



Current status of TAVR in Japan

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Disclosure

A clinical proctor for Edwards Lifesciences

TAVI history in Japan



SAPIEN XT
2013 OCT.



SAPIEN 3
2016 MAY

2016 JAN.
CoreValve



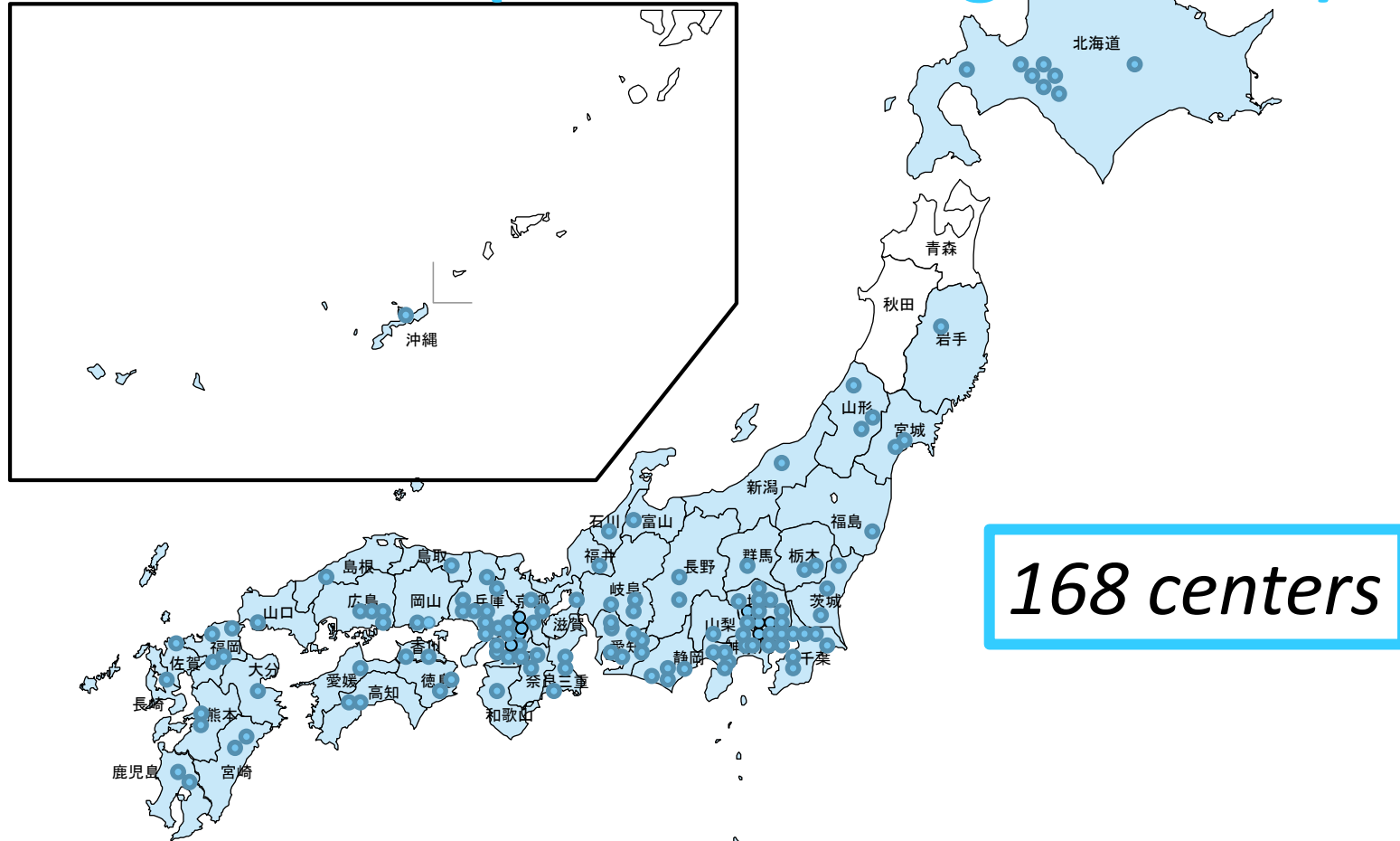
2016 DEC.
Evolut-R



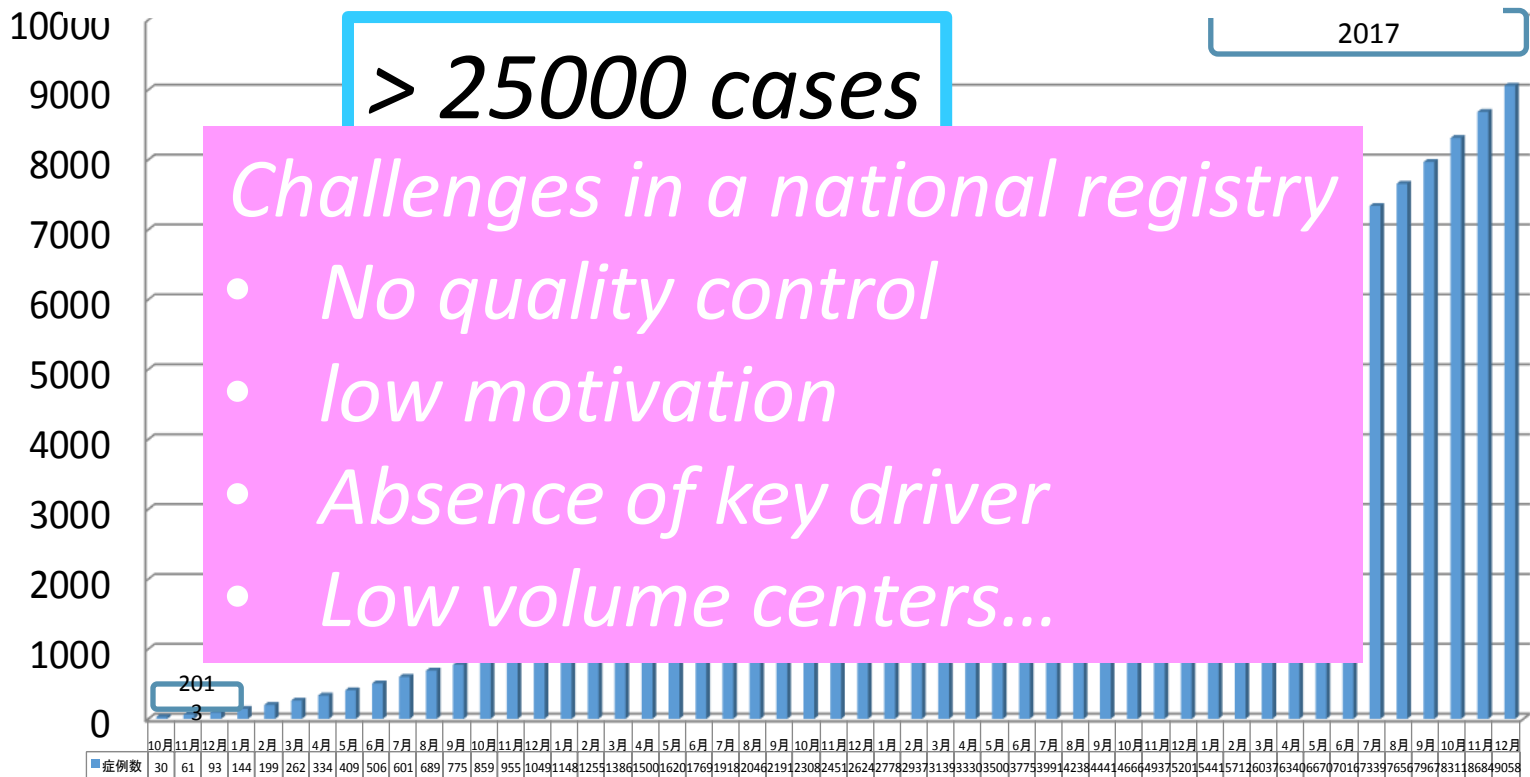
2018
Evolut-Pro



TAVI centers (Oct 2013-August 2019)



