



OCEAN-SHD family

Current status and future perspectives

Kentaro Hayashida MD, PhD, FESC, FACC, FJCS

Disclosure

A clinical proctor for Edwards Lifesciences, Medtronic, and Abbott



History of SHD interventions in Japan

TAVI for AS



Edwards SAPIEN XT
2013 Oct



SAPIEN 3
2016 May



TAVI for HD-AS
2021 Feb



S3 Ultra RESILIA
TAV in TAV 2023



Medtronic CoreValve
2016



Evolut-R
2016



TAV in SAV
2018



Evolut-PRO
2018



Navitor
2022



Evolut-FX
2023



TEER for MR

Abbott MitraClip
2018 April



MitraClip G4
2020 March

LAAC for AF

Boston
WATCHMAN 2.5
2019 Sep



WATCHMAN FLX
2021 May

OCEAN-SHD family (TAVI, MitraClip, LAAC)

北海道

- ・札幌東徳洲会病院
- ・札幌心臓血管クリニック

東北地方

- ・岩手医科大学
- ・仙台厚生病院

中部地方

- ・豊橋ハートセンター
- ・名古屋ハートセンター
- ・岐阜ハートセンター
- ・富山大学附属病院

関東地方

- ・聖マリアンナ医科大学
- ・帝京大学
- ・新東京病院
- ・筑波メディカルセンター
- ・東京ベイ・浦安市川医療センター
- ・慶應義塾大学
- ・東京女子医科大学
- ・済生会横浜市東部病院
- ・三井記念病院
- ・榊原記念病院
- ・東海大学
- ・湘南鎌倉総合病院
- ・済生会宇都宮病院
- ・順天堂大学医学部附属順天堂医院

近畿地方

- ・国立循環器病研究センター
- ・近畿大学

中国地方

- ・倉敷中央病院
- ・広島市立広島市民病院

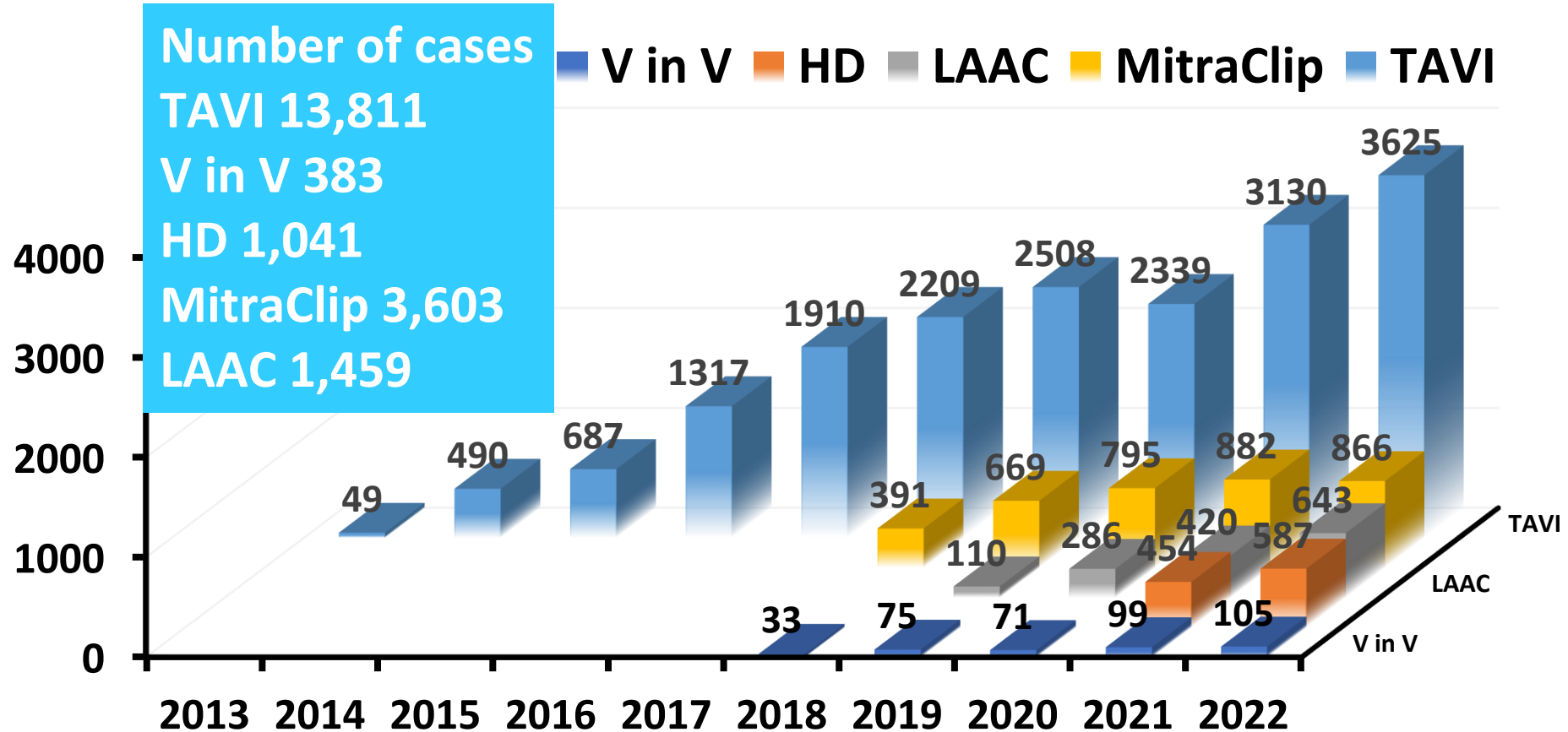
九州地方

- ・小倉記念病院
- ・済生会熊本病院



28 centers, 280 members (June 2023)

Annual number of SHD interventions in OCEAN



OCEAN-TAVI registry

Original Studies

Streamlining the Learning Process for TAVI: Insight From a Comparative Analysis of the OCEAN-TAVI and the Massy Registries

Taku Inohara,¹ Kentaro Hayashida,^{1*} Yugo Nara,² Masanori Yamamoto,³ Takahide Arai,⁴ Thierry L...

Comparison of aortic annulus dimensions between Japanese and European patients undergoing transcatheter aortic valve implantation as determined by multi-detector computed tomography: results from the OCEAN-TAVI (Optimised transCathETER vAlvular interveNtion) registry and a European

MD, PhD;
miaki Yashima⁴, MD;
ichi Fukuda⁴, MD, PhD;



Impact of preparatory
risk of acute coronary
valve implantation

Masanori Yamamoto^{a,b,*}, Tetsuro Shimura^a, Seiji Kano^a, Ai Kagase^a, Atsuko Kodama^a, Yutaka Koyama^a, Yusuke Watanabe^c, Norio Tada^d, Kensuke Takagi^e, Motoharu Araki^f, Shinichi Shirai^g, Kentaro Hayashida^h

Comparison of Results of Transcatheter Aortic Valve Implantation in Patients With Versus Without Active Cancer

Yusuke Watanabe, MD^{a,*}, Ken Kozuma, MD, PhD^a, Hirofumi Hioki, MD^a, Hideyuki Kawashima, MD^a, Yugo Nara, MD^a, Akihisa Kataoka, MD, PhD^a, Shinichi Shirai, MD^b, Norio Tada, MD^c, Motoharu Araki, MD^d, Kensuke Takagi, MD^e, Futoshi Yamanaka, MD^f, Masanori Yamamoto, MD, PhD^{g,h}, and Kentaro Hayashida, MD, PhD^h

The procedural and anaphylactic therapy in patients undergoing transcatheter aortic valve implantation increases risk of bleeding

Hirofumi Hioki,¹ Yusuke Watanabe,¹ Ken Kozuma,¹ Yugo Nara,¹ Hideyuki Kawashima,¹ Akihisa Kataoka,¹ Masanori Yamamoto,² Kensuke Takagi,³ Motoharu Araki,⁴ Norio Tada,⁵ Shinichi Shirai,⁶ Futoshi Yamanaka,⁷ Kentaro Hayashida,⁸ And on behalf of OCEAN-TAVI investigators

>100 papers accepted

>50 projects ongoing

Clinical frailty scale predicts mortality after TAVI



Clinical Frailty Scale

<p>1 Very Fit - People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.</p>	<p>7 Severely Frail - Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~6 months).</p>
<p>2 Well - People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally, e.g. seasonally.</p>	<p>8 Very Severely Frail - Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.</p>
<p>3 Managing Well - People whose medical problems are well controlled, but are not regularly active beyond routine walking.</p>	<p>9 Terminally Ill - Approaching the end of life. This category applies to people with a life expectancy <6 months, who are not otherwise evidently frail.</p>
<p>4 Vulnerable - While not dependent on others for daily help, often symptoms limit activities. A common complaint is being "slowed up", and/or being tired during the day.</p>	
<p>5 Mildly Frail - These people often have more evident slowing, and need help in high order IADLs (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.</p>	
<p>6 Moderately Frail - People need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing.</p>	

