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Comparison Of Excluder Versus Endurant Endografts For EVAR: Which Graft Is Best And In What Circumstances: From A Multicenter Propensity Score Matched Study

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COI Disclosure

Speaker name :

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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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Endurant Stent Graft System vs Excluder Endoprosthesis: ADVANCE Trial

A Global, Prospective, 1:1 Randomized Clinical Trial in Sac Regression

Jan, 2023 to May, 2025

550 cases at 100 global sites

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Materials and methods

1144 Endurants and Excluders (2012.1-2022.7, @10 affiliating hospitals of Keio University Vascular Surgery Group)

Applied inclusion and exclusion criteria

153 Endurants

194 Excluders

Propensity score matching extracted 124 pairs for the analysis

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Keio Vascular Surgery group

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ADVANCE Trial: Inclusion criteria

1) Subject is >= 20 years old
2) Subject and the treating physician agree that the subject will return for all required follow-up visit s
3) Subject or legal representative or consultee, as applicable, has consented for study participation and signed the Informed Consent approved by the sponsor and by the Ethics Committee/Institutional Review Board
4) Subject has an aneurysm diameter of
>= 5 cm (if woman)
>= 5.5 cm (if man)
5) Subject's AAA anatomy is appropriate for both Endurant II/IIs Stent Graft System and Gore Excluder/Excluder Conformable AAA Endoprosthesis as per assessment of both treating physician and Cor e Lab in accordance with the overlapping commercially available IFUs per
applicable region. Japan specific anatomical criteria will be referenced in the Japan Addendum.

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Our study

Inclusion criteria

- > 20 years old
- Treatment indication of AAA > 5.5 → 5.0cm, and also included rapid growth more than 5mm/6months, saccular aneurysm < 5 cm, etc.
- All patients within IFU

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ADVANCE Trial: Exclusion criteria

1. Subject is participating in an investigational drug or device study which may bias or interfere with the endpoints and follow-up of this study
2. Subject has an estimated life expectancy of << 3 years as judged by the investigator
3. Subject has an aneurysm that is: a) Suprarenal/pararenal/juxtarenal b) Isolated iliac-femoral c) Mycotic d) Inflammatory e) Pseudoaneurysm f) Concomitant or prior dissection involving the abdominal aorta or iliac arteries g) Ruptured, including leaking
h) Symptomatic AAA
4. Subject has significant thrombus and / or calcium at the arterial implantation sites, specifically the proximal aortic neck and distal iliac artery interface. Significant thrombus may be quantified as thrombus >= 2 mm in thickness and / or >= 25% of t he vessel circumference in the intended seal zone of the aortic neck. Irregular calcium and / or plaque may compromise the fixation and sealing of the implantation sites.
5. Subject requires emergent aneurysm treatment, for example, trauma or rupture
6. Subject with connective tissue disease that may have caused the aneurysm e.g. Marfan syndrome,
Ehlers Danlos, Loeys-Deitz
7. Subject has previously undergone surgical treatment for abdominal aortic aneurysm
8. Planned use of aorto-uni-iliac (AUI) main body device
9. Any planned additional device during index procedure (e.g. endostaple or anchor, iliac branch endoprosthesis, sac or side branch embolization etc.)
10. Subject has an estimated glomerular filtration rate (eGFR) < 45 ml/min/1.73m2 or subject is on dialysis
11. Subject has a systemic infection who may be a t increased risk of endovascular graft infection
12. Subject has a psychiatric or other condition that may interfere with the study
13. Subject is a female of childbearing potential in whom pregnancy cannot be excluded
14. Subject has a known hypersensitivity or contra indication to anticoagulants, anti-platelets, or contrast media, which is not amenable to pre-treatment
15. Subject belongs to a vulnerable population per investigator's judgment
16. Subject has an active COVID-19 infection or relevant history of COVID-19

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Our study

changed criteria

- eGFR < 45 → 30 ml/min
- did include side branch embolization (IMA)
- did include one hypogastric artery embolization

Primary endpoint

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	Endurant (n=124)	Excluder (n=124)	P value
Sac regression more than 5mm at 1 year[a]	38.9% [36.9% to 40.9%]	36.6% [32.2% to 41.0%]	0.74

a. after multiple imputation (missing value for Endurant n=10, Excluder n=13)

No difference between the groups for sac regression of more than 5mm at 1 year !!