TAVI cases (Oct 2013 - Aug 2019)



OCEAN-TAVI registry

Keio Univ

Toyohashi/Nagoya

Teikyo Univ

Advantages of the OCEAN-TAVI registry

- *Highly-motivated high-volume centers*
- *Beyond politics*
- *Quality control by monitoring*
- *99% follow-up at 1-year*
- *Experienced data*

St Marianna

Tsukuba Medical

Sapporo Tokusyukai

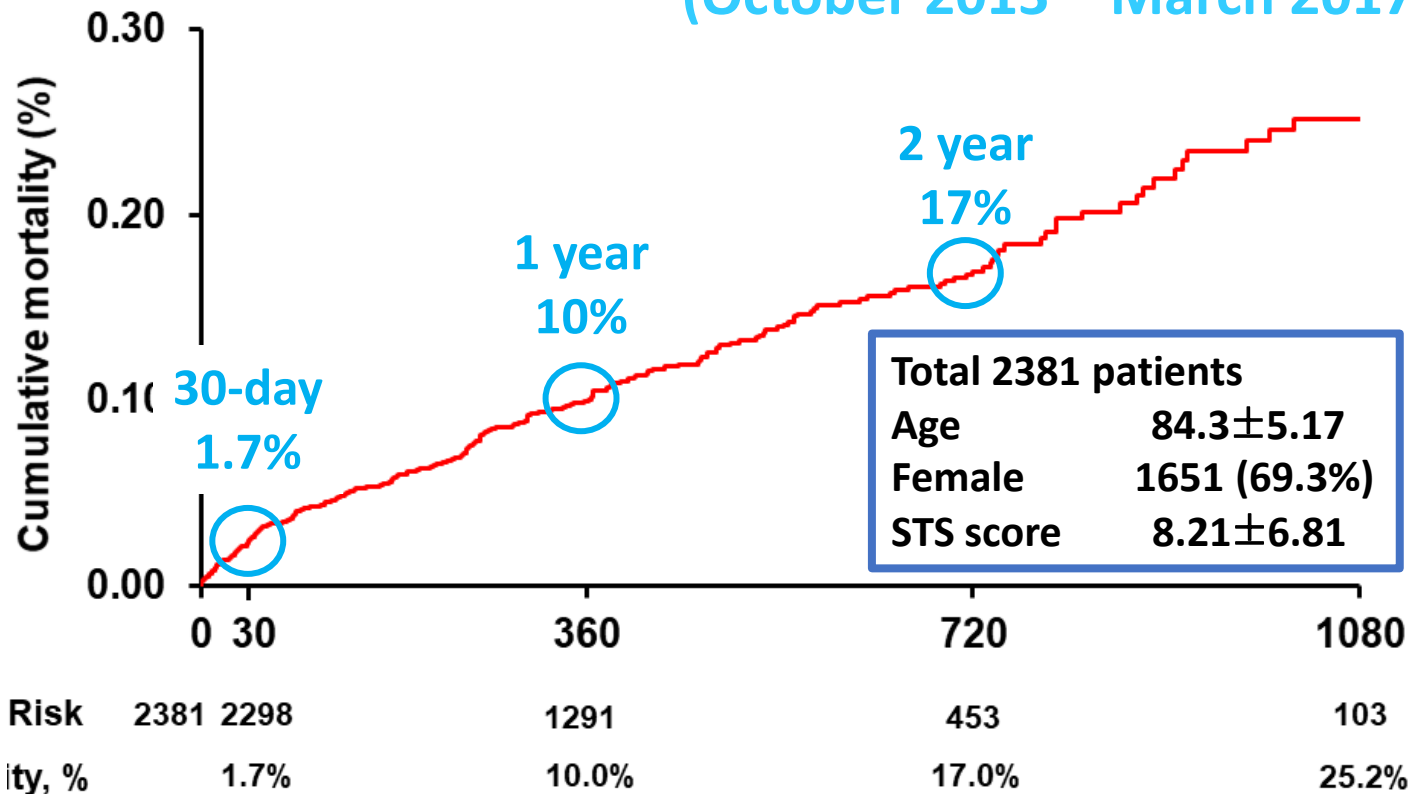
Iwate Medical

Saiseikai Kumamoto

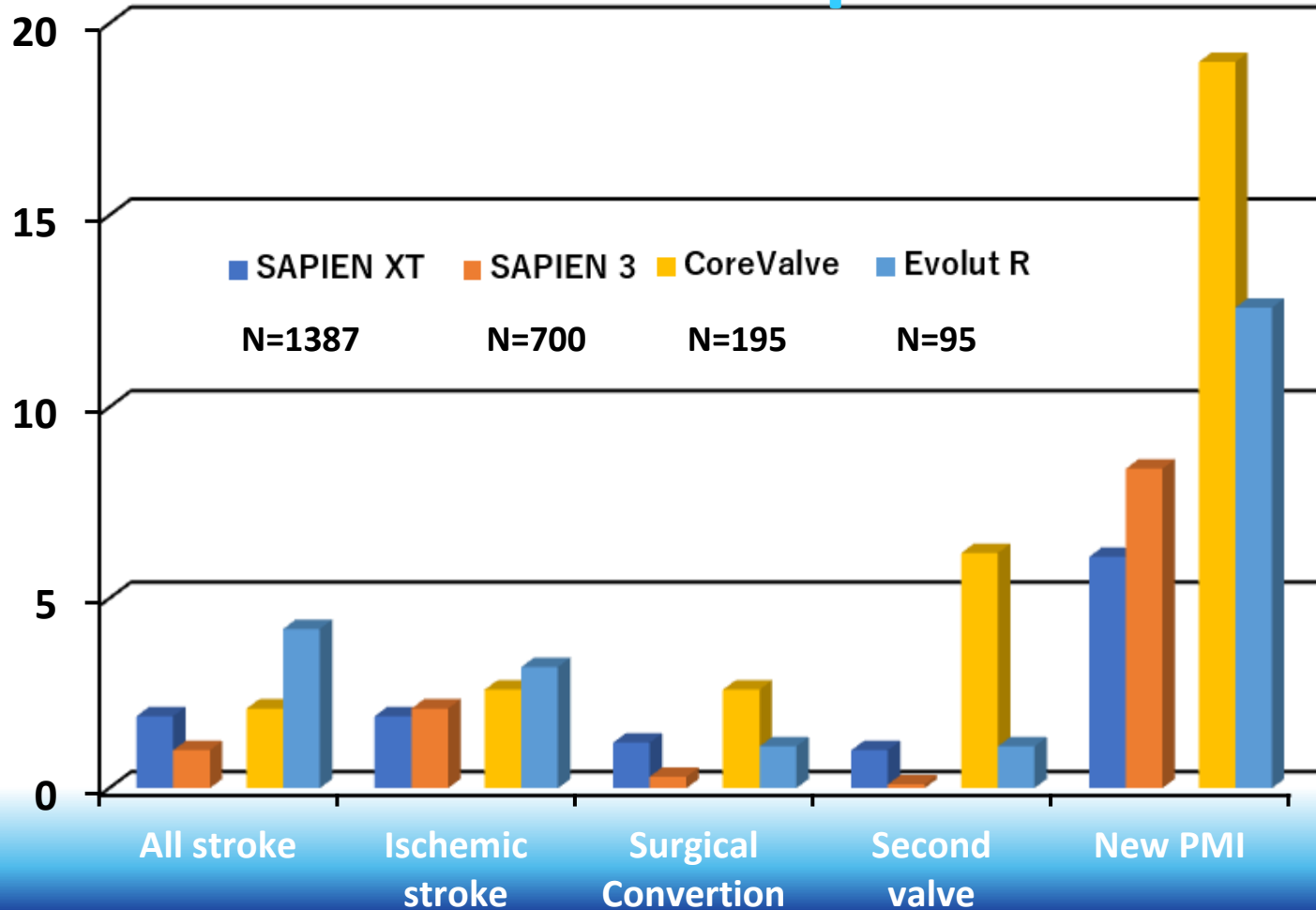


Overall cumulative mortality

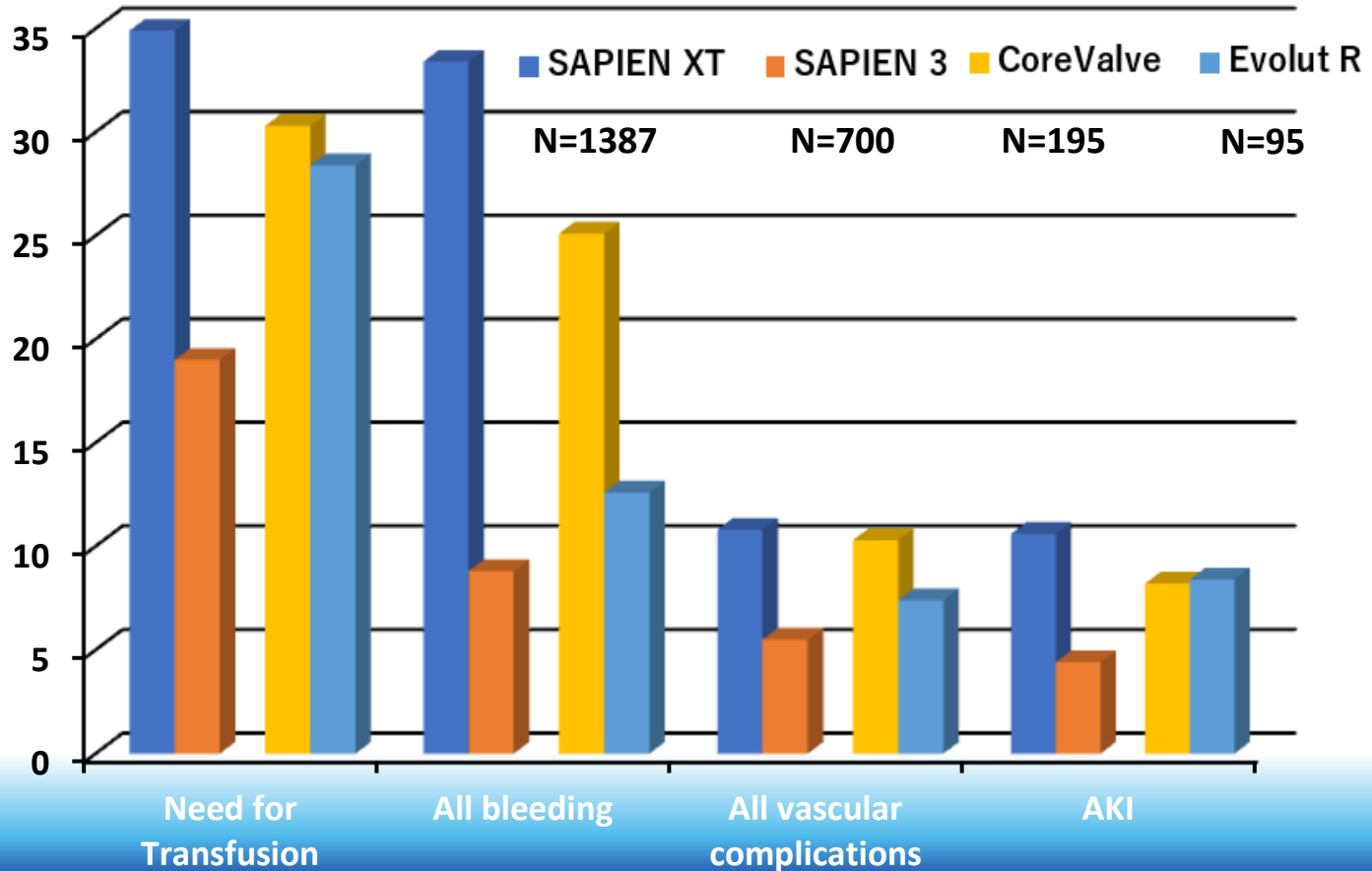
(October 2013 – March 2017)