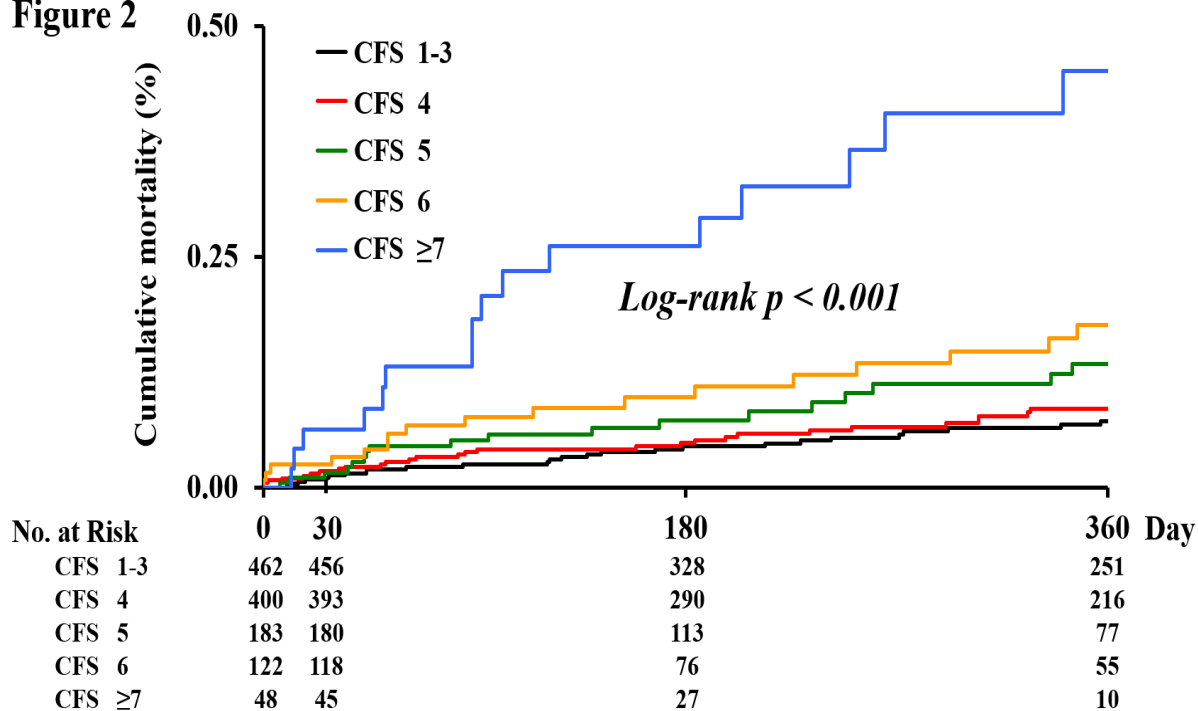
Scoring frailty in people with dementia

The degree of frailty corresponds to the degree of dementia. Common **symptoms in mild dementia** include forgetting the details of a recent event, though still remembering the event itself; repeating the same question/story and social withdrawal.

In **moderate dementia**, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

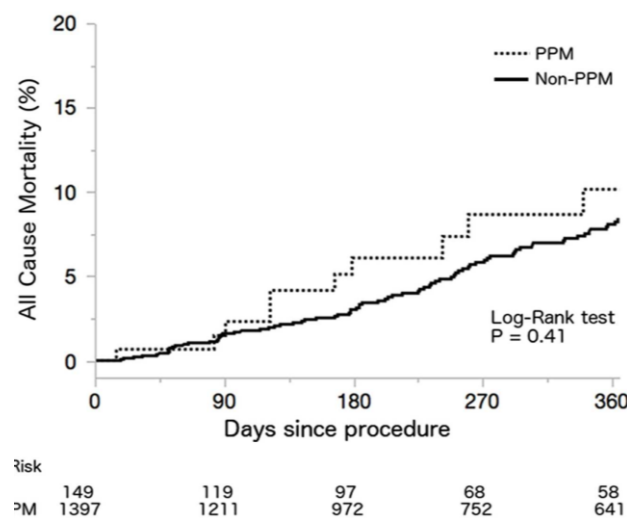
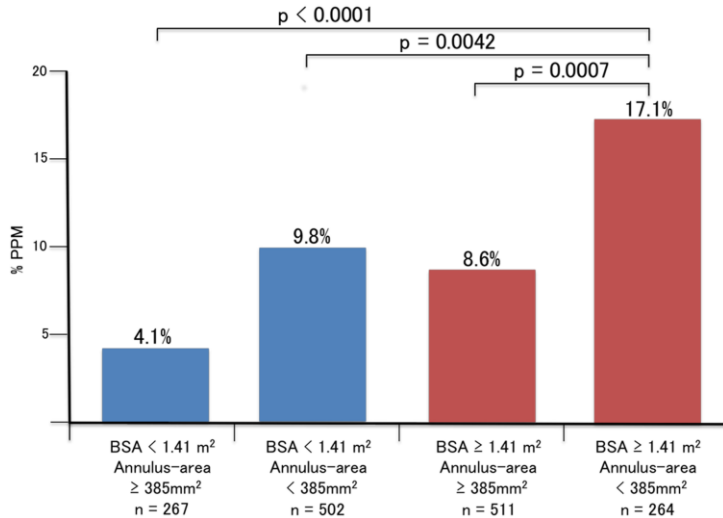
In **severe dementia**, they cannot do personal care without help.

Figure 2



Shimura, Yamamoto et al. Circulation 2017

Low prevalence of PPM in Japan

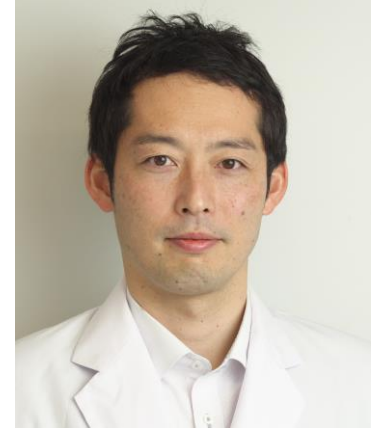


moderate PPM: 8.9% (138)

severe PPM: 0.7% (11)

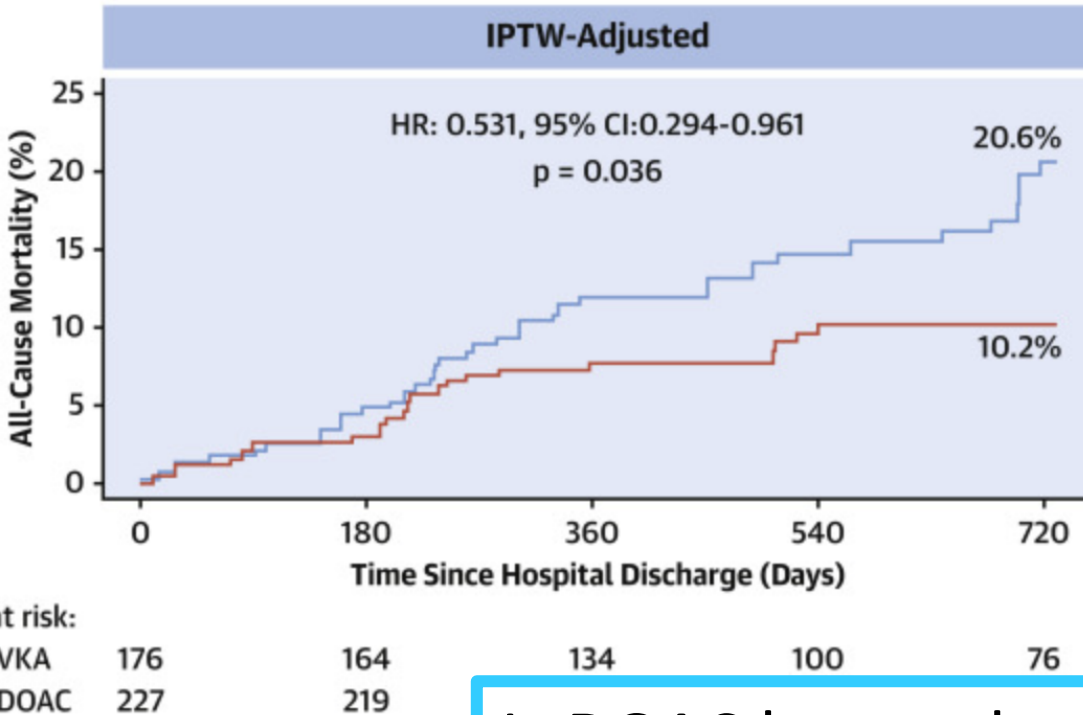
12% in US*

mean BSA: 1.4m² (JP) vs. 1.9m² (US)



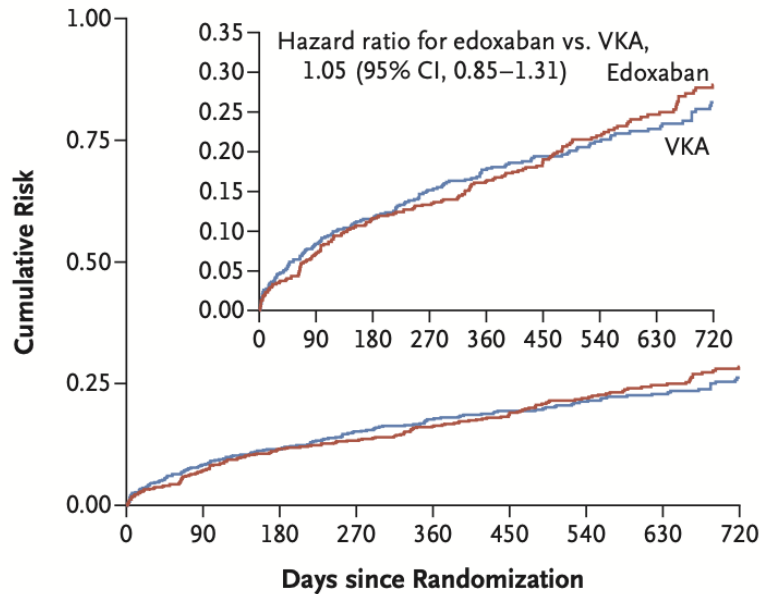
Miyasaka, Tada et al. JACC Int in 2017, Herman et al. JACC 2018*

DOAC vs. VKA after TAVI for patients with Af



Is DOAC better than Warfarin?