ADVANCE Trial: Secondary Endpoints

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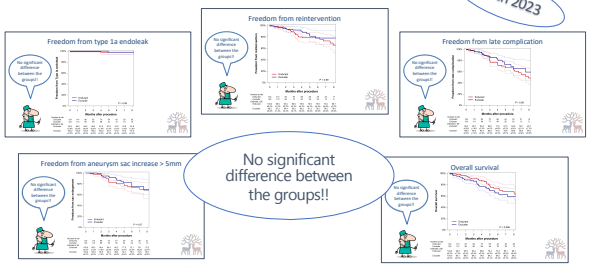

No significant difference between the groups!!

Final take home message !!

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Our head to head comparison using propensity score matching demonstrated both endografts had similar clinical results!!

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Let' see how ADVANCE trial does!!!

In reality,,,

50 – 60% of patients are outside IFU in Japan

460 Endurants

684 Excluders

We should include all patients for the comparison!!

Materials and methods

1144 Endurants and Excluders (2012.1-2022.7, @10 affiliating hospitals of Keio University Vascular Surgery Group)

Applied inclusion and exclusion criteria

325 Endurants

353 Excluders

Propensity score matching extracted 266 pairs for the analysis

Keio Vascular Surgery group

Baseline characteristics

	Overall population (Before matching)			After matching		
	Endurant	Excluder	P value	Endurant	Excluder	P value
	(n = 325)	(n = 353)		(n = 266)	(n = 266)	
Male sex, n	259 (79.7%)	264 (74.8%)	0.15	204 (76.7%)	206 (77.4%)	0.92
Age, years	77 ± 8	76 ± 8	0.42	76 ± 8	76 ± 8	0.90
HTN, n	241 (74.2%)	282 (79.9%)	0.092	203 (76.3%)	204 (76.7%)	> 0.99
DM, n	45 (13.8%)	57 (16.1%)	0.47	37 (13.9%)	36 (13.5%)	> 0.99
CAD, n	104 (32.0%)	100 (28.3%)	0.34	84 (31.6%)	80 (30.1%)	0.78
CVD, n	65 (20.0%)	53 (15.0%)	0.11	44 (16.5%)	46 (17.3%)	0.91
COPD, n	55 (16.9%)	50 (14.2%)	0.38	42 (15.8%)	39 (14.7%)	0.81
CKD, n	151 (46.5%)	161 (45.6%)	0.88	123 (46.2%)	120 (45.1%)	0.86
History of smoking, n	213 (65.5%)	234 (66.3%)	0.90	173 (65.0%)	174 (65.4%)	> 0.99
ASA.score > 3, n	40 (12.3%)	54 (15.3%)	0.31	36 (13.5%)	32 (12.0%)	0.69
Antiplatelet therapy, n	150 (46.2%)	131 (37.1%)	0.021	120 (45.1%)	111 (41.7%)	0.48
Anticoagulation, n	25 (7.7%)	34 (9.6%)	0.45	24 (9.0%)	24 (9.0%)	> 0.99

