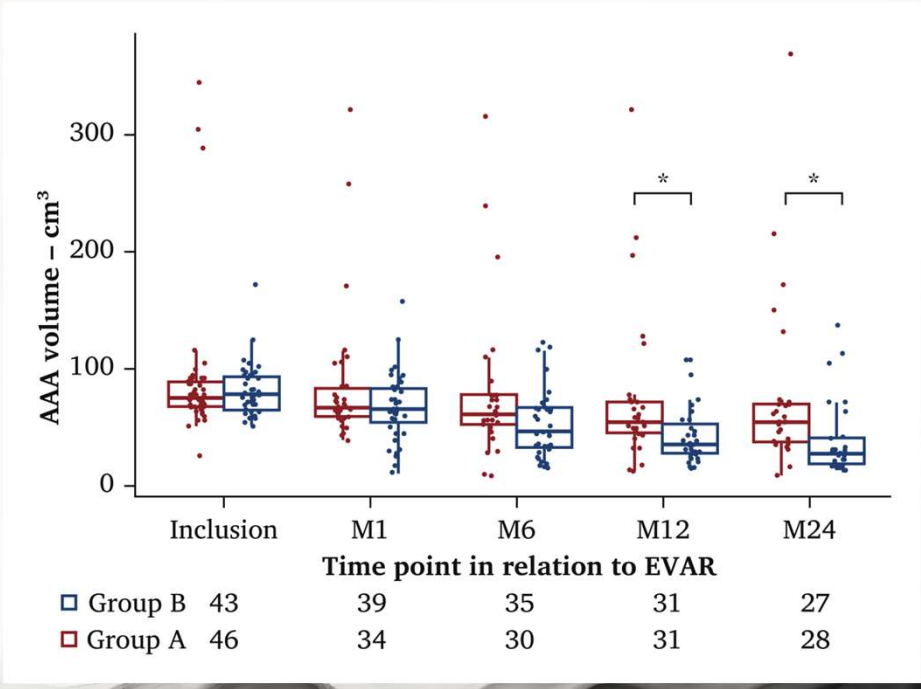
Reduced EL at 1,6 and 12 months

Feb 2021

Prospective, Randomised Two Centre Trial of Endovascular Repair of Abdominal Aortic Aneurysm With or Without Sac Embolisation