ENVISAGE-TAVI AF trial



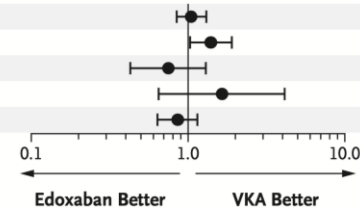
No. at Risk

Edoxaban	713	618	568	543	504	410	332	245	181
VKA	713	597	545	510	474	387	322	247	175

Event

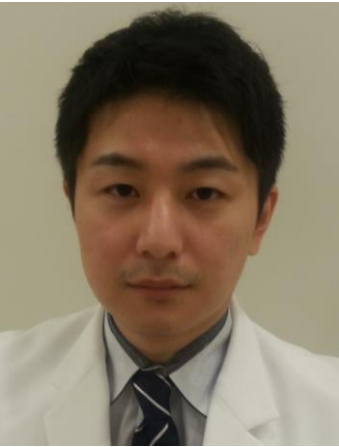
	Edoxaban rate per 100 person-yr (no. of patients/total no.)	VKA
Net adverse clinical events	17.3 (170/713)	16.5 (157/713)
Major bleeding	9.7 (98/713)	7.0 (68/713)
Ischemic stroke	2.1 (22/713)	2.8 (28/713)
Myocardial infarction	1.1 (12/713)	0.7 (7/713)
Death from any cause	7.8 (85/713)	9.1 (93/713)

Hazard Ratio (95% CI)

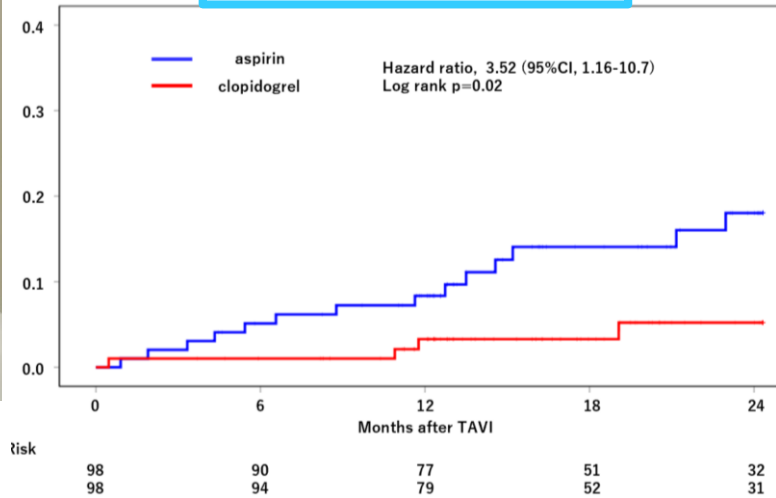


Edoxaban noninferior to Warfarin

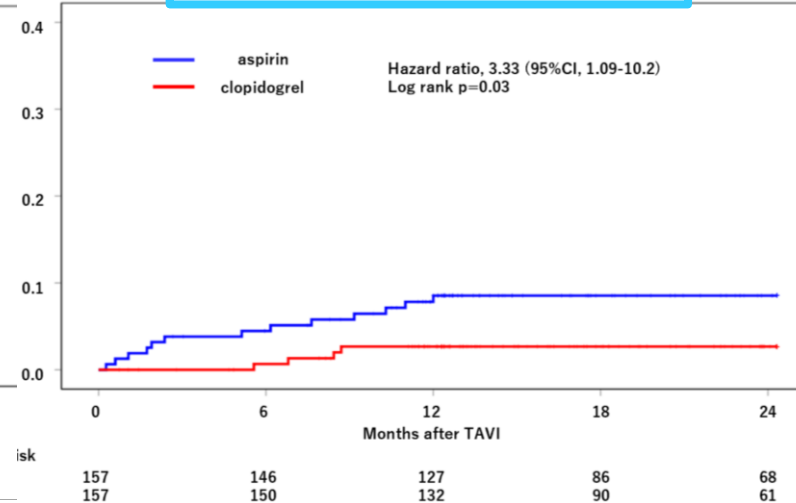
Clopidogrel is better than ASA to reduce cardiovascular death after TAVI



With anticoagulation



Without anticoagulation

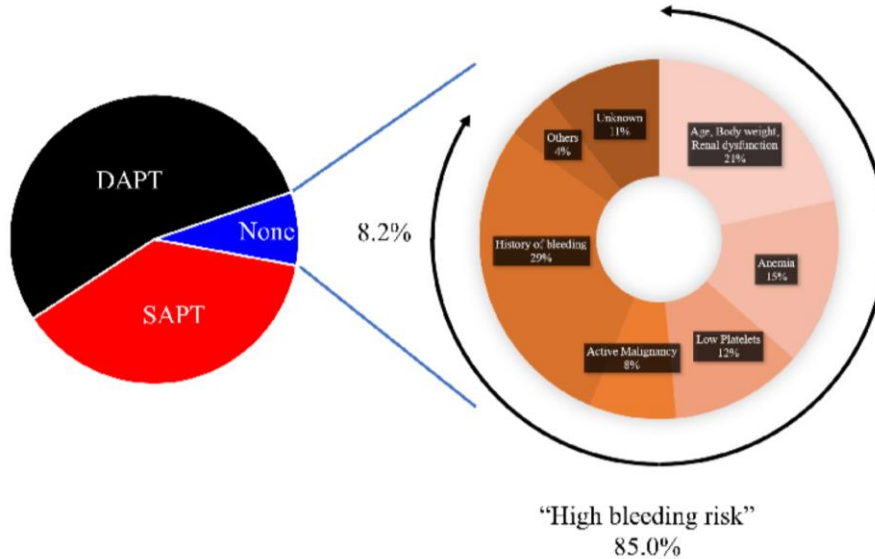


Clopidogrel was better than ASA

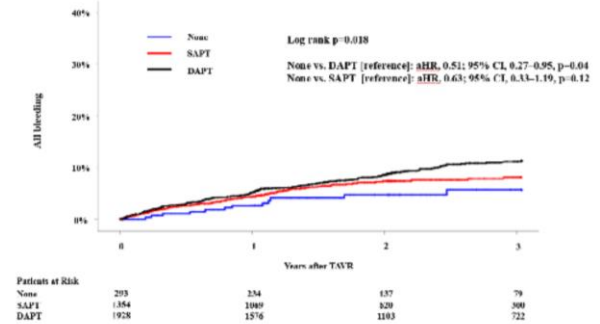
No antithrombotic regimen after TAVI

Antiplatelets regimen at discharge

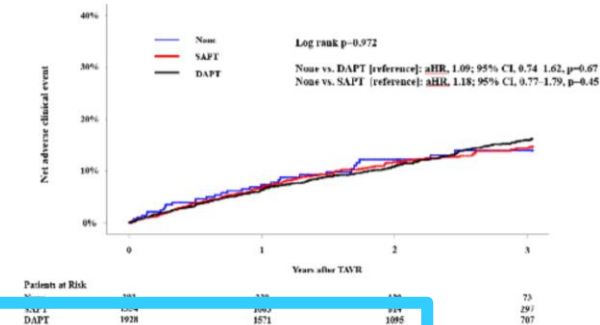
Reason for No Antithrombotic Therapy



All bleeding



NACE



We do not need an antiplatelet Tx?