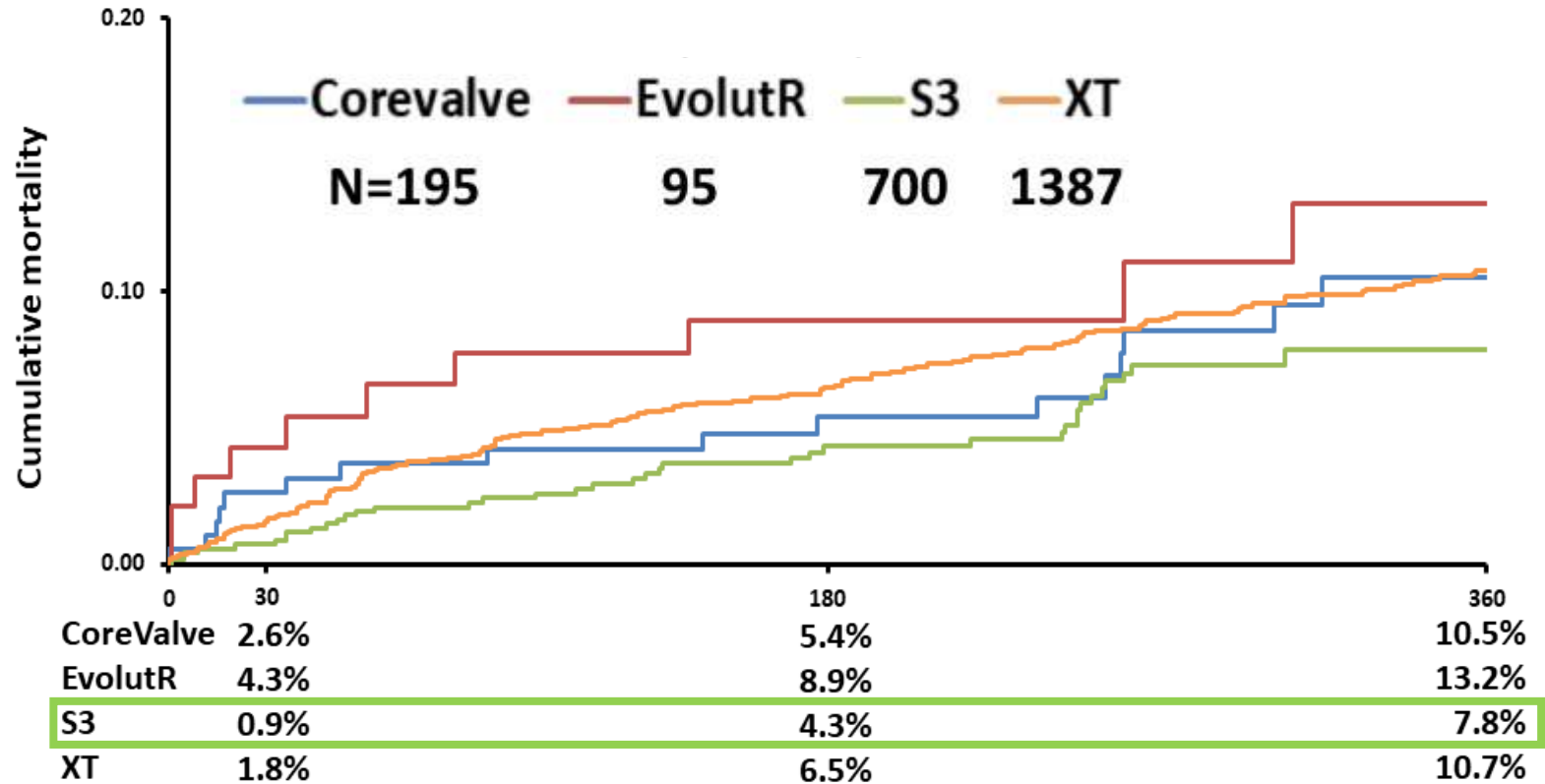
Decreased complication rates



Decreased complication rates

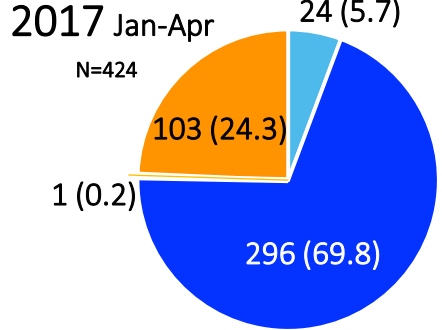
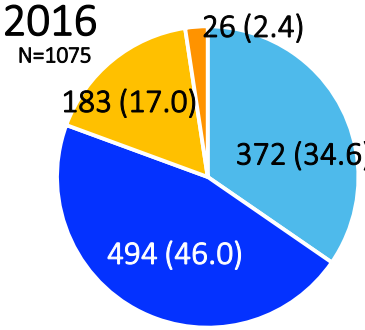
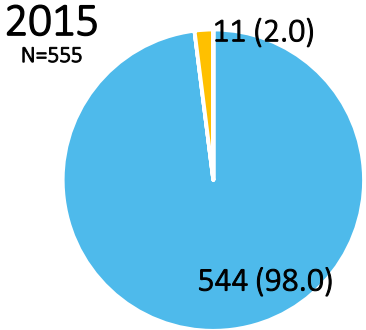
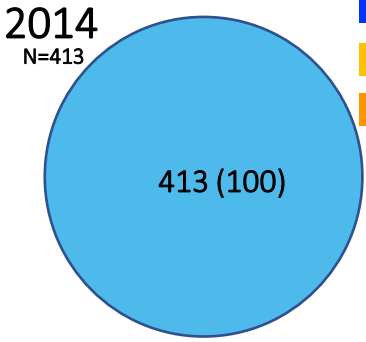
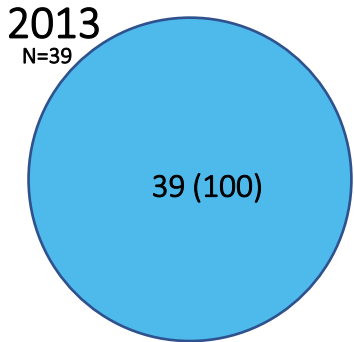


S3 demonstrated the lowest mortality

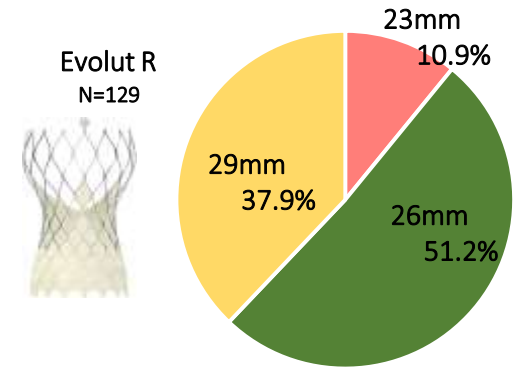
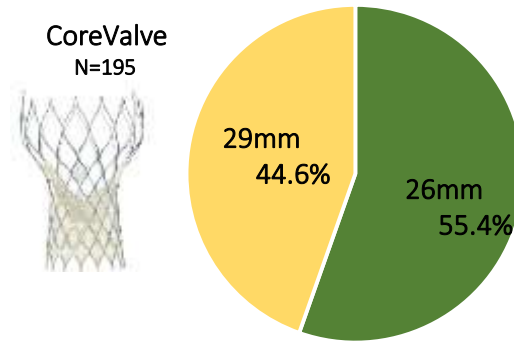
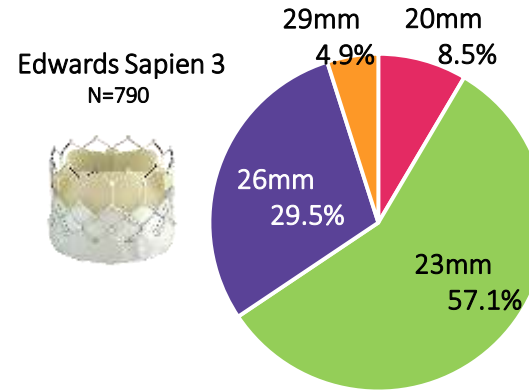
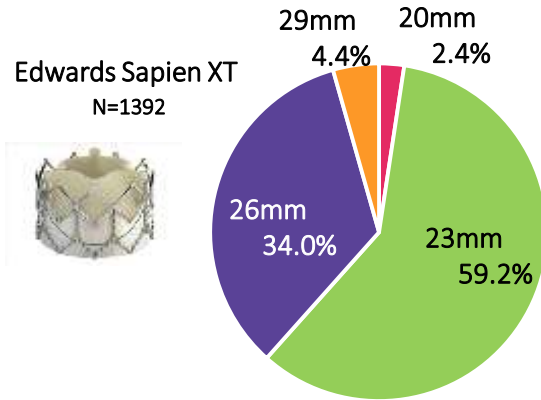


