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OCEAN-TAVI Japanese multicenter registry

Kentaro Hayashida MD, PhD, FESC

17th, August 2017, AP valves 2017, Seoul

TAVI history in Japan

Edwards SAPIEN XT
2013 OCT.

SAPIEN 3
2016 MAY

Lotus
Only trial (n=70)

2016 JAN.
Medtronic CoreValve

2016 DEC.
Evolut-R

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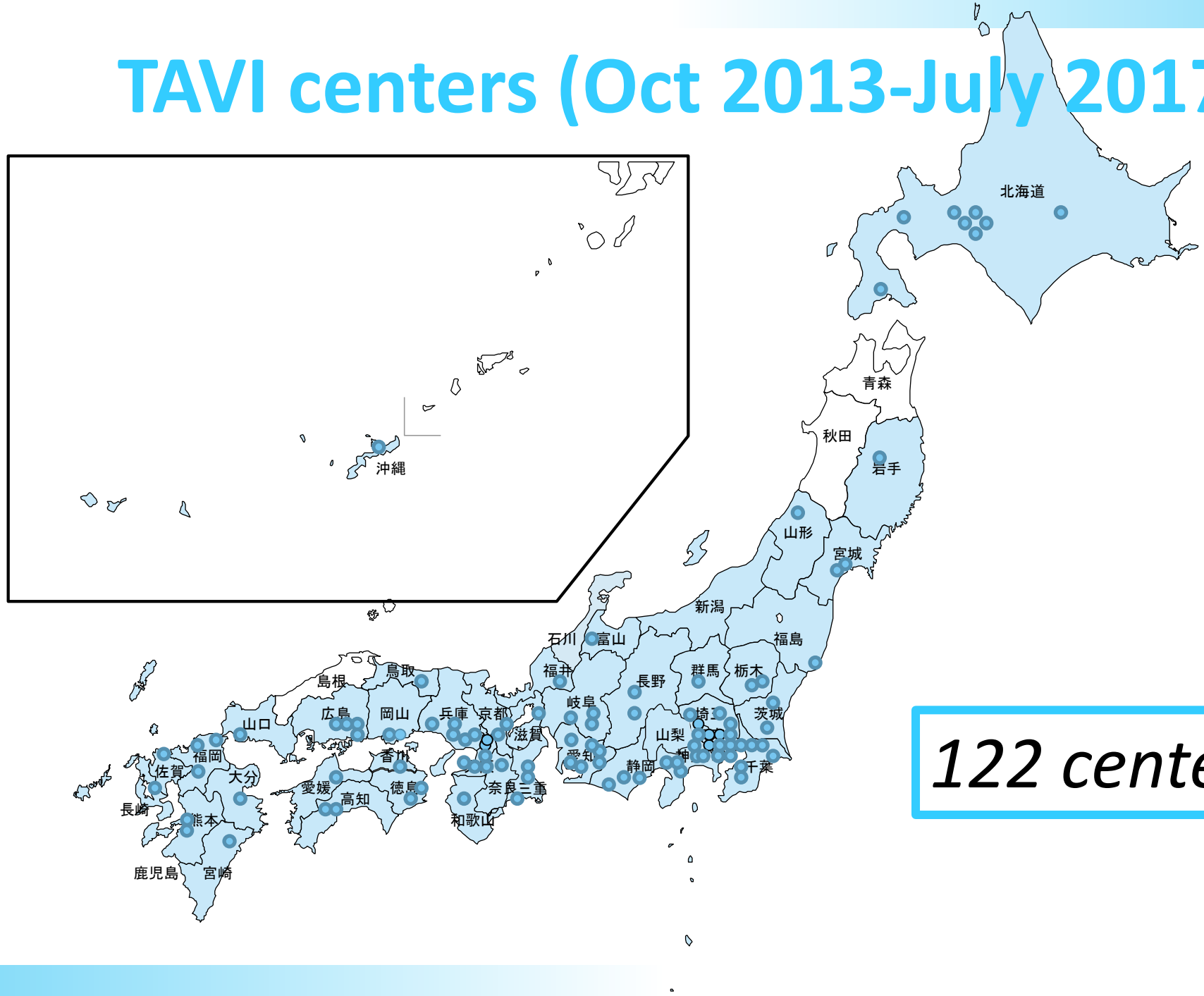
TAVI centers (Oct 2013-July 2017)



