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When Should We Reintervene And Keep Reintervening For Persistent Type 2 Endoleaks:
What Factors With Persistent Type 2 Endoleaks Are Predictors Of AAA Rupture

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COI Disclosure

Speaker name :

Naoki Fujimura, MD, PhD

I have the following potential conflicts of interest to report:

- ■ Consulting: Cook Medical, and Endologix
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ■ Honorarium: BD, Boston Scientific, Canon, Cook Medical, Cordis, Japan Lifeline, Medtronic, Terumo, and WL Gore.
- ☐ I do not have any potential conflict of interest

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Background

Previously, type 2 endoleak was believed to be benign in the western countries

Not frequent

Clinically irrelevant

→ reported incidence 5 to 10%

→ rupture extremely rare

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Background

However, recent evidences from Japan has suggested,,,

Not frequent
→ reported incidence 5 to 10%

Clinically irrelevant
→ rupture extremely rare

more frequent than previously thought

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Type 2 endoleak in Japanese population

Early sac shrinkage is a good surrogate marker of durable success after endovascular aneurysm repair in Japanese patients

Naoki Fujimura, MD, PhD,†,‡ Kentaro Matsubara, MD, PhD,* Mitsuyoshi Takahara, MD, PhD,† Hirohisa Harada, MD, PhD,‡ Atsunori Asami, MD, PhD,§ Shintaro Shibutani, MD, PhD,† Susumu Watada, MD, PhD,‡ Hideaki Obara, MD, PhD,† and Yuko Kitagawa, MD, PhD,† Tokyo, Osaka, Chiba, Saitama, and Kanagawa Japan

(J Vasc Surg 2018;67:1410-8.)

205 T2ELs (29.1%) in 697 EVARs

Type IIIb Endoleak Is Not Extremely Rare and May Be Underdiagnosed after Endovascular Aneurysm Repair

Naoki Fujimura, MD, PhD, Shigeo Ichihashi, MD, PhD, Kentaro Matsubara, MD, PhD, Shintaro Shibutani, MD, PhD, Hirohisa Harada, MD, PhD, Hideaki Obara, MD, PhD, Kimihiko Kichikawa, MD, PhD, and Yuko Kitagawa, MD, PhD

J Vasc Interv Radiol 2019;∎:1–7

91 T2ELs (21.0%) in 433 Zenith

Early Clinical Outcomes of the Active Seal Technology of the AFX Endovascular Aortic Aneurysm System With the VELA Cuff for Patients With a Conical Proximal Neck

Naoki Fujimura, MD, PhD*†‡, Hideaki Obara, MD, PhD†, Takaaki Nagano, MD†, Yukihisa Ogawa, MD, PhD†, Taira Kobayashi, MD†, Takahiro Ohmine, MD, PhD†, Yasuhiro Ozeki, MD, PhD†, Shinsuke Kikuchi, MD, PhD†, Terutoshi Yamaoka, MD, PhD†, Hideki Ueda, MD, PhD†, Makoto Sumi, MD†, Satoshi Taniguchi, MD, PhD†, and Shigeo Ichihashi, MD, PhD†,‡

11 T2ELs (28.2%) in 53 AFX

Long-term Outcomes of the Endurant and Excluder Stent Grafts for Endovascular Aneurysm Repair in a Japanese Cohort

Yasuhisa Sekimoto, MD, PhD*†‡, Naoki Fujimura, MD, PhD*†‡, Kentaro Matsubara, MD, PhD†, Norio Uchida, MD, PhD†, Atsunori Asami, MD, PhD†, Hirohisa Harada, MD, PhD†, Tsunehiro Shintani, MD, PhD†, Susumu Watada, MD, PhD†, Shigeki Ono, MD, PhD†, Taku Fujii, MD, PhD†, Tatsuya Shirongawara, MD†, Keita Hayashi, MD†, Masanori Hayashi, MD†, Hideaki Obara, MD, PhD†, and Yuko Kitagawa, MD, PhD†

93 T2ELs (28.2%) in 332 Endurant
174 T2ELs (46.0%) in 378 Excluder

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Background

However, recent evidences from Japan has suggested,,,

Not frequent
→ reported incidence 5 to 10%

Clinically irrelevant
→ rupture extremely rare

More frequent with reported incidence around 25 to 40%

Type 2 endoleak was associated with worse clinical outcomes

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Type 2 endoleak is a malignant condition

Circulation

ORIGINAL RESEARCH ARTICLE

Nationwide Analysis of Persistent Type II Endoleak and Late Outcomes of Endovascular Abdominal Aortic Aneurysm Repair in Japan: A Propensity-Matched Analysis

Yoshimasa Seike, MD, PhD; Hitoshi Matsuda, MD, PhD; Hideyuki Shimizu, MD, PhD; Shin Ishimaru, MD, PhD; Katsuyuki Hoshina, MD, PhD; Nobuaki Michihata, MD, PhD; Hideo Yasunaga, MD, PhD; Kimihiro Komori, MD, PhD; on behalf of the Japanese Committee for Stentgraft Management (JACSM)*

Circulation. 2022;145:1056–1066. DOI: 10.1161/CIRCULATIONAHA.121.056581

Retrospective analysis of 17099 EVARs (age < 75) performed for AAA from 2006 to 2015 using Japanese Committee for Stentgraft Management (JACSM) registry

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Japanese Committee for Stentgraft Management (JACSM)

- On December 21, 2006, eleven academic associations founded Japanese Committee for Stentgraft Management (JACSM).
- All EVARs and TEVARs have been prospectively registered into JACSM registry.