a. CKD defined as eGFR below 60 ml/min

Anatomical characteristics

	Overall population (Before matching)			After matching		
	Endurant (n = 325)	Excluder (n = 353)	P value	Endurant (n = 266)	Excluder (n = 266)	P value
Maximal diameter of AAA, mm	54 ± 11	52 ± 10	0.005	54 ± 10	53 ± 10	0.61
Suprarenal shaggy aorta, n	28 (8.6%)	27 (7.6%)	0.75	23 (8.6%)	21 (7.9%)	0.87
Proximal neck length, mm	31 ± 15	36 ± 16	< 0.001	32 ± 16	33 ± 14	0.35
Proximal neck diameter, mm	22 ± 4	22 ± 3	0.020	22 ± 4	22 ± 3	0.46
Maximal diameter of right CIA, mm	19 ± 9	17 ± 7	0.030	18 ± 8	18 ± 7	0.50
Maximal diameter of left CIA, mm	18 ± 8	17 ± 7	0.18	17 ± 7	17 ± 8	0.80
Right CIA length, mm	41 ± 18	41 ± 18	0.78	41 ± 17	40 ± 17	0.54
Left CIA length, mm	45 ± 18	46 ± 18	0.43	45 ± 18	45 ± 17	0.79
Minimal diameter of right EIA, mm	8 ± 2	8 ± 2	0.037	8 ± 2	8 ± 2	0.88
Minimal diameter of left EIA, mm	8 ± 2	8 ± 2	0.033	8 ± 2	8 ± 2	0.95
Suprarenal aortic angulation	20 ± 23	19 ± 25	0.34	20 ± 22	20 ± 26	0.88
Infrarenal aortic angulation	41 ± 29	38 ± 33	0.17	41 ± 28	41 ± 34	0.82
Reversed tapered proximal neck, n	44 (13.5%)	15 (4.2%)	< 0.001	19 (7.1%)	15 (5.6%)	0.57
IFU violation, n	172 (52.9%)	159 (45.0%)	0.048	129 (48.5%)	123 (46.2%)	0.64
IFU violation due to PN, n	161 (49.5%)	134 (38.0%)	0.003	118 (44.4%)	108 (40.6%)	0.39

Results!!

266 Endurants

VS

266 Excluders

Operative results

	Endurant (n = 266)	Excluder (n = 266)	P value
Operative time, minutes	152 (128 – 184)	154 (129 - 202)	0.099
Bleeding, mL	49 (10 - 90)	49 (10 - 85)	0.56
Blood transfusion, n	8 (3.0%)	12 (4.5%)	0.48
Internal iliac artery embolization, n	62 (23.3%)	80 (30.1%)	0.092
Intraoperative type Ia endoleak, n	6 (2.3%)	9 (3.4%)	0.61
Intraoperative type Ib endoleak, n	2 (0.8%)	3 (1.1%)	> 0.99
Intraoperative type II endoleak, n	31 (11.7%)	91 (34.2%)	< 0.001
Intraoperative type III endoleak, n	0 (0.0%)	2 (0.8%)	> 0.99
Intraoperative type IV endoleak, n	126 (47.4%)	0 (0.0%)	> 0.99
Intraoperative complication, n	10 (3.8%)	14 (5.3%)	0.54
Intraoperative additional procedure, n	50 (18.8%)	80 (30.1%)	0.004
Perioperative complication, n	4 (1.5%)	11 (4.1%)	0.12
Operative time, minutes	152 (128 - 184)	154 (129 - 202)	0.099
Bleeding, mL	49 (10 - 90)	49 (10 - 85)	0.56
Blood transfusion, n	8 (3.0%)	12 (4.5%)	0.48
Internal iliac artery embolization, n	62 (23.3%)	80 (30.1%)	0.092
Intraoperative type Ia endoleak, n	6 (2.3%)	9 (3.4%)	0.61

a. Include distal artery rupture, hypogastric artery coverage, distal embolization, and CFA dissection

b. Include SMA stent, sac embolization, and CFA TEA.

c. Include pulmonary embolism, rt EIA dissection, type 1a endoleak, CFA dissection, limb stenosis, distal embolization, brachial artery pseudoaneurysm, and type B dissection

Endoleaks during follow up

	Endurant (n = 266)	Excluder (n = 266)	P value
Type Ia endoleak	13 (4.9%)	8 (3.0%)	0.36
Type Ib endoleak	16 (6.0%)	3 (1.1%)	0.006
Type II endoleak	81 (30.5%)	135 (50.8%)	< 0.001
Type III endoleak	7 (2.6%)	4 (1.5%)	0.55
Type V endoleak	15 (5.6%)	4 (1.5%)	0.022