RCT by the OCEAN-SHD family

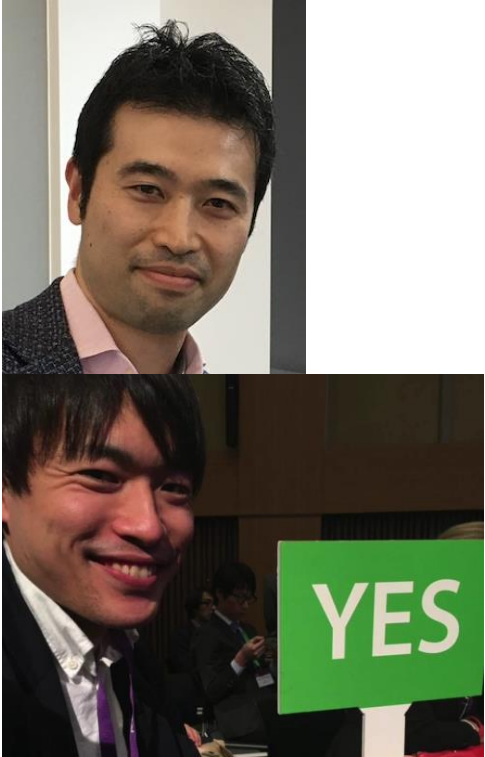
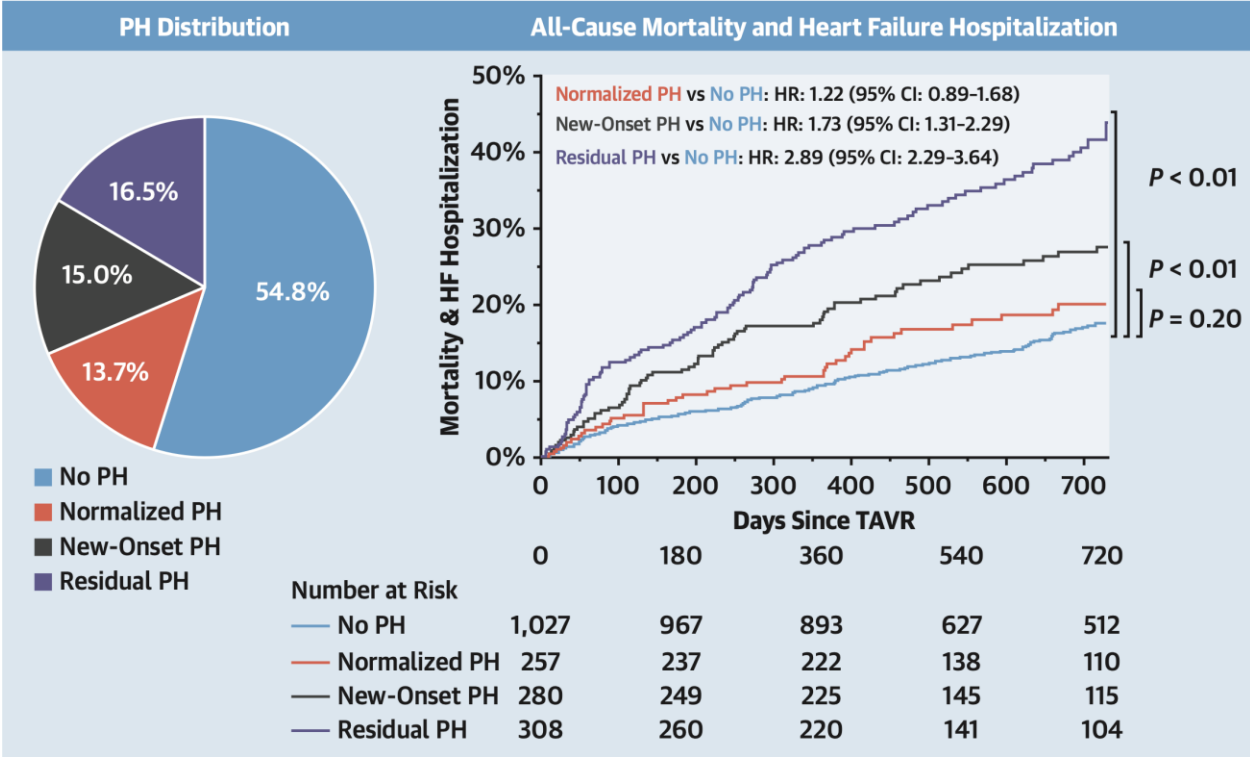
- No APT (n=180) vs. ASA (n=180) after TF-TAVI
- Multicenter RCT (20 centers)



NAPT trial

Non-Antithrombotic theraPy after Transcatheter
aortic valve implantation - trial

Impact of Periprocedural PH on Outcomes After TAVR



OCEAN-SHD family (Jan 2016, 8 centers)



OCEAN-SHD family (Feb 2020, 25 centers)



OCEAN-SHD family (Jan 2023, 28 centers)





PIs: OCEAN-SHD family



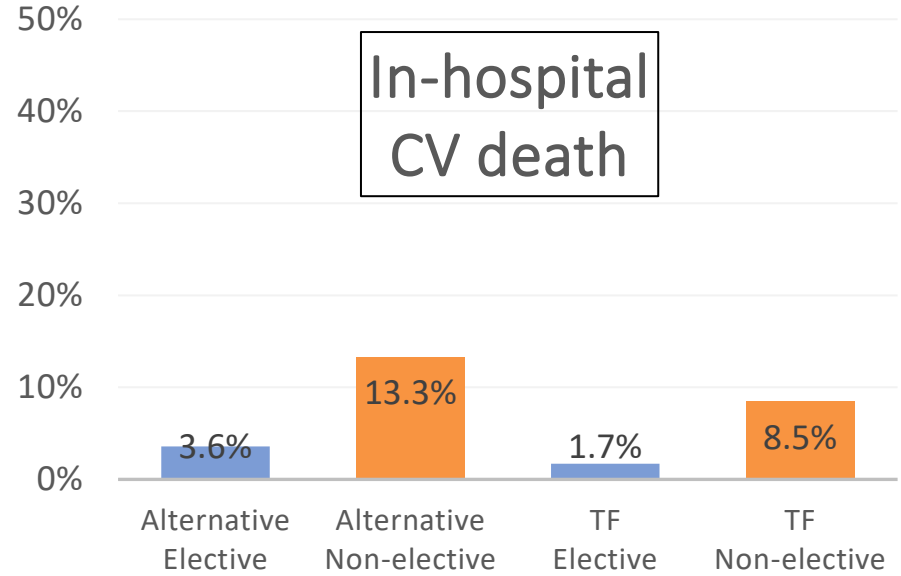
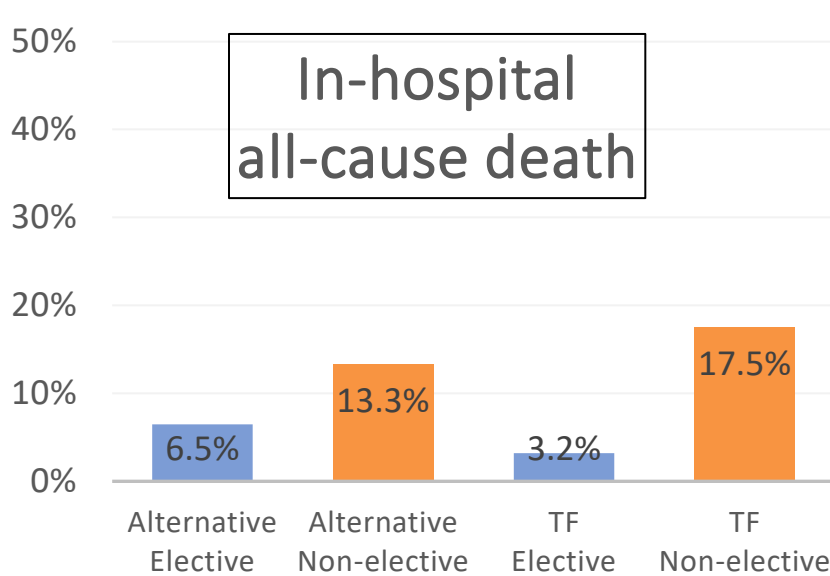
TAVI for Dialysis Patients

Insights From the OCEAN-TAVI Dialysis Cohort

Taku Inohara, Masanori Yamamoto, Yusuke Watanabe, Norio Tada, Toru Naganuma, Futoshi Yamanaka, Kazuki Mizutani, Masahiko Noguchi, Hiroshi Ueno, Kensuke Takagi, Masahiko Asami, Kazumasa Yamasaki, Hiroto Suzuyama, Masaki Izumo, Yohei Ohno, Shinichi Shirai, Kentaro Hayashida, OCEAN-TAVI investigators

Preliminary results @ 10th March 2023, Japanese Circulation Society Annual Meeting

High mortality in emergent cases



Overall in-hospital mortality: 43/885 (4.9%)
Overall in-hospital CV death: 24/885 (2.7%)

Reason of non-CV death	N=19
Infection	6
Non-obstructive intestinal ischemia	4
Suffocation	3
Stroke	3
Multi-organ failure	1
Undetermined	2

Patient selection is important



***The 87th Annual Scientific Meeting of the Japanese
Circulation Society, 10th March 2023, Fukuoka***

Outcomes of Transcatheter Aortic Valve Implantation for Failed Surgical Bioprosthesis: Insights from the OCEAN-TAVI TAV-in-SAV Cohort



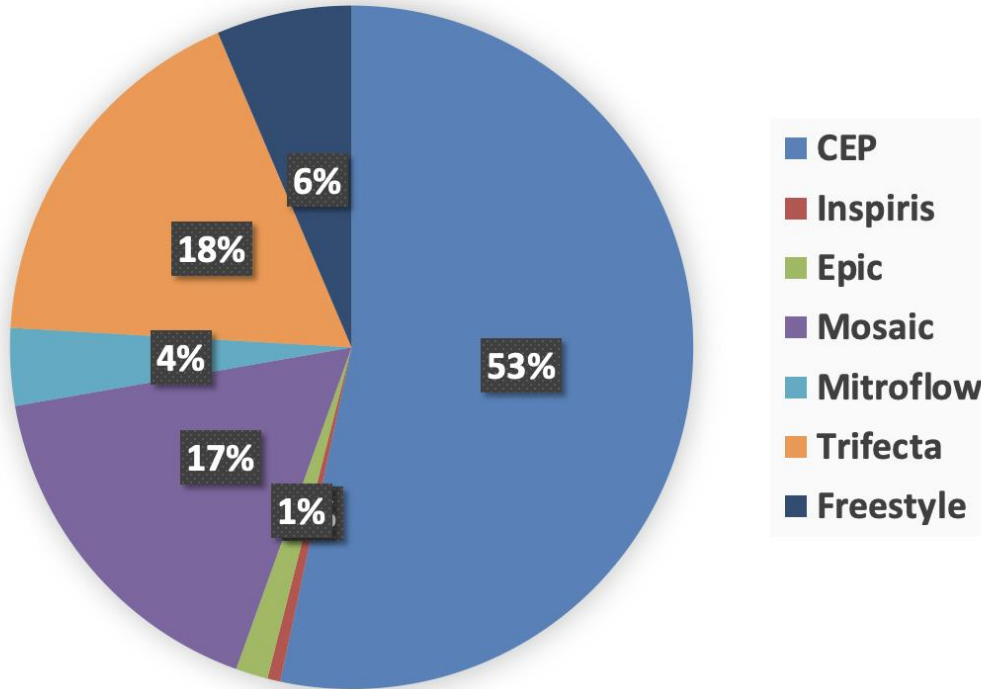
***Yohei Ohno, MD, PhD, FESC
Tokai University School of Medicine, Isehara, Japan
on behalf of the OCEAN-TAVI Investigators***