122 centers

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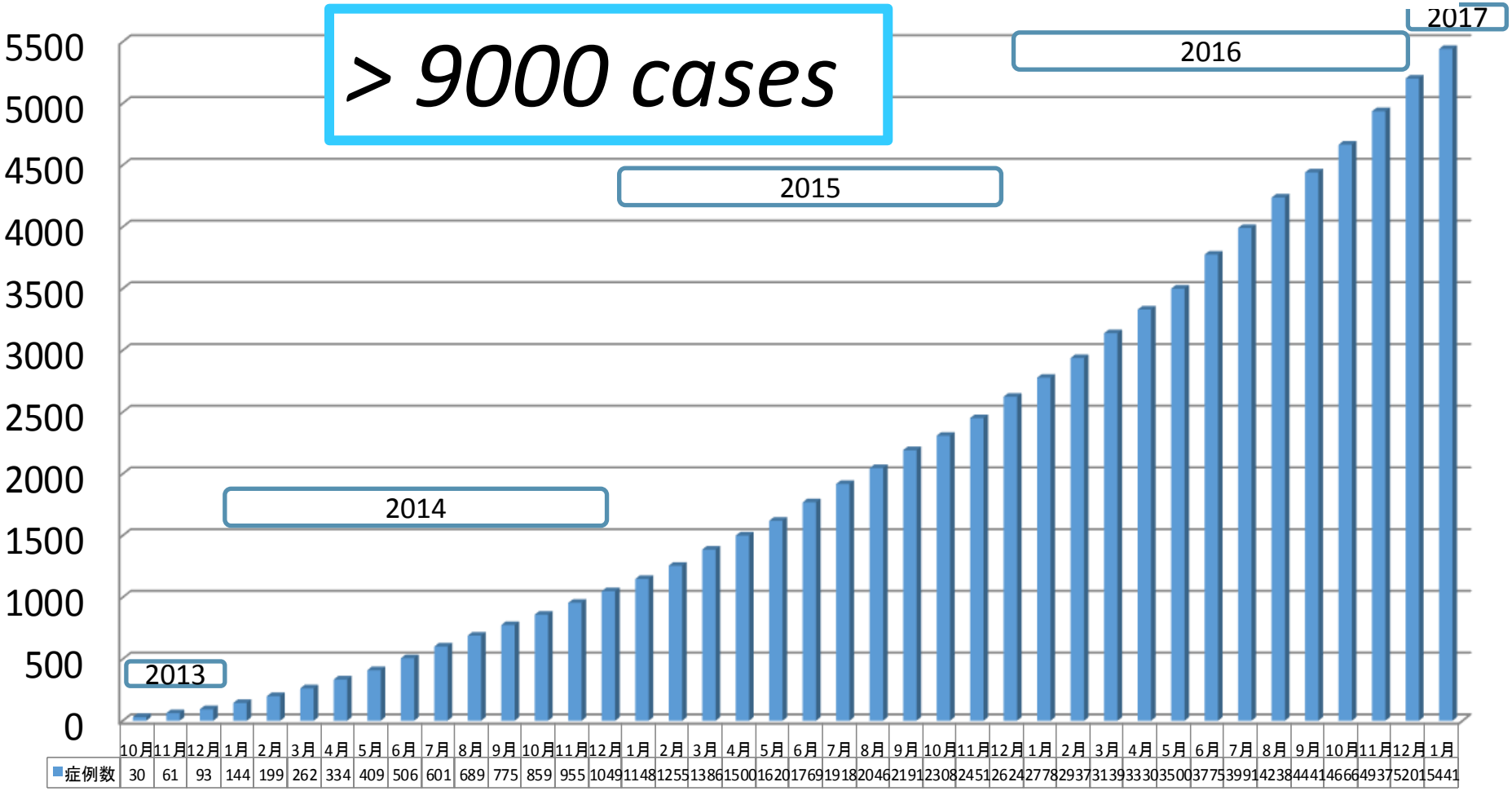
TAVI cases (Oct 2013-July 2017)



Data from Edwards Lifesciences

My “public missions”