ADVANCE Trial: Endpoints

Primary endpoint
- Proportion of subjects with sac regression of more than 5mm at 1 year

Secondary endpoints
- Aneurysm sac change by diameter
- Aneurysm sac change by volume
- Type II Endoleaks incidence
- Type I Endoleaks incidence
- Secondary Interventions
- All-Cause Mortality incidence

All up to 5 years

Our study

Primary endpoint
- Proportion of subjects with sac regression of more than 5mm at 1 year

Secondary endpoints
- Aneurysm sac increase by diameter
- Type I Endoleaks incidence
- Secondary Interventions
- Late complication incidence
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All up to 5 years

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All up to 5 years

Primary endpoint

	Endurant (n=266)	Excluder (n=266)	P value
Sac regression more than 5mm at 1 year[a]	33.5% [32.7% to 34.2%]	35.0% [32.7% to 37.2%]	0.74

a. after multiple imputation

No difference between the groups for sac regression of more than 5mm at 1 year !!

ADVANCE Trial: Endpoints

Primary endpoint
- Proportion of subjects with sac regression of more than 5mm at 1 year

Secondary endpoints
- Aneurysm sac change by diameter
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All up to 5 years

Our study

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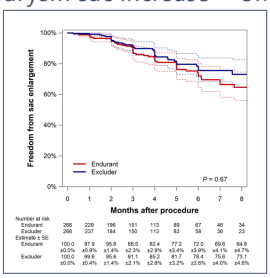
- Proportion of subjects with sac regression of more than 5mm at 1 year

Secondary endpoints
- Aneurysm sac increase by diameter
- Type I Endoleaks incidence
- Secondary Interventions
- Late complication incidence
- All-Cause Mortality incidence

All up to 5 years

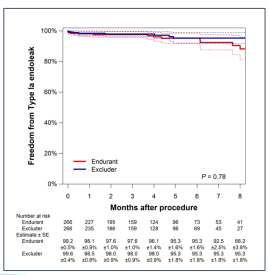
Freedom from aneurysm sac increase > 5mm

No significant difference between the groups!!



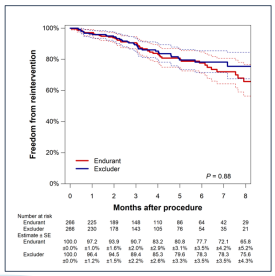
Freedom from type 1a endoleak

No significant difference between the groups!!



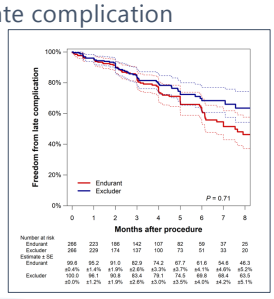
Freedom from reintervention

No significant difference between the groups!!



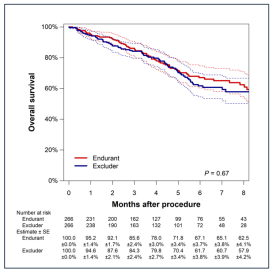
Freedom from late complication

No significant difference between the groups!!

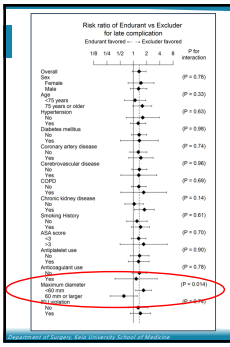


Overall survival

No significant difference between the groups!!



Interaction analysis



Aneurysm ≧ 60mm favors Endurant
Aneurysm < 60mm favors Excluder

Final take home message !!

Our head to head comparison using propensity score matching demonstrated both endografts had similar clinical results!!

≧ 60mm ??? < 60mm

Let' see how ADVANCE trial does!!!

Thank you for your attention !!

25-27 APRIL 2025
GRAND FRONT OSAKA, JAP

Osamu Iida
Masahiko Fujihara

Far Together