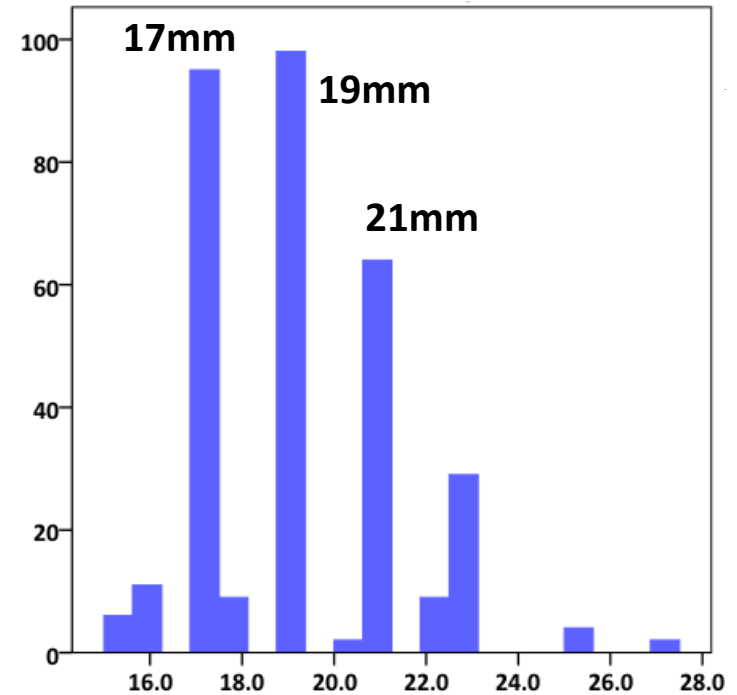
JCS 2023

Surgical Valve Characteristics

Failed Bioprosthetic Surgical Valve



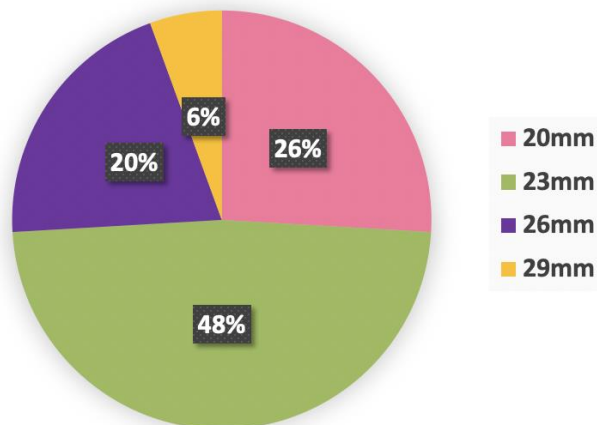
True Internal Diameter (mm)



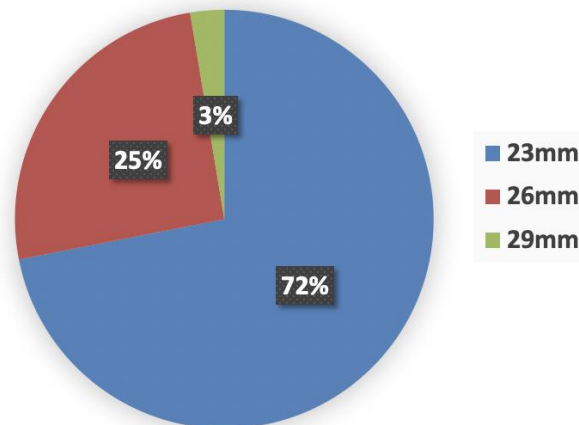
Procedure details

	Overall N=329	Small Bioprosthesis N=221	Large Bioprosthesis N=108	p
TF-approach, n (%)	302 (91.8)	202 (91.4)	100 (92.6)	0.712
Percutaneous approach, n (%)	272 (82.7)	183 (82.8)	89 (82.4)	0.449
Local Anesthesia, n (%)	164 (49.8)	112 (50.7)	52 (48.1)	0.666
Pre-TAVR BAV, n (%)	11 (3.3)	10 (4.5)	1 (0.9)	0.088
Post-TAVR BAV, n (%)	103 (31.3)	81 (36.7)	22 (20.4)	0.003
≥ 2 valves implanted	3 (0.9)	3 (1.4)	0 (0)	0.285
Sapien 3	54 (16.5)	29 (13.2)	25 (23.4)	0.02
Evolut series	267 (81.2)	186 (84.2)	81 (75.0)	0.134

Sapien 3 Valve Size



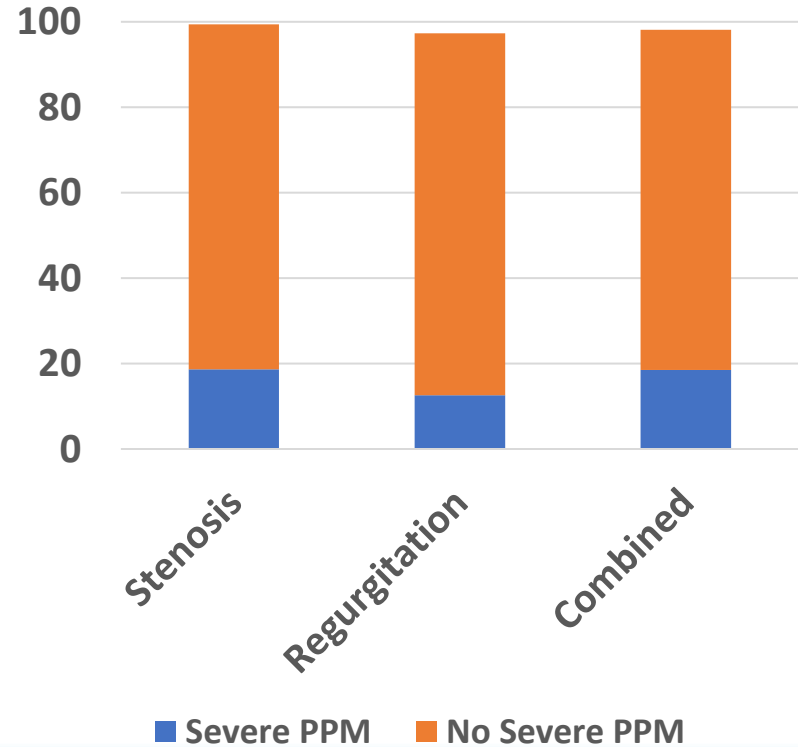
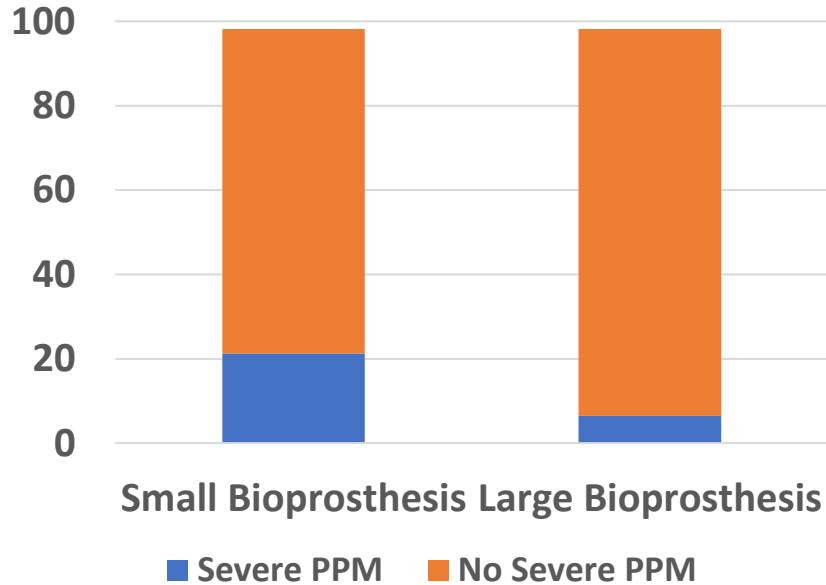
Evolut Valve Size



Post-Procedural Outcomes

	Overall	Small Bioprosthesis	Large Bioprosthesis	p
	N=329	N=221	N=108	
In-hospital Outcome				
All-cause mortality, n (%)	5 (1.5)	4 (1.8)	1 (0.9)	1.000
CV mortality, n (%)	2 (0.6)	2 (0.9)	0 (0.0)	0.612
Disabling stroke, n (%)	3 (0.9)	3 (1.4)	0 (0.0)	0.554
Coronary obstruction, n (%)	2 (0.6)	1 (0.5)	1 (0.9)	0.549
Life-threatening bleeding, n (%)	10 (3.0)	6 (2.7)	4 (3.7)	0.734
Major bleeding, n (%)	18 (5.5)	13 (5.9)	5 (4.6)	0.639
Major vascular complication, n (%)	7 (2.1)	6 (2.7)	1 (0.9)	0.433
New pacemaker implantation, n (%)	11 (3.3)	9 (4.1)	2 (1.9)	0.514

Incidence of severe PPM ($<0.65\text{cm}^2/\text{m}^2$)