1. Safe introduction of TAVI to Asian patients
2. Publication from Asia to the global community as an equal partner

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Massy Henri-Mondor registry

1				PERSONAL DATA		
2						
3	#	STUDY	last name	First nam	Date birth	Date
4	1	REVIVE	VISSIAN	Marcel	4/10/20	11/10/06
5	3	REVIVE	GAUTIER	Marcel	15/7/19	21/11/06
6	2	REVIVE	CORBIN	Gaston	27/4/19	21/11/06
		REVIVE	OGER	Robert	22/6/11	30/11/06
		REVIVE	GRANGER	Pierre	27/8/13	5/12/06
		REVIVE	GARCIA BALLE	Jean	10/3/24	9/1/07
		REVIVE	RENARD	Juliette	2/3/23	6/2/07
		REVIVE	SAVIARD	Aimée	5/9/21	6/2/07
		REVIVE	DELAFOY	Renée	8/9/26	13/2/07
		REVIVE	BRAULT	Simone	23/1/31	5/3/07
		REVIVE	GORLIER	Simonne	17/2/28	6/3/07
		REVIVE	GARULO DIES	Ramona	24/2/21	3/4/07
		REVIVE	NONIN	Roland	4/1/19	23/5/07
		PARTNER	DA CRUZ	Anna	21/12/25	28/8/07
		PARTNER	ALLEMANDOU	Pierre	18/3/30	30/8/07
		PARTNER	GAGEY	Marcelle	28/6/24	3/10/07

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Massy Henri-Mondor registry

Original article

First direct comparison of clinical outcomes between European and Asian cohorts in transcatheter aortic valve implantation: The Massy study group vs. the PREVAIL JAPAN trial

Yusuke Watanabe (MD)[a,*], Kentaro Hayashida (MD, PhD, FESC)[a], Morimasa Takayama (MD, PhD, FJCC)[b], Kazuaki Mitsudo (MD, PhD, FJCC)[c], Shinsuke Nanto (MD, PhD, FJCC)[d], Shuichiro Takanashi (MD, PhD)[b], Tatsuhiko Komiya (MD, PhD)[c], Toru Kuratani (MD, PhD)[d], Tetsuya Tobaru (MD, PhD)[b], Tsuyoshi Goto (MD, PhD)[c], Thierry Lefèvre (MD, FSCAI, FESC)[a], Yoshiki Sawa (MD, PhD, FJCC)[d], Marie-Claude Morice (MD, FESC, FACC)[a]

Transfemoral Aortic Valve Implantation in Patients With an Annulus Dimension Suitable for Either the Edwards Valve or the CoreValve

Yusuke Watanabe, MD[a], Kentaro Hayashida, MD, PhD[a], Masanori Yamamoto, MD, PhD[b], Gauthier Mouillet, MD[b], Bernard Chevalier, MD[a], Atsushi Oguri, MD, PhD[b], Jean-Luc Dubois-Rande, MD, PhD[c,d], Marie-Claude Morice, MD[a], Emmanuel Teiger, MD, PhD[b,d], and Thierry Lefèvre, MD[b,*]

Renal Function–Based Contrast Dosing Predicts Acute Kidney Injury Following Transcatheter Aortic Valve Implantation

Masanori Yamamoto, MD, PHD,* Kentaro Hayashida, MD, PHD,† Gauthier Mouillet, MD,* Bernard Chevalier, MD,† Kentaro Meguro, MD, PHD,* Yusuke Watanabe, MD,† Jean-Luc Dubois-Rande, MD, PHD,‡§ Marie-Claude Morice, MD,† Thierry Lefèvre, MD,† Emmanuel Teiger, MD, PHD*§

Massy and Créteil, France

Effect of Body Mass Index <20 kg/m^2 on Events in Patients Who Underwent Transcatheter Aortic Valve Replacement

Masanori Yamamoto, MD[a,*], Kentaro Hayashida, MD[b], Yusuke Watanabe, MD[b], Gauthier Mouillet, MD[a], Thomas Hovasse, MD[b], Bernard Chevalier, MD[b], Atsushi Oguri, MD[a], Jean-Luc Dubois-Randé, MD[c,d], Marie-Claude Morice, MD[b], Thierry Lefèvre, MD[b], and Emmanuel Teiger, MD[a,d]

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CLINICAL RESEARCH — Interventional Cardiology

Prognostic Value of Chronic Kidney Disease After Transcatheter Aortic Valve Implantation

Masanori Yamamoto, MD, PHD,* Kentaro Hayashida, MD, PHD,† Gauthier Mouillet, MD,* Thomas Hovasse, MD,† Bernard Chevalier, MD,† Atsushi Oguri, MD, PHD,* Yusuke Watanabe, MD,† Jean-Luc Dubois-Randé, MD, PHD,‡§ Marie-Claude Morice, MD,† Thierry Lefèvre, MD,† Emmanuel Teiger, MD, PHD*‡