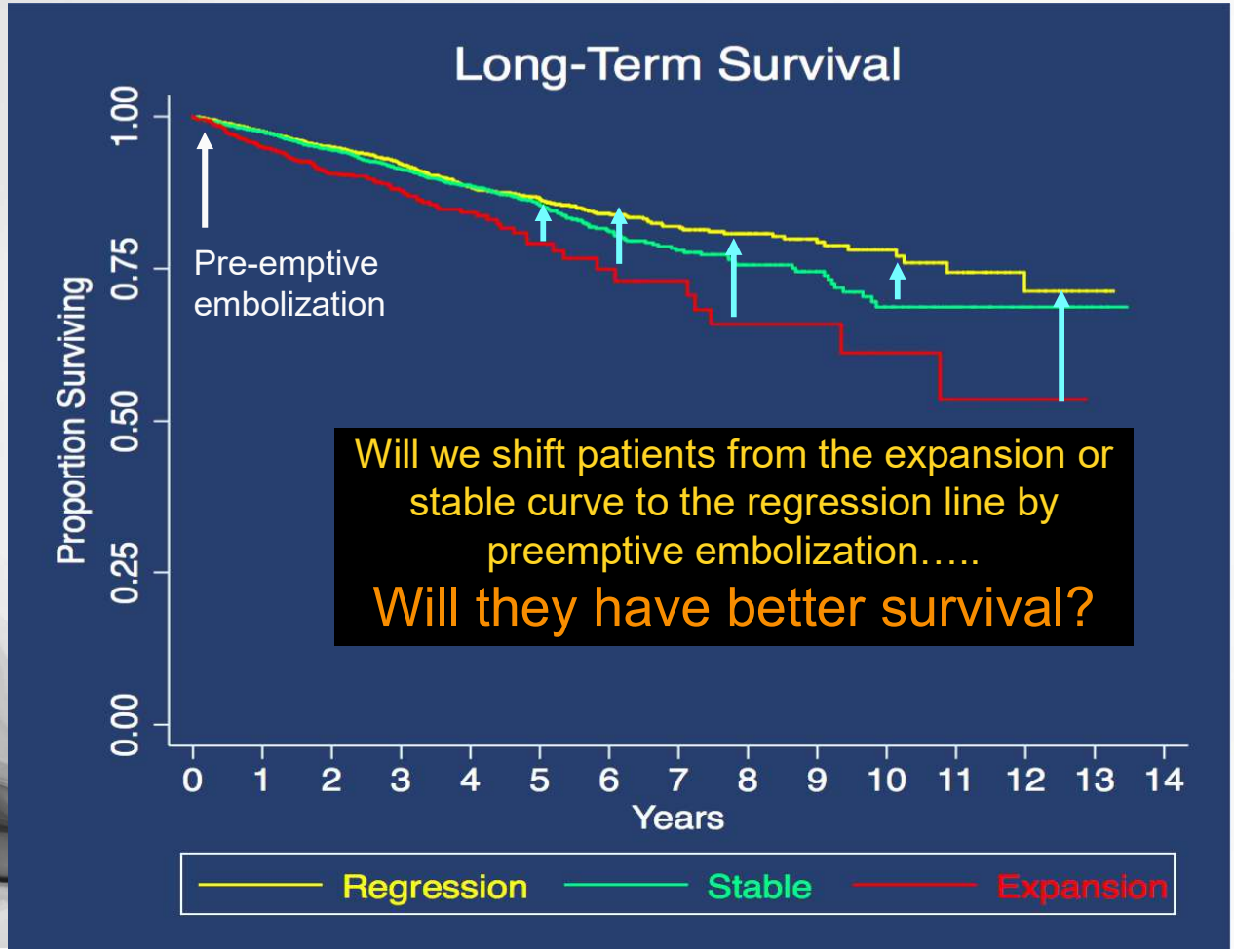
Dominique Fabre [a,*], Justine Mougin [a], Delphine Mitilian [a], Frederic Cochennec [b], Carlos Garcia Alonso [a], Jean-Pierre Becquemin [b], Pascal Desgranges [b], Eric Allaire [b], Sarah Hamdi [a], Philippe Brenot [a], Riyad Bourkaib [a], Stephan Haulon [a]

A significantly faster aneurysm volume shrinkage was observed at one and two years following surgery.



Feb 2021

Impact on Survival?



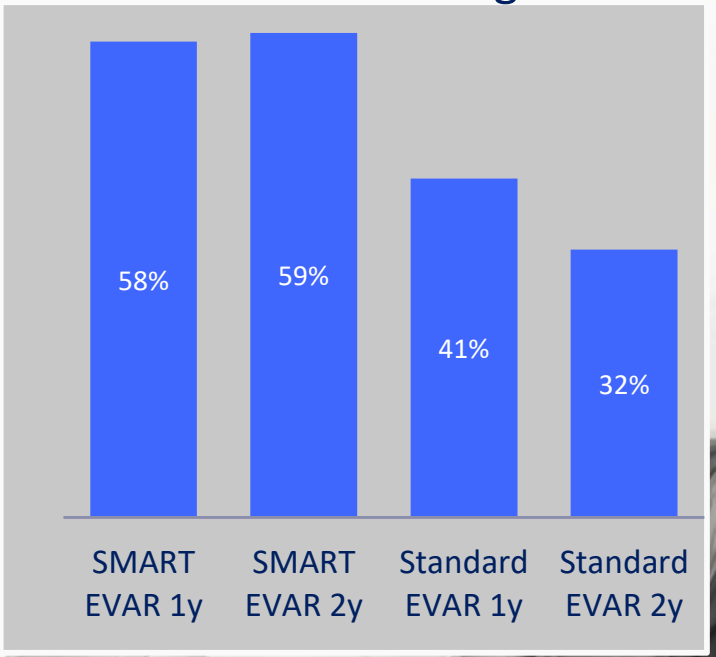
AAA-SHAPE Early Feasibility Study: Durable Clinical Results through 2 Years

One-year follow-up after active aortic aneurysm sac treatment with shape memory polymer devices during endovascular aneurysm repair