Type of TAVI valves used

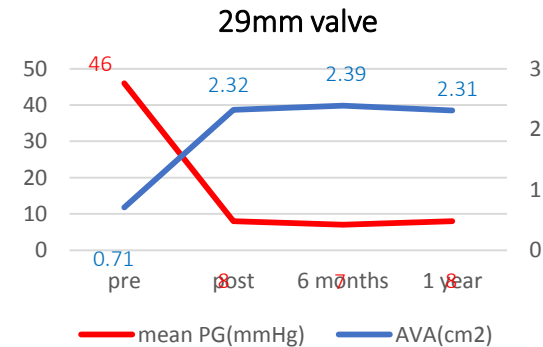
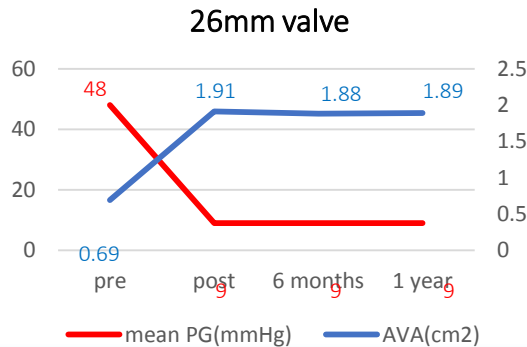
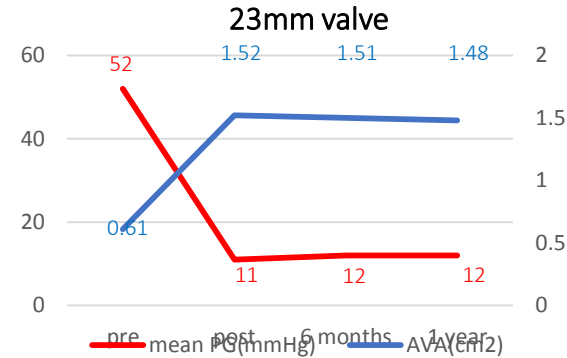
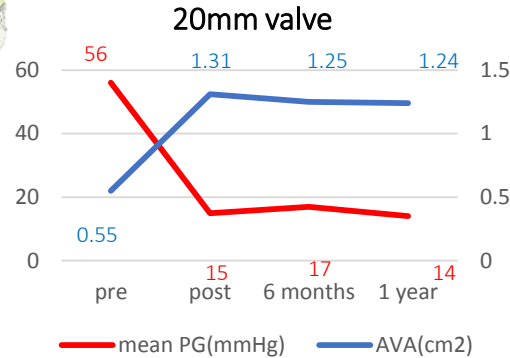
- Sapien XT
- Sapien 3
- Corevalve classic
- Evolute R



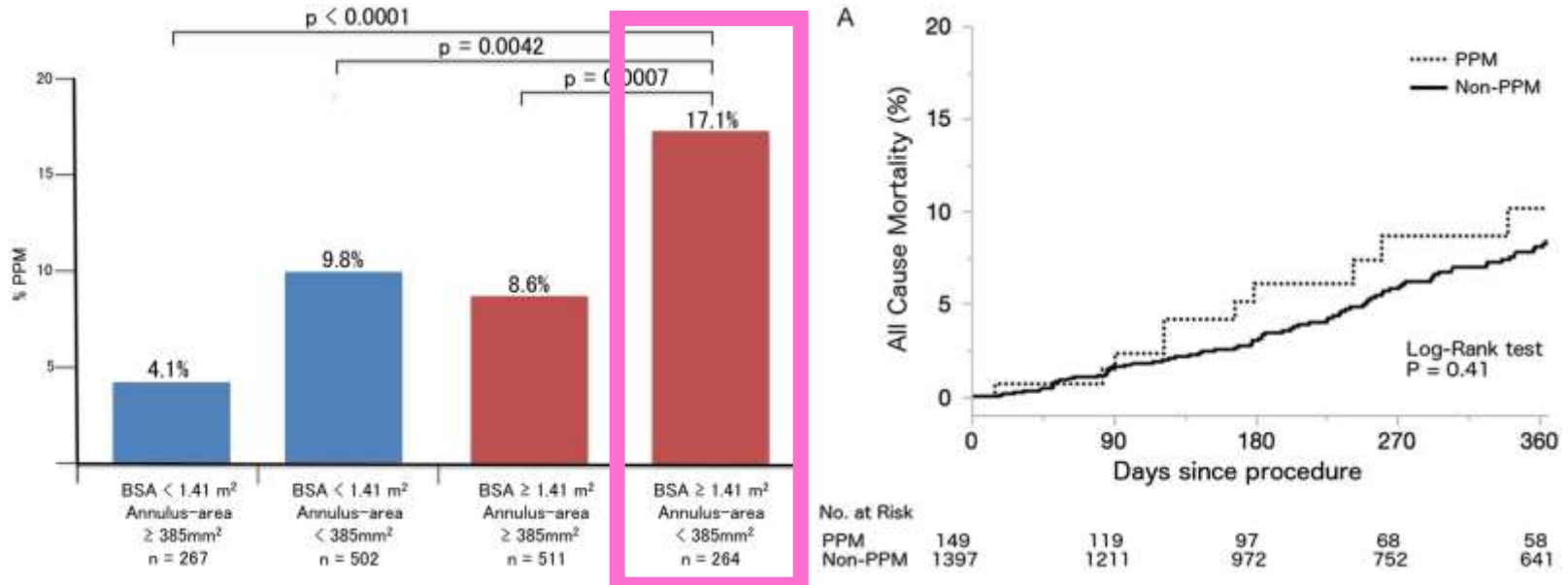
Size of valves



Hemodynamic performance of balloon expandable valves



Low prevalence of PPM in Japan



Moderate PPM : 8.9% (138)
Severe PPM : 0.7% (11)



Clinical frailty score predicts mortality after TAVR

Clinical Frailty Scale

1 Very Fit – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.

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.

3 Managing Well – People whose medical problems are well controlled, but are not regularly active beyond routine walking.

4 Vulnerable – While not dependent on others for daily help, others symptoms limit activities. A common complaint is being “slowed up”, and/or being tired during the day.

5 Mildly Frail – These people often have more evident slowing, and need help in high under IADLs (finances, transportation, heavy household, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.

6 Moderately Frail – People need help with all outside activities and with keeping house. Inside, they often have problem with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing.

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).

8 Very Severely Frail – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.

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.

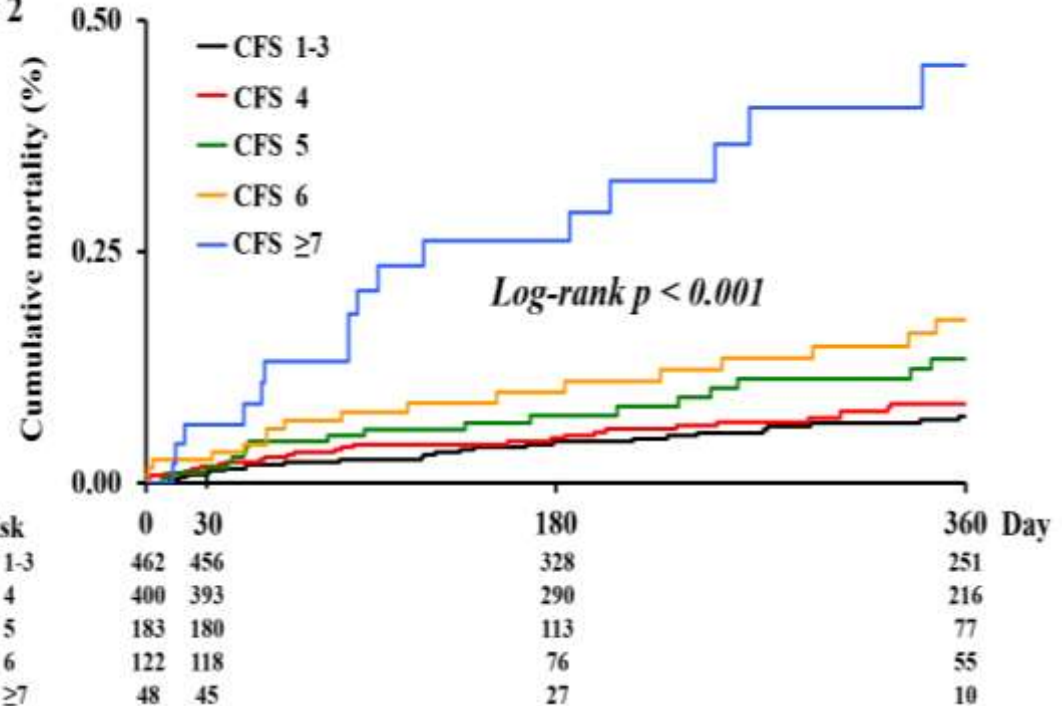
Scoring frailty in people with dementia

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.