ORIGINAL ARTICLE

Outcomes of Endovascular Repair for Abdominal Aortic Aneurysms
A Nationwide Survey in Japan

Katsuyuki Hoshina, MD, PhD; Shin Ichimura, MD, PhD; Naoki Sumitachi, MD, MPH;
Hideo Yasunaga, MD, PhD; and Kimihiro Komori, MD, PhD, on behalf of the Japan Committee for Stentgraft Management (JACSM)*

(*Ann Surg* 2019;269:564–573)

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Type 2 endoleak is a malignant condition

Circulation. 2022;145:1056–1066. DOI: 10.1161/CIRCULATIONAHA.121.056581

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Type 2 endoleak is a malignant condition

Even after propensity score matching, persistent type 2 endoleak was an independent predictor for adverse events !!

Circulation. 2022;145:1056–1066. DOI: 10.1161/CIRCULATIONAHA.121.056581

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Short summary for type 2 endoleak in Japan

Recent evidences from Japan has suggested,,,

more frequent than previously thought (25 to 40%)

Related to clinically adverse events including death

However, trans-arterial embolization is only effective in 30% of cases, and open surgical repair is the only definitive treatment

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Short summary for OSR after EVAR for endoleaks

OSR is the only definitive treatment for persistent type 2 endoleak, however, OSR after EVAR is associated with high mortality and morbidity.

- 30-day mortality rate reported was 9.1-12.9%.
  Kouvelos G. J Vasc Surg 2015;61:1350-6.
- Mortality rates were different between elective and urgent operation (2.9-3.2% vs. 25-29.2%).
  Chastant R. J Vasc Surg 2021;73:502-9

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Clinical question for OSR for type 2 endoleak

So, when should we perform OSR during persistent type 2 endoleak??

High mortality and morbidity associated with OSR

However, definitely should perform OSR electively = before rupture!!

Let's find out risk of rupture for pT2EL using JACSM registry!!

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Materials and methods

58838 EVARs (Japan Committee for Stentgraft Management registry, 2006-2015)

Excluded aortoiliac aneurysms and iliac artery aneurysms

42904 EVARs for abdominal aortic aneurysms

Excluded pseudo, inflammatory, infectious, and dissection aneurysms, etc.

38551 EVARs for true abdominal aortic aneurysms

Excluded debranch and snorkel EVARs, preemptive embolization for IMA, LA, and sac (both coil and glue), open conversion and graft replacement, etc.

37823 EVARs for infrarenal AAA

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Materials and methods

37823 EVARs for infrarenal AAA

Excluded patients with death, T1EL and T3 EL at discharge

36532 EVARs for infrarenal AAA with follow-up

Defined persistent type 2 endoleak as patients that had at least two T2ELs observed during the follow-up

8579 EVARs with persistent type 2 endoleaks for analysis

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Patient demographics and characteristics

Variable	All patients (n = 8579) No. (%)
Age[a]	76.2 (7.6)
<65	704 (8.2%)
65-74	2515 (29.3%)
75-84	4257 (49.6%)
≧85	1103 (12.9%)
Male sex	6612 (77.1%)
Aneurysm size at discharge[a] (mm)	50 (45-55)
Hypertension	5997 (69.9%)
Diabetes	1051 (12.3%)
Coronary artery disease	2278 (26.6%)
Cerebrovascular disease	1171 (13.6%)
COPD	1461 (17.0%)
CRI (Cr > 1.2)	1216 (14.2%)

COPD, chronic obstructive pulmonary disease; CRI, chronic renal insufficiency; [a]Continuous data are shown as the mean (standard deviation).

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Stent grafts used

Variable	All patients (n = 8579) No. (%)
Zenith	1656 (19.3%)
Excluder	4641 (54.1%)
Endurant	1689 (19.7%)
Powerlink	455 (5.3%)
Aorfix	138 (1.6%)

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Materials and methods

37823 EVARs for infrarenal AAA

Excluded patients with death, T1EL and T3 EL at discharge

36532 EVARs for infrarenal AAA with follow-up

Defined persistent type 2 endoleak as patients that had at least two T2ELs observed during the follow-up

8579 EVARs with persistent type 2 endoleaks for analysis

death, lost to follow-up, and open conversion were handled as right censored data

132 ruptures during the follow-up

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Comparison of rupture and non-rupture groups