Currently available TAVR devices in Japan

Sapien 3
Ultra RESILIA



Evolut FX



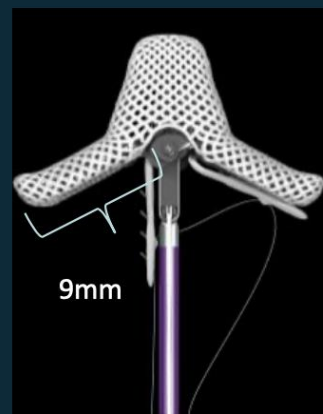
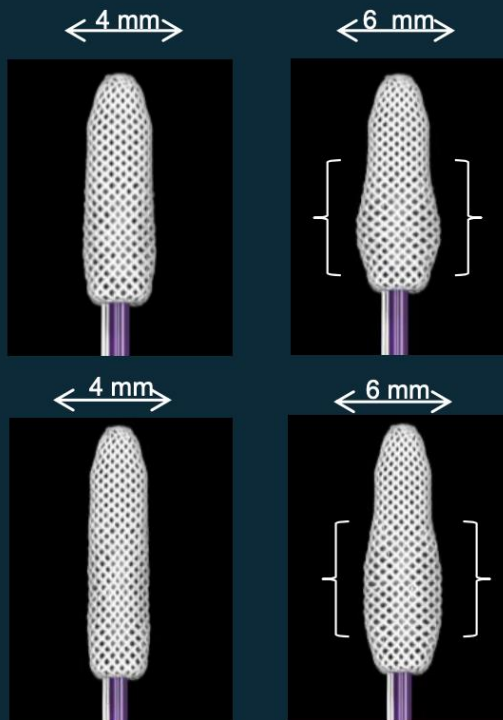
Navitor



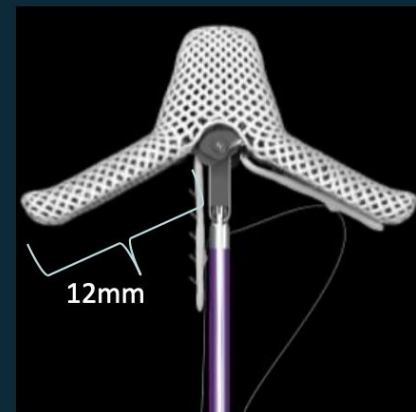
MitraClip G4

MitraClip™ G4

4 Clip sizes



17 mm at 120 degrees
20 mm at 180 degrees



22 mm at 120 degrees
25 mm at 180 degrees



Current MitraClip Results from OCEAN-Mitral Registry

Shunsuke Kubo

On the behalf of OCEAN-SHD family

Preliminary results @ 24th September 2022, JCC

OCEAN-Mitral registry

04/01/2018 ~ 09/30/2021

北海道

- ・札幌東徳洲会病院

東北地方

- ・岩手医科大学
- ・仙台厚生病院

中部地方

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- ・筑波メディカルセンター
- ・東京ベイ・浦安市川医療センター
- ・慶應義塾大学
- ・東京女子医科大学
- ・済生会横浜市東部病院
- ・三井記念病院
- ・榊原記念病院
- ・東海大学
- ・湘南鎌倉総合病院
- ・済生会宇都宮病院

近畿地方

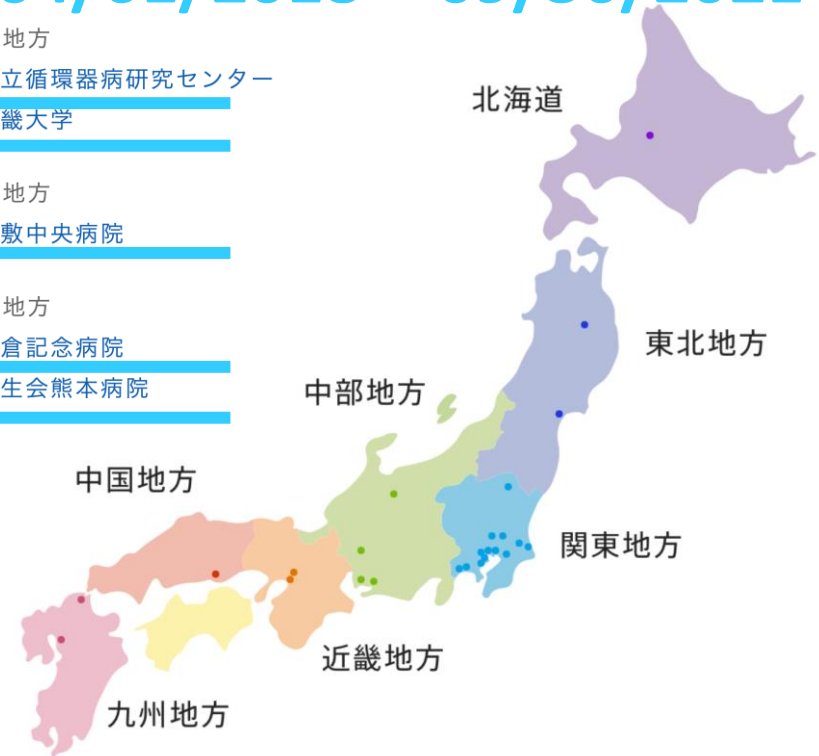
- ・国立循環器病研究センター
- ・近畿大学

中国地方

- ・倉敷中央病院

九州地方

- ・小倉記念病院
- ・済生会熊本病院



Procedural Results

N = 2158

Acute procedural success

2037 (94.4)

Inhospital mortality

48 (2.2)

Procedure time

98 ± 50 min

Device time

70 ± 43 min

Fluoroscopic time

31 ± 21 min

of clips

1.4 ± 0.5

SLDA

33 (1.5)

Leaflet tear

24 (1.1)

Access site complications

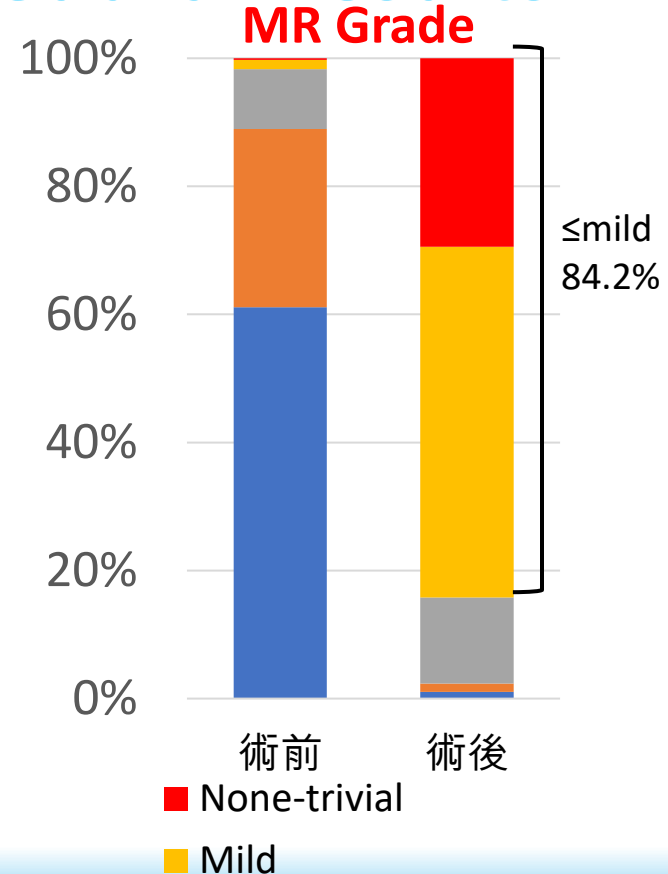
49 (2.3)

iASD closure

26 (1.2)