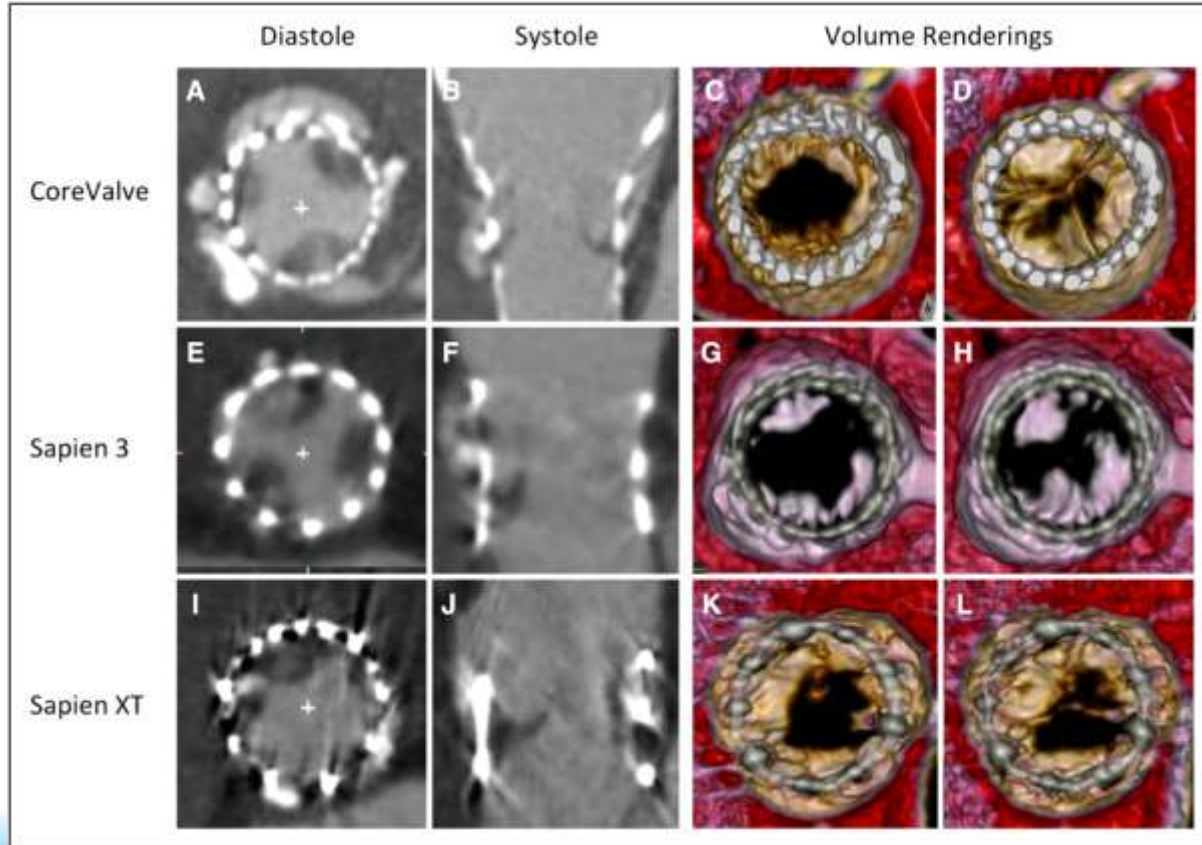
In **moderate dementia**, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

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

Figure 2



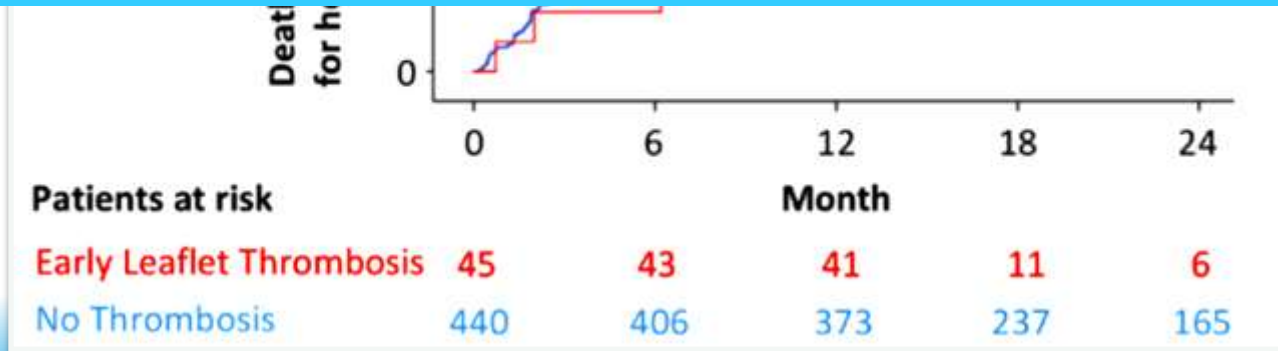
Leaflet thrombosis (OCEAN-TAVI)



Leaflet thrombosis (OCEAN-TAVI)



*Predictors for early leaflet thrombosis
LFLGAS, severe PPM, 29mm bioprosthesis*



OCEAN-TAVI registry

Original Studies

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

Teku Inohara,¹ Masanori Yamamoto,² Takahide Araki,³ 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 Fukuda⁵, MD, PhD;

>40 papers accepted

>40 projects ongoing



Impact of preparat
risk of acute corona
valve implantation

Masanori Yamamoto^{1,2}, Tetsuro Sumimura³, Seiji Kano⁴, Ai Kagase⁵, Hisako Kodama⁶, Tetsuaki Koyama⁷, Yusuke Watanabe⁸, Norio Tada⁹, Kensuke Takagi⁵, Motoharu Araki¹, Shinichi Shirai⁸, Kentaro Hayashida⁸

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

Yusuke Watanabe, MD^{1,2}, Ken Kozuma, MD, PhD³, Hirofumi Hioki, MD⁴, Hideyuki Kawashima, MD⁵, Yugo Nara, MD⁶, Akihisa Kataoka, MD, PhD⁶, Shinichi Shirai, MD⁷, Norio Tada, MD⁸, Motoharu Araki, MD¹, Kensuke Takagi, MD², Futoshi Yamanaka, MD¹, Masanori Yamamoto, MD, PhD^{1,2}, and Kentaro Hayashida, MD, PhD¹

The procedure for transcatheter aortic valve implantation 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



OCEAN-SHD family (Jan 2016, 8 centers)