Créteil and Massy, France

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OCEAN-TAVI registry

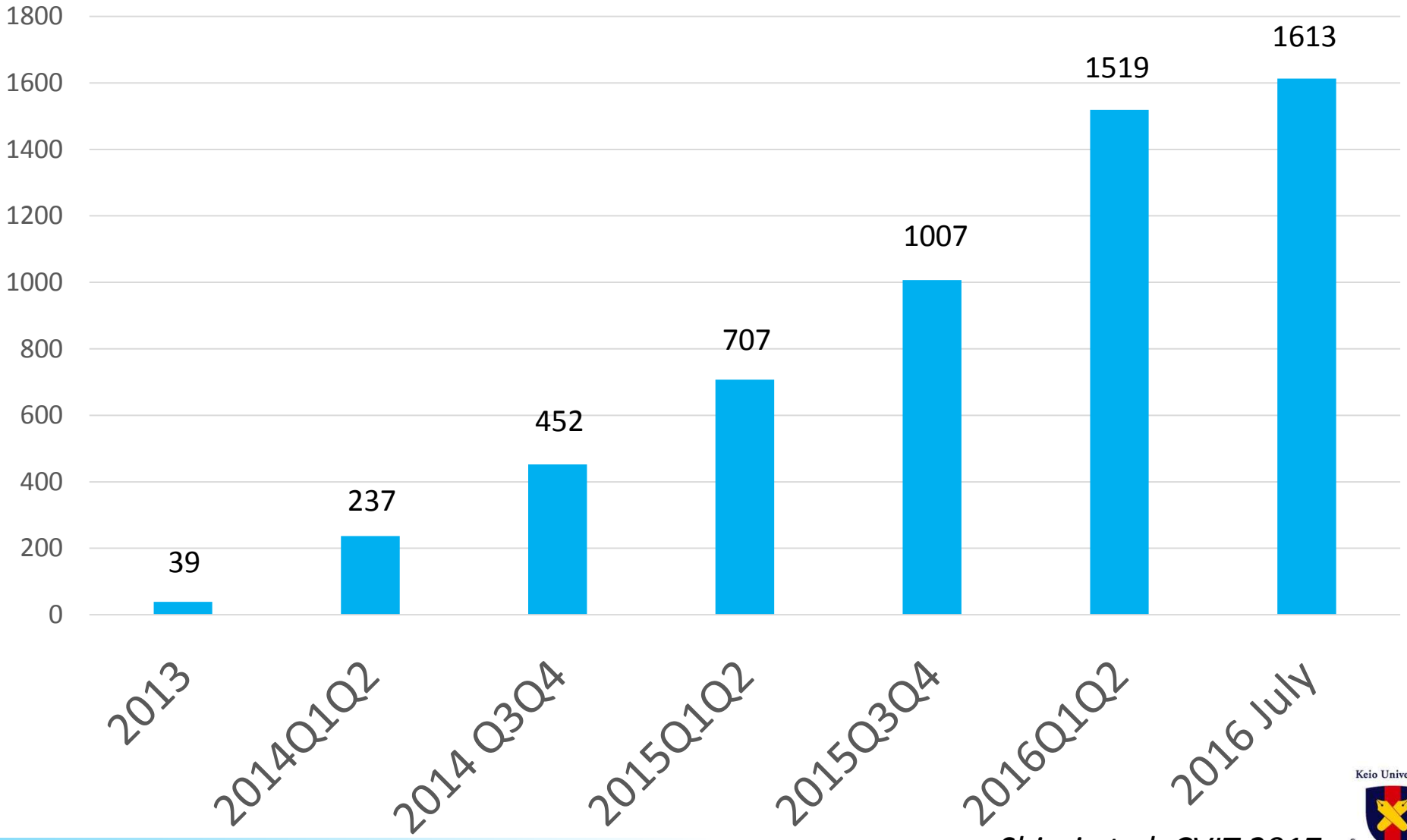
14/122 cen

>2500 case

30-40% sh

Keio Univ
Toyohashi
Teikyo Univ
New Tokyo
Kokura
Yokohama
Sendai
Kamakura
Ogaki
Kishiwada
Osaka City Univ
Tokyo Bay
Toyama

Number of enrolled patients



Shirai et al. CVIT 2017

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Baseline characteristics (Oct 2013 – July 2016)