Andrew Holden, MBChB,[a] Andrew A. Hill, MBChB,[b] Manar Khashram, MBChB, PhD,[c] Jan M. M. Heyligers, MD, PhD,[d] Arno M. Wiersema, MD, PhD,[e] Paul D. Hayes, MD,[f] *and* Michel M. P. J. Reijnen, MD, PhD,[g,h] *Auckland, New Zealand; Tilburg, and Hoorn, the Netherlands; Cambridge, UK; and Arnhem and Enschede, the Netherlands*

- Prospective Safety and Early Feasibility Study
- 5 Centers (NZ, NL)
- 35 Patients, Infrarenal AAA
- 100% Technical Success
- No Procedure/Device-Related **Major Adverse Events**
- Nearly 2x More Patients with Sac Regression at 2y*

% Patients with **Sac Diameter** Regression



1y: Holden A, et al. J Vasc Surg. 2024 Jan 5:S0741-5214
2Y: Holden A. Presented at Charing Cross Symposium, April 2025, London, UK

*AAA-SHAPE EFS compared to a standard EVAR control group select from Cleveland Clinic Commercial usage from 2014 to 2019 that meet AAA-SHAPE EFS inclusion/exclusion criteria. This consisted of 26 Gore, 9 Cook, 4 Terumo, and 2 Medtronic grafts.

AAASHAPE

Abdominal **A**ortic **A**neurysm **S**ac **H**ealing **a**nd **P**revention of **E**xpansion

Randomized Controlled Pivotal Trial

180 total subjects, 2:1

Up to 50 sites (39 in US; 11 in EU/NZ)

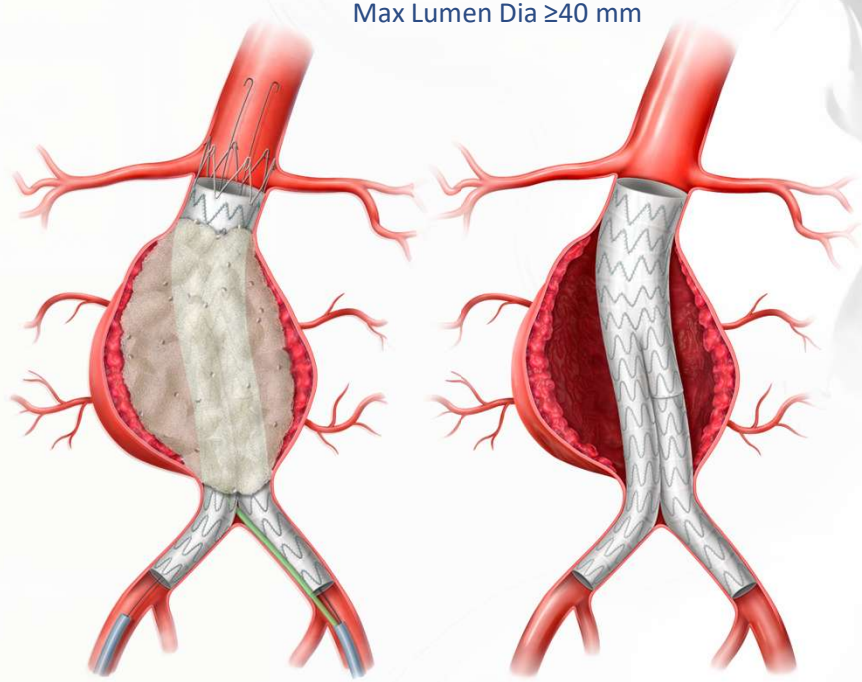
Stent Grafts: Gore, Medtronic, Cook, Terumo

Primary Efficacy Endpoint

*% patients with ≥10% sac volume reduction at **1y** and no AAA-related intervention through **1y***

5y follow-up: clinical, imaging, health economics

Elective, infrarenal AAA,
Thrombus <50%,
Max Lumen Dia ≥40 mm



EVAR *plus*
IMPEDE-FX RapidFill
120 patients

VS

Standard
EVAR
60 patients

~70% enrolled

Conclusions

- Pre-emptive embolization may be warranted in a subgroup
  - enhance sac shrinkage
  - volume reduction
  - potentially reduce re-intervention rates

- However, whether this translates into improved survival remains to be proven