OCEAN-SHD family (Jan 2019, 23 centers)



Keio experience: 757 cases (Oct 2013 - July 2019)

635

Sapien XT: 219
Sapien 3: 418



101

CoreValve: 15
Evolut R/Pro: 86



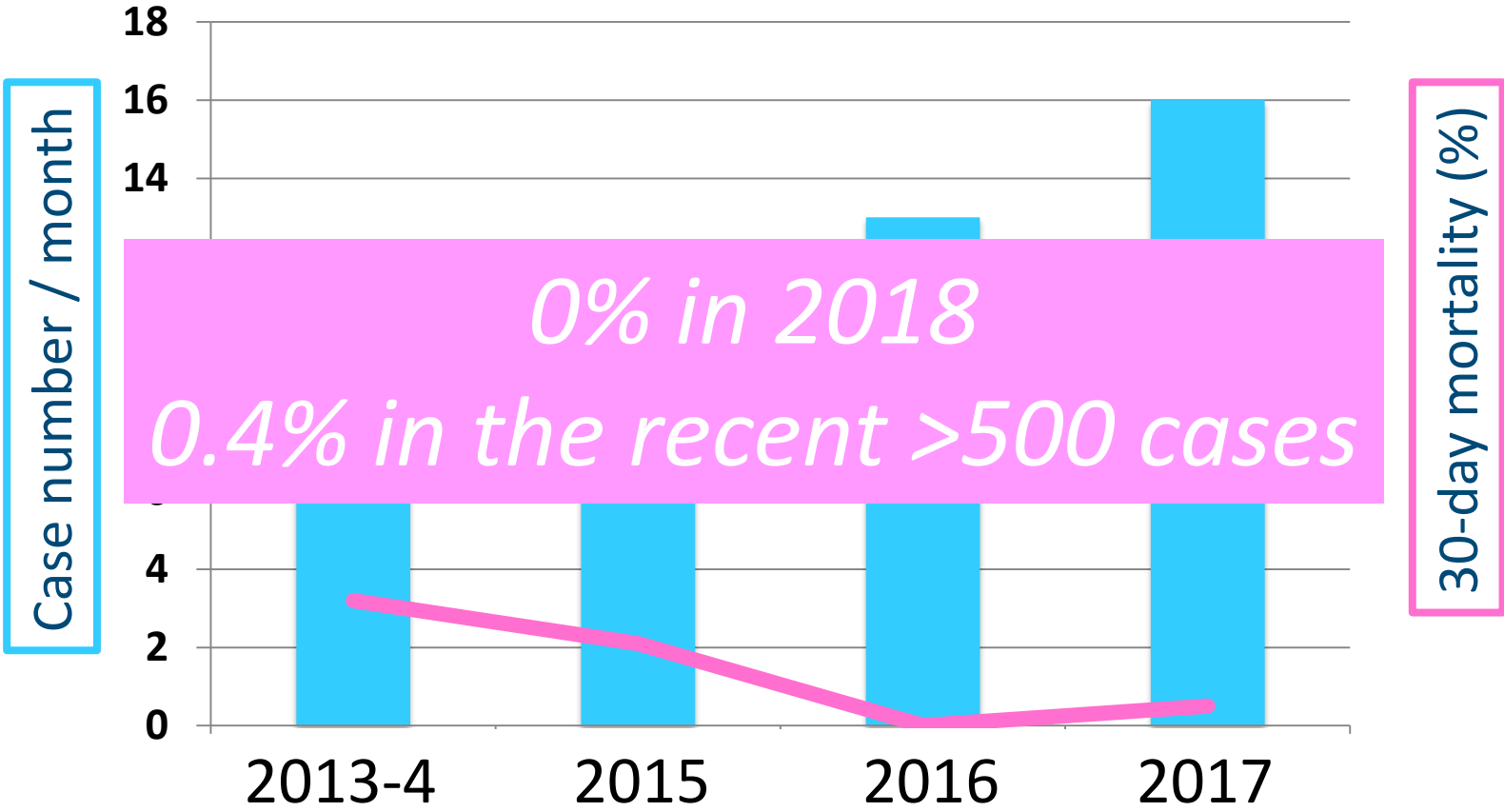
Lotus: 18



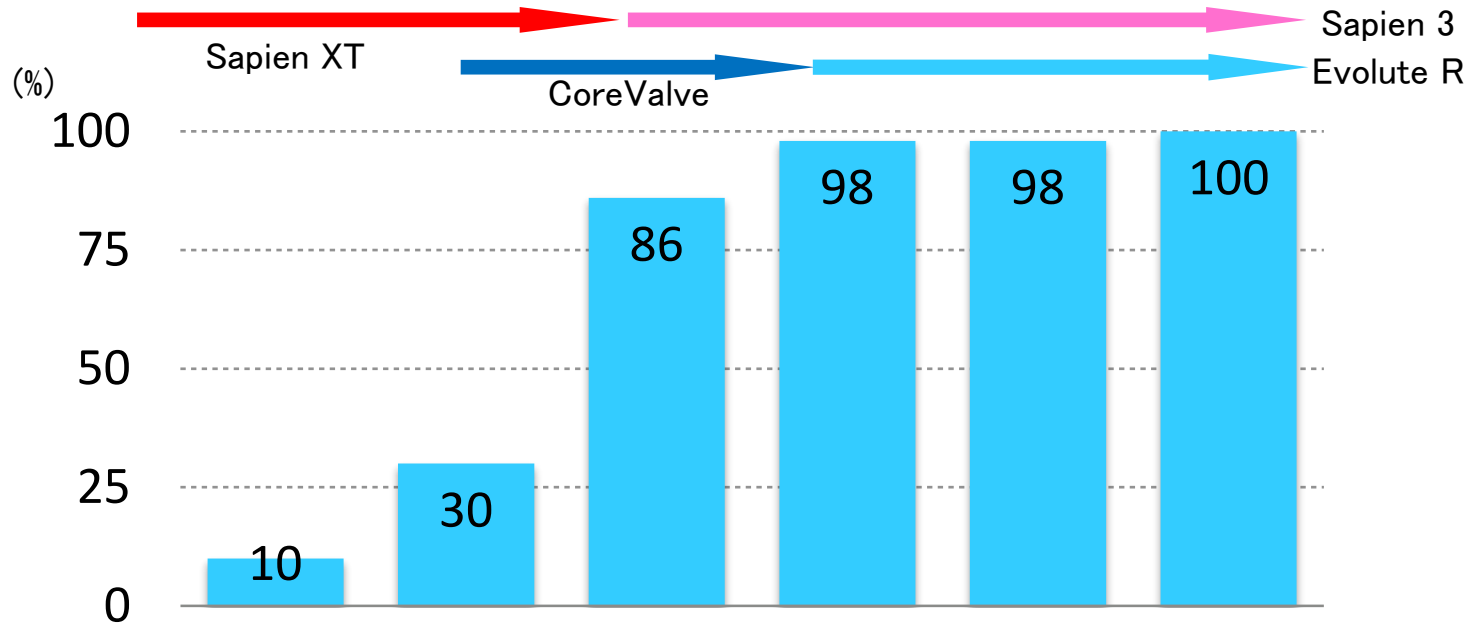
Portico: 1



30-day mortality and procedural volume



TAVI under local anesthesia



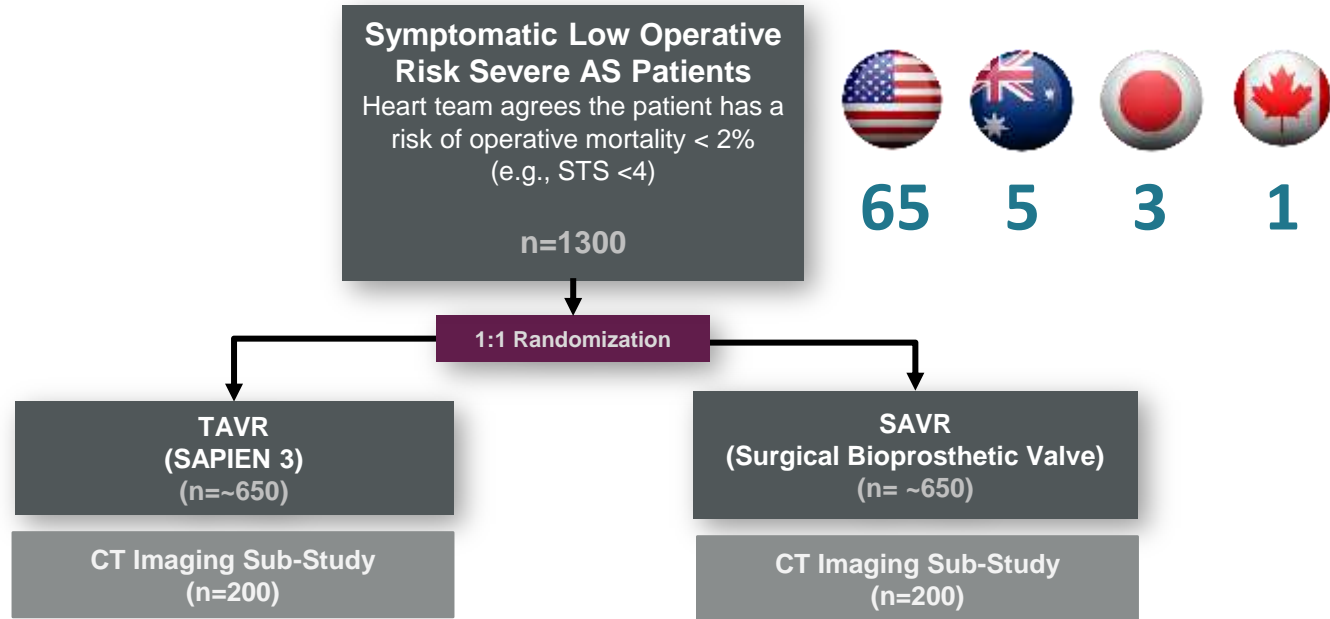
Group	Time Period	Alternative approach (TA/DA/SC)
#1-100	2013/10 - 2015/1	14
#201-300	2015/2 - 2016/1	13
#201-300	2016/1 - 2016/9	4
#201-300	2016/10 - 2017/4	1
#401-500	2017/4 - 2017/10	3
#401-500	2017/10 - 2018/4	0