Post-procedural TMPG

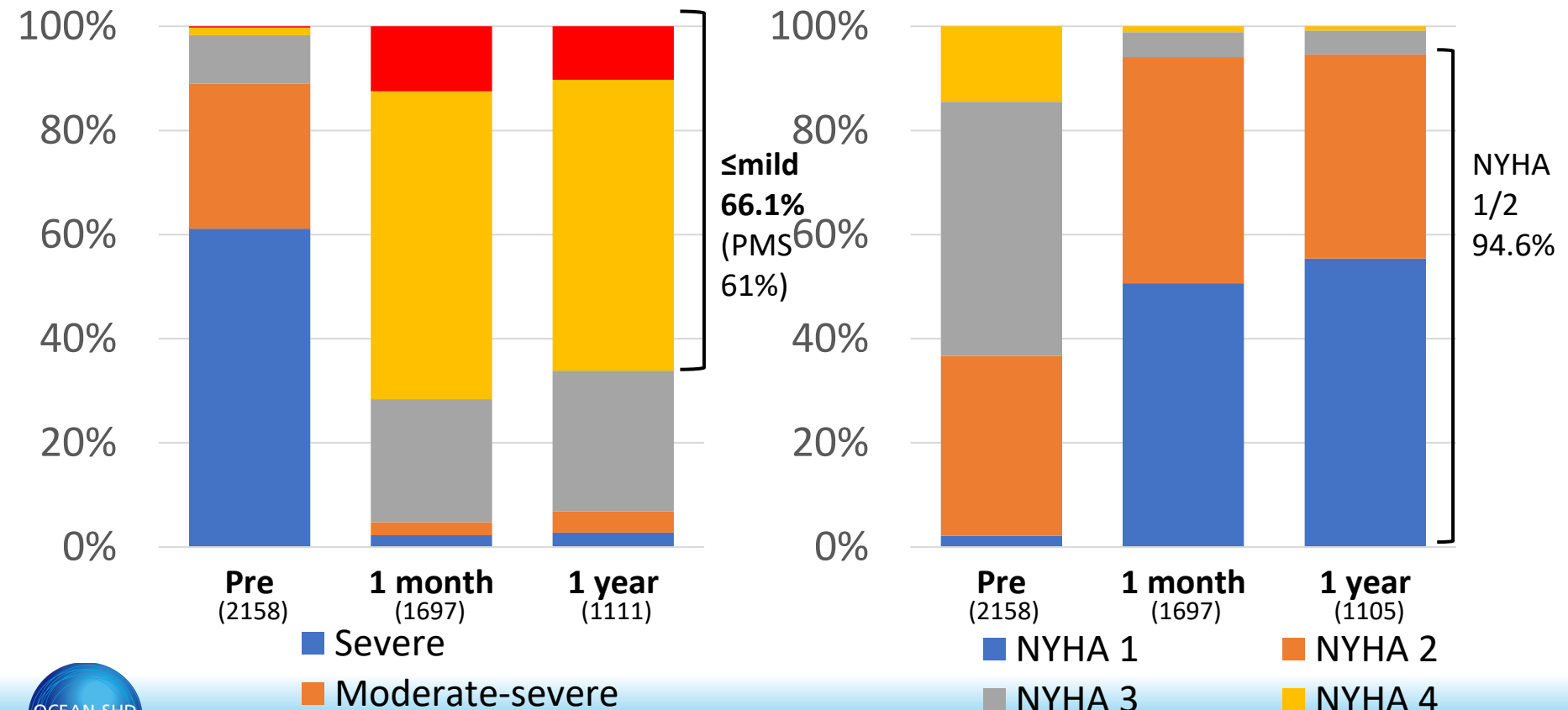
2.8 ± 1.5 mmHg



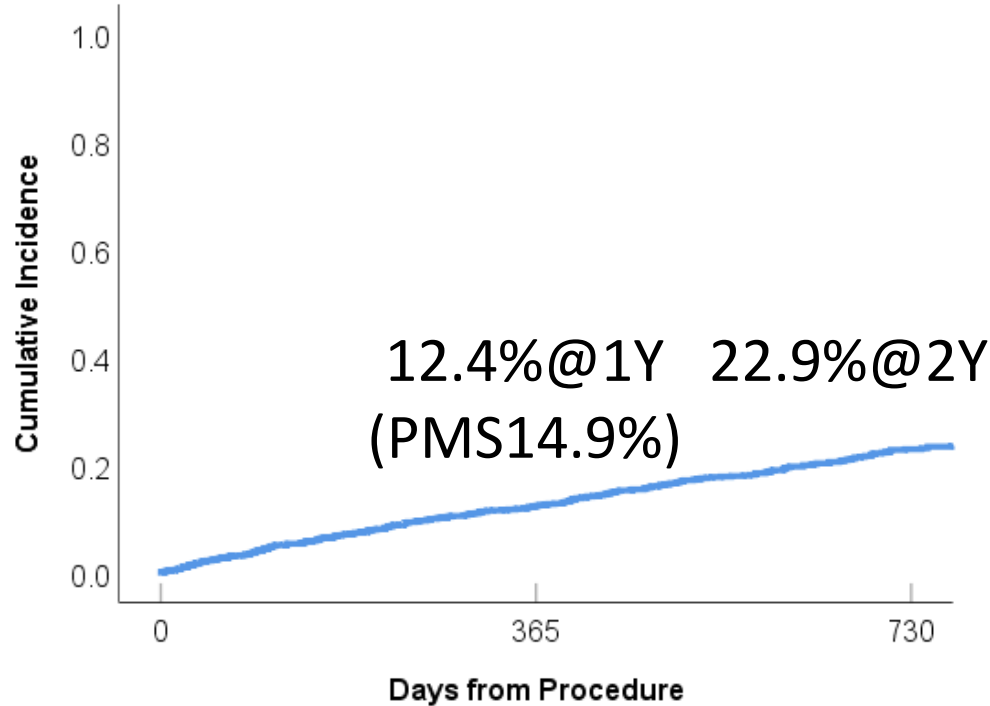
Serial MR grade and NYHA class

MR Grade

NYHA Class



All-Cause Death



2-Year Follow-up

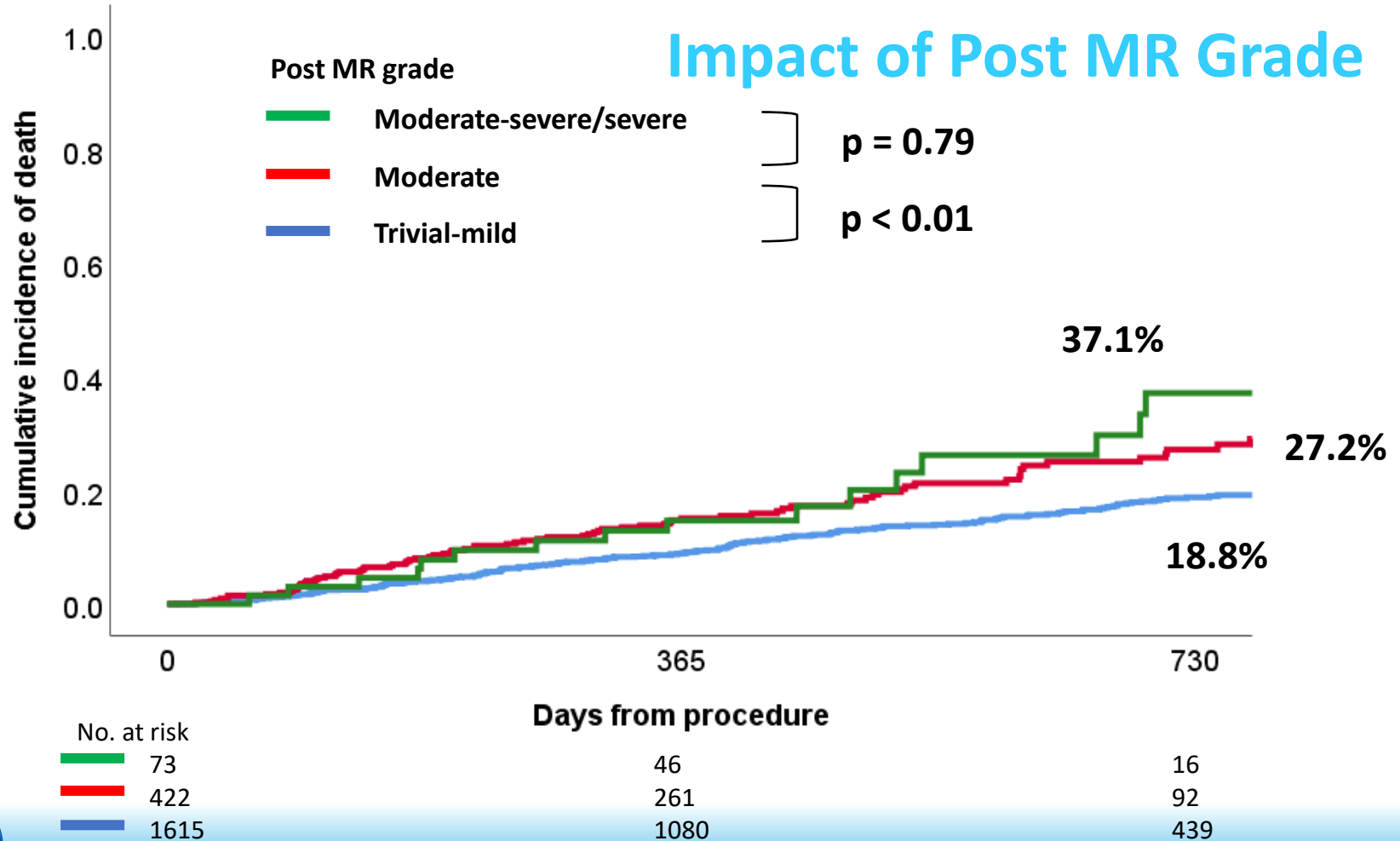
Cumulative incidence at 2 years

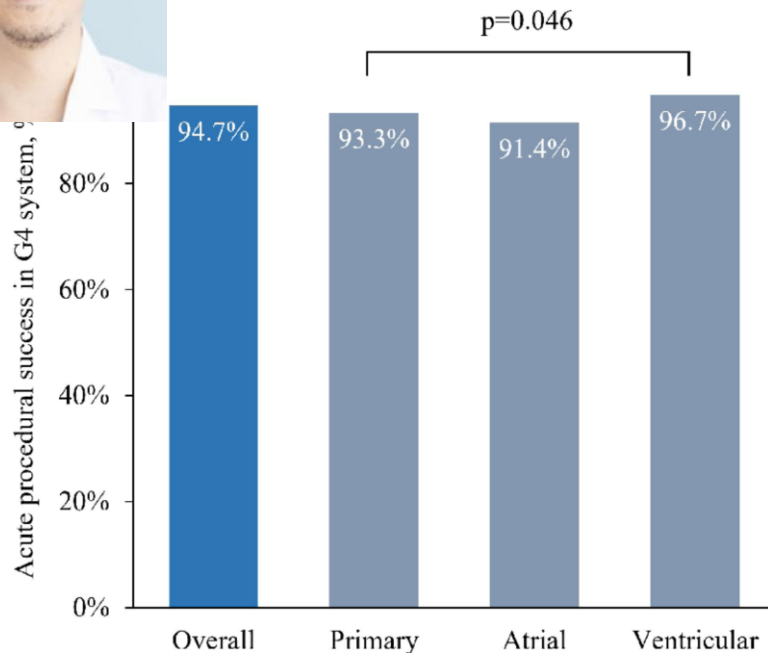
Death	339 (22.9)
Cardiac death	177 (12.7)
All hospitalization	561 (36.0)
CHF hospitalization	344 (23.2)
Conversion to op	34 (2.0)
Re-MitraClip	24 (2.2)
Stroke	38 (2.6)