Patient	N=1613
Age, years	**84.4±5.1**
Female	**1136 (70.4%)**
Body weight, kg	49.9 ± 10.5 (110 pound)
Height, cm	**149.7 ± 9.3 (58.6 inch)**
BSA, m2	**1.4 ± 0.2**
BMI, kg/m2	22.4 ± 10.4
NYHA class 3 or 4	816 (50.6%)
eGFR	51.9 ± 20.3
PAD	246 (15.3%)
Previous CABG	120 (7.5%)
STS PROM, %	**8.3 ± 7.0**

OCEAN-SHD

Shirai et al. CVIT 2017

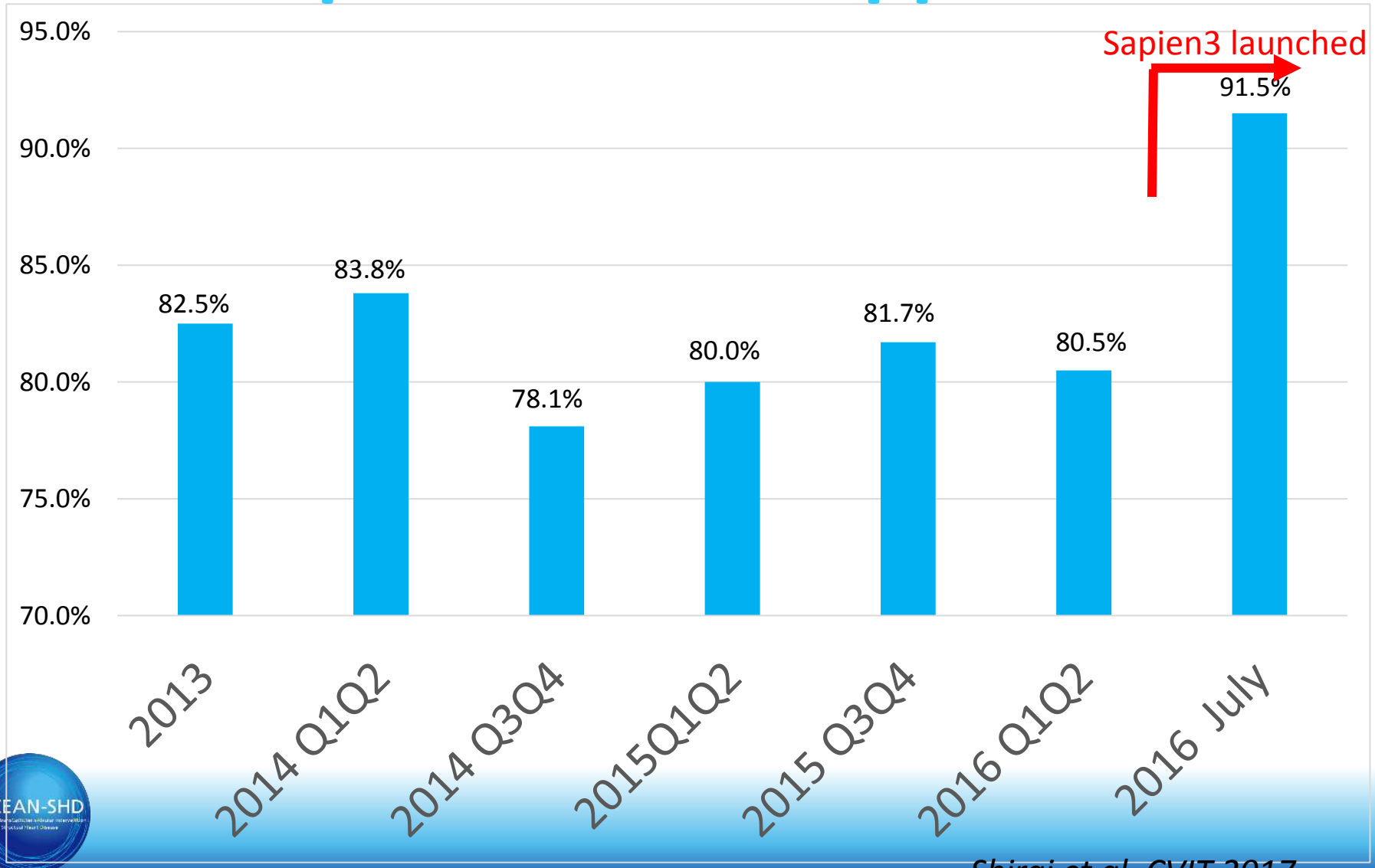
Procedural characteristics (Oct 2013 – July 2016)