Variable	Rupture (n = 132)	Non-rupture (n = 8447)	P-value
Age[a]	76.6 (7.3)	76.2 (7.6)	0.54
<65	7 (5.3%)	697 (8.3%)	0.39
65-74	45 (34.1%)	2470 (29.2%)	
75-84	61 (46.2%)	4196 (49.7%)	
≧85	19 (14.4%)	1084 (12.8%)	
Male sex	84 (63.6%)	6528 (77.3%)	< 0.001
Hypertension	94 (71.2%)	5903 (69.9%)	0.74
Diabetes	18 (13.6%)	1033 (12.2%)	0.62
Coronary artery disease	42 (31.8%)	2236 (26.5%)	0.17
Cerebrovascular disease	19 (14.4%)	1152 (13.6%)	0.80
COPD	20 (15.2%)	1441 (17.1%)	0.56
CRI (Cr > 1.2)	23 (17.4%)	1193 (14.1%)	0.28
Sent graft used			< 0.001
Zenith	34 (25.8%)	1622 (19.2%)	
Excluder	44 (33.3%)	4597 (54.4%)	
Endurant	46 (34.8%)	1643 (19.5%)	
Powerlink	6 (4.5%)	449 (5.3%)	
Aorfix	2 (1.5%)	136 (1.6%)	
Aneurysm size at last follow up[a] (mm)	70.0 (16.1)	42.2 (25.9)	< 0.001

COPD, chronic obstructive pulmonary disease; CRI, chronic renal insufficiency; [a]Continuous data are shown as the mean (standard deviation).
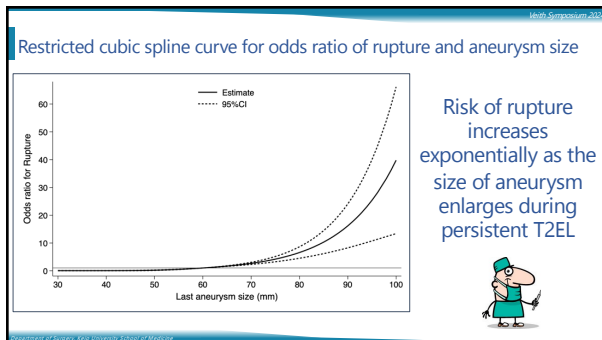
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Multivariate analysis (logistic regression) for rupture during persistent T2EL

Significant risk factors for rupture were

- Female gender
- Zenith and Endurant compared to Excluder
- Larger aneurysm size at the last follow-up

COPD, chronic obstructive pulmonary disease; CRI, chronic renal insufficiency; [a]Continuous data are shown as the mean (standard deviation).

Variables	Odds ratio (95% Confidence Interval)	P value
Age[a]		
< 65	1 (base)	
65 - 74	1.36 (0.60 – 3.08)	0.46
75 - 84	0.91 (0.40 – 2.04)	0.81
≧85	0.90 (0.36 – 2.24)	0.82
Male sex	0.44 (0.30 – 0.65)	< 0.001
Hypertension	0.94 (0.64 – 1.40)	0.78
Diabetes	0.99 (0.59 – 1.68)	0.98
Coronary artery disease	1.39 (0.94 – 2.05)	0.10
Cerebrovascular disease	0.96 (0.58 – 1.59)	0.87
COPD	1.02 (0.62 – 1.67)	0.95
CRI (Cr > 1.2)	1.06 (0.66 – 1.70)	0.80
Sent graft used		
Zenith	2.37 (1.48 – 3.77)	< 0.001
Excluder	1 (base)	
Endurant	2.83 (1.84 – 4.35)	< 0.001
Powerlink	1.98 (0.82 – 4.76)	0.13
Aorfix	1.60 (0.37 – 6.89)	0.53
Aneurysm size at discharge[a] (mm)		
< 60	1 (base)	
60 – 69	3.90 (2.37 – 6.44)	< 0.001
70 – 79	9.39 (6.37 – 16.90)	< 0.001
≧80	18.64 (11.43 – 30.42)	< 0.001

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Restricted cubic spline curve for odds ratio of rupture and aneurysm size

Risk of rupture increases exponentially as the size of aneurysm enlarges during persistent T2EL

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Incidence of rupture and aneurysm size

rupture	aneurysm size at the last follow-up (mm)				Total
	< 60	60–69	70–79	>=80	
0	7,263	769	241	110	8,447
	99.47	96.49	87.96	75.34	98.40
1	39	28	33	36	132
	0.53	3.51	12.04	24.66	1.60
Total	7,302	797	274	146	8,549
	100.00	100.00	100.00	100.00	100.00

Incidence of aneurysm rupture is more than 20% for aneurysm size > 80mm

➡ Considering reported 30-day mortality rate of 9.1-12.9% for OSR, aneurysm size > 80mm may be an optimal timing for OSR???

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Final take home message for the optimal timing to treat type 2 endoleak

Incidence of rupture for persistent T2EL from JACSM registry suggests

Aneurysm size > 80mm may be an optimal timing to consider OSR

Especially for female gender and non-Excluder cases

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Thank you for your attention !!

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GRAND FRONT OSAKA, JAP

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Far Together