Mortality 20.2% @1Y, HF hospitalization 14.1% @1Y in TRAMI registry
 Mortality 25.8% @1Y, HF hospitalization 20.2% @1Y in TVT registry

Impact of Post MR Grade



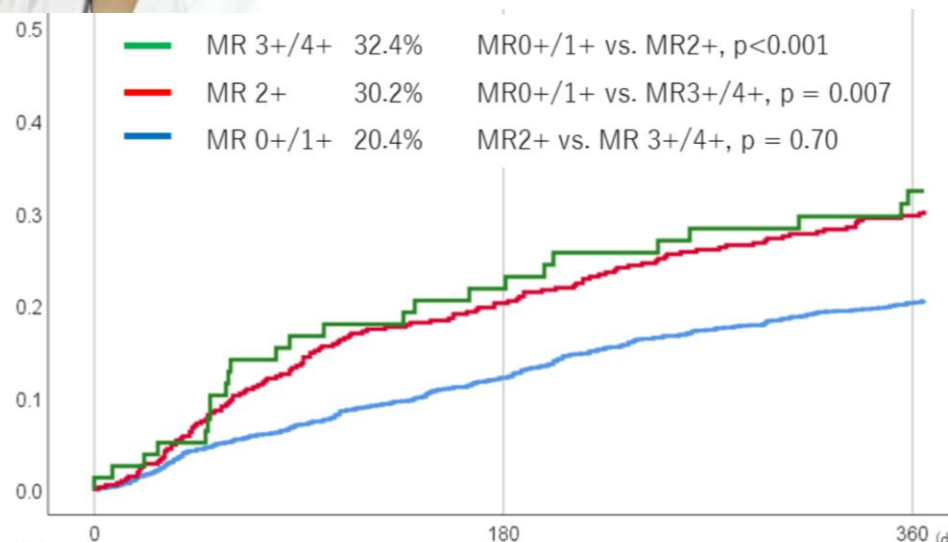


Mitral: 30-day outcome

Saji et al. JACC Asia in press



OCEAN-Mitral



Mitral: 1-year outcome

Kubo et al. JAHA in press

Devices for LAAC in Japan

Watchman FLX, Boston Scientific



Amulet, Abbott





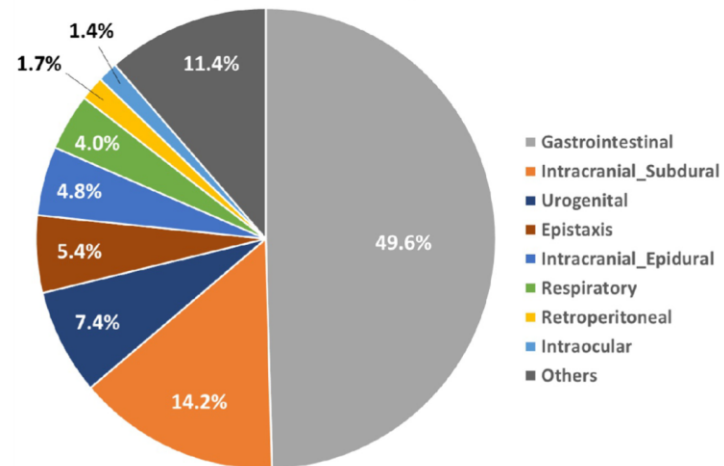
The OCEAN-LAAC registry

The OCEAN-LAAC registry (n = 548)

Mean CHADS₂ score of 3.1 ± 1.3 , CHA₂DS₂-VAsC score of 4.7 ± 1.5 , and HAS-BLED score of 3.2 ± 1.0 points

Device success: **96.5%** Technical success: **96.0%** Procedural success: **90.5%**

History of bleeding



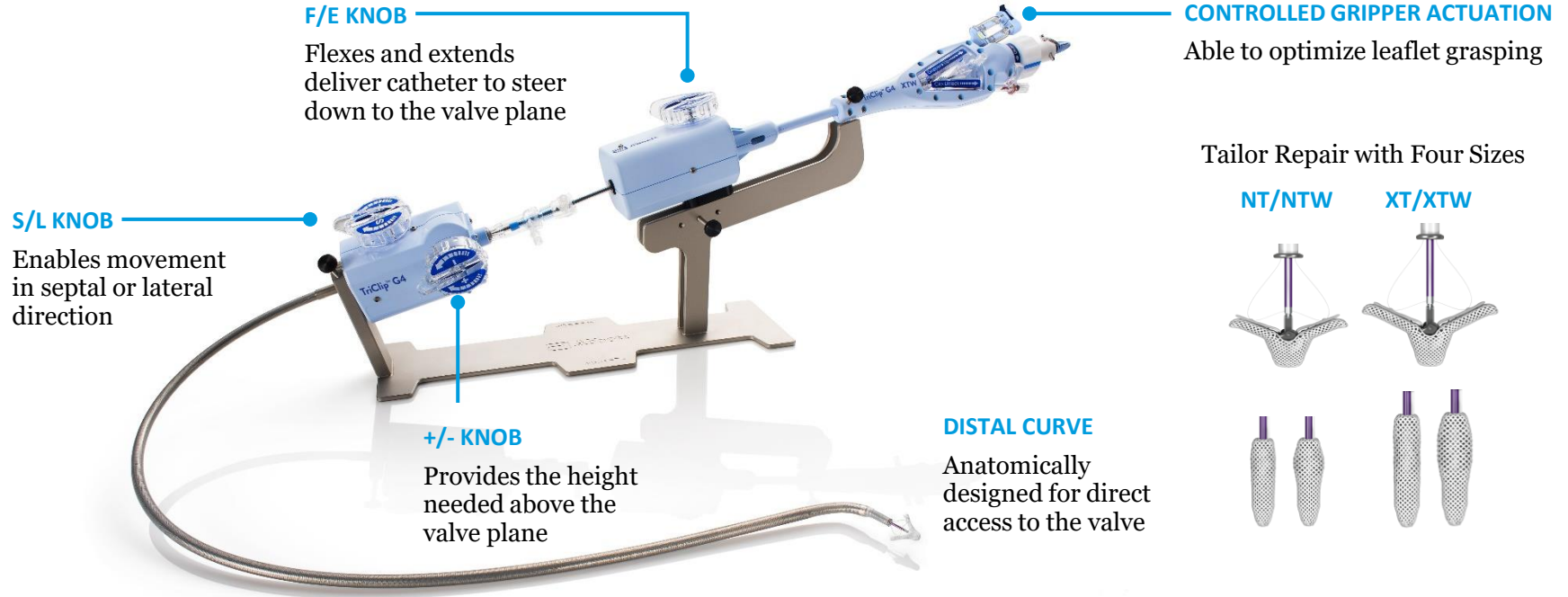
Anticoagulants cessation at 45-day follow-up: 89.9%

	Younger group (age ≤70) n = 104	Middle-aged group (70< age ≤80) n = 271	Elderly group (80< age) n = 173
	In-hospital/at 45-day	In-hospital/at 45-day	In-hospital/at 45-day
All-cause death	0.0%/1.0%	0.0%/0.4%	0.0%/0.0%
Any strokes	0.0%/0.0%	0.0%/0.7%	0.0%/0.0%
Any bleedings	1.9%/5.8%	1.5%/5.9%	4.6%/10.4%
Pericardial effusions	1.0%/1.0%	1.5%/1.5%	3.5%/4.6%
Device embolization	0.0%/0.0%	0.0%/0.0%	0.0%/0.0%



TriClip™ G4 TVRS

A NEW TREATMENT OPTION FOR SEVERE, SYMPTOMATIC PATIENTS AT HIGH RISK FOR SURGERY



Enrollment complete for the clinical trial

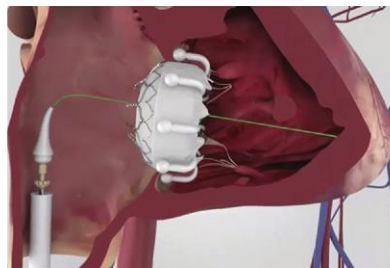
The 1st case of TriClip G4 @KEIO 2022/3/1



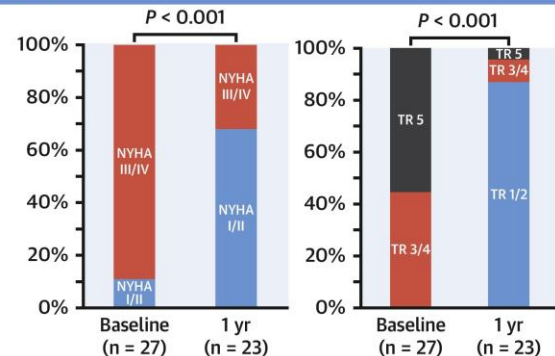
EVOQUE transfemoral tricuspid replacement 1-year outcome

CENTRAL ILLUSTRATION: 1-Year EVOQUE Transfemoral Transcatheter Tricuspid Valve Replacement for Severe Tricuspid Regurgitation

EVOQUE Transfemoral Tricuspid Replacement 1-Year Clinical and Echocardiographic Outcomes



1-Year Follow-Up



27 patients with severe TR
treated with the EVOQUE system
7 sites (Canada, Europe, U.S.)
May 2019 to July 2020

All-cause mortality: 7%
HF hospitalization: 7%
New pacemaker: 7% within 30 days,
4% beyond 30 days

Sustained improvement in NYHA functional class as well as improvement in TR degree suggesting that the EVOQUE System is a promising treatment option for this population

Webb, J.G. et al. J Am Coll Cardiol Interv. 2022;15(5):481-491.

The 1st case of TTVI in Japan 2023/3/28