Alternative approach
(TA/DA/SC)



4 case/day

PARTNER III Trial Design

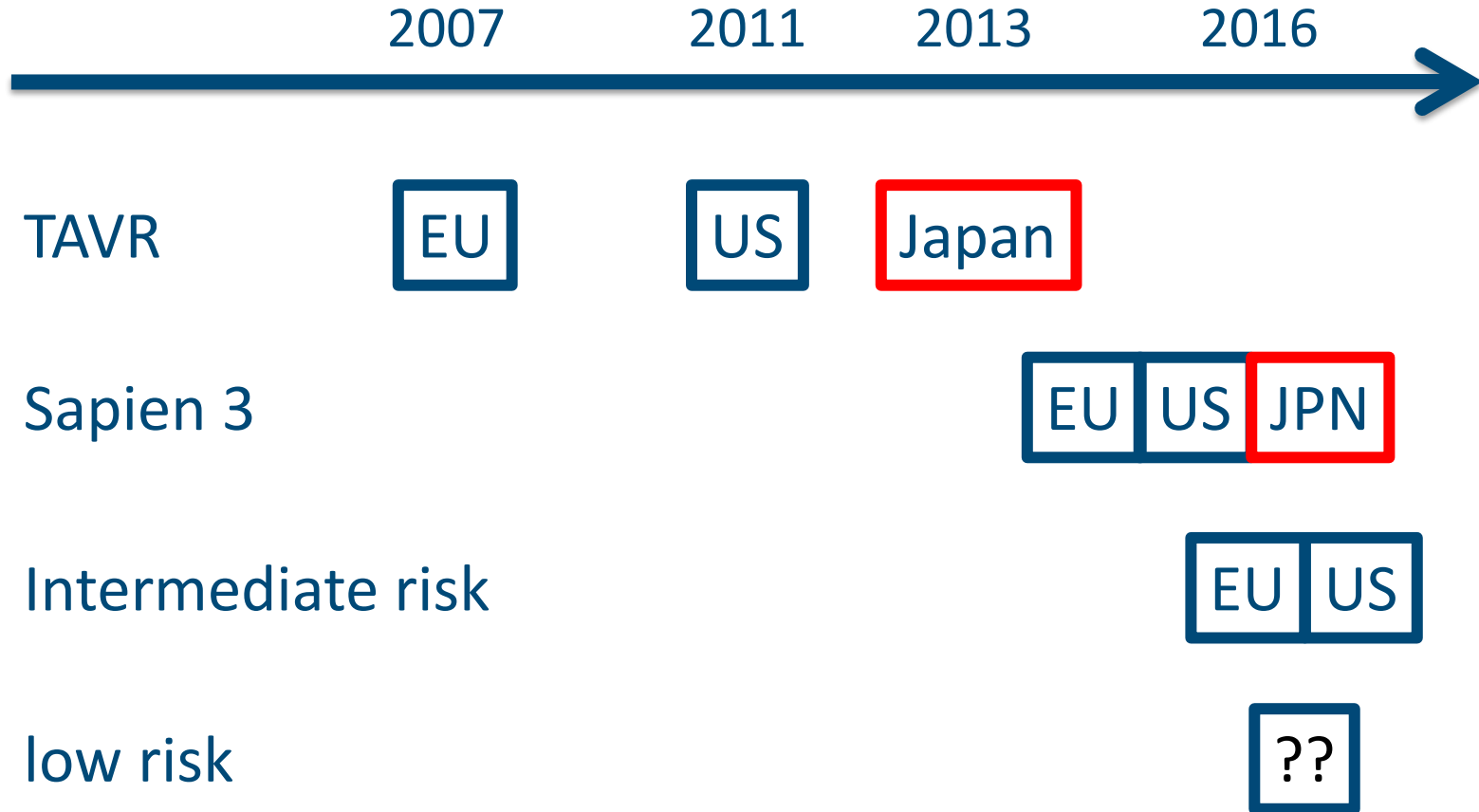


Primary Endpoint: Composite of all-cause mortality, all stroke, and re-hospitalization at 1 year post procedure (non-inferiority)

Follow-up: 30 day, 6 month, and annually through 10 years

6 cases /1000 from Japan

Regulatory process (TAVR)



Take home messages

- High motivation and quality control is the keys
- Initial safety leads to late expansion
- Now TAVR can be the 1st choice treatment for elderly patients with AS
- We are now trying to contribute to this field as a part of the global community.