Patient	N=1613
Approach	
TF	**1283 (79.5%)**
TA	287 (17.9%)
TI	30 (1.9%)
DA	7 (0.4%)
TS	6 (0.4%)
Valve type	
Edwards Sapien XT	**1328 (82.3%)**
Edwards Sapien 3	141 (8.7%)
Medtronic CoreValve	144 (8.9%)
Local anesthesia	199/1283 TF (15.5%)
Puncture	**702/1283 TF (54.7%)**

OCEAN-SHD

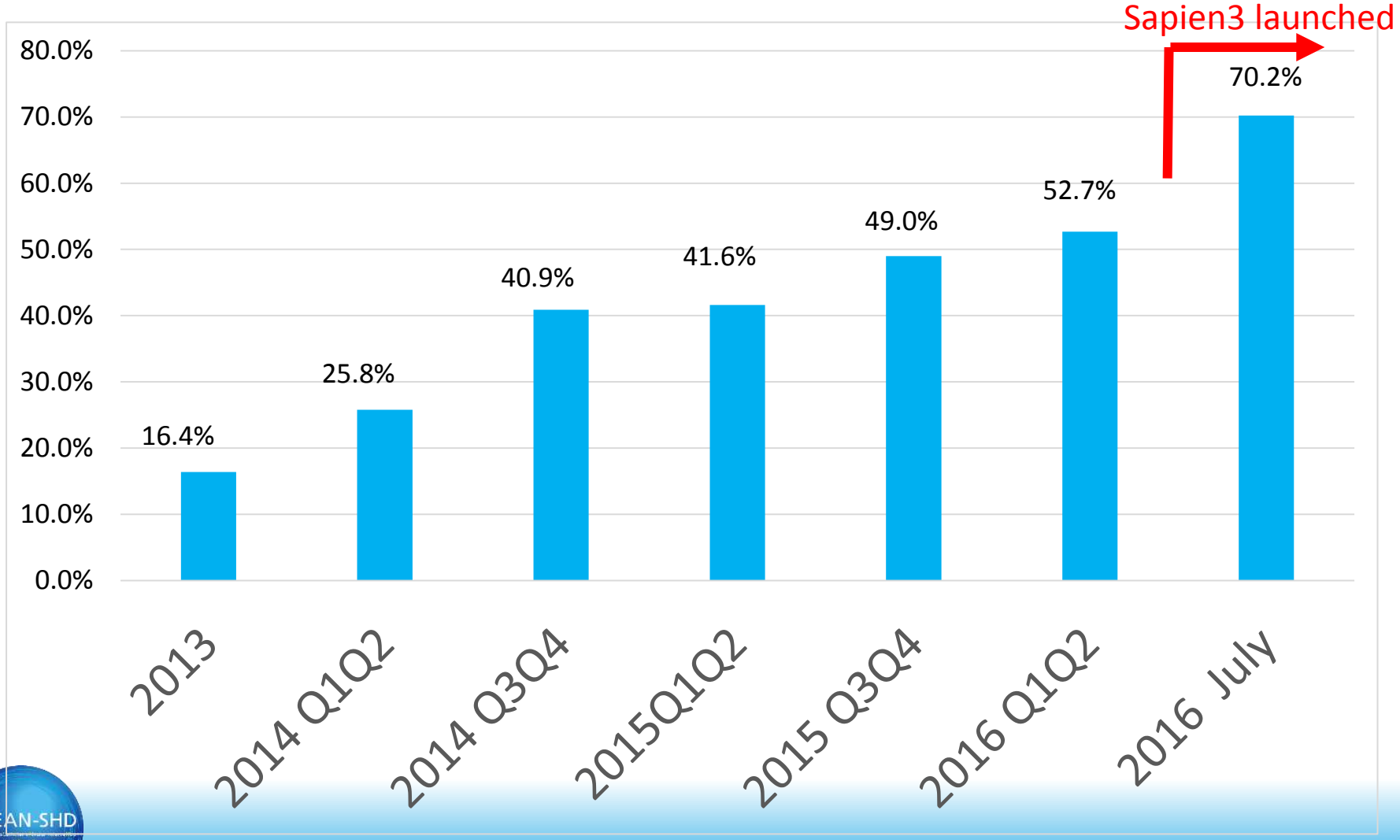
Shirai et al. CVIT 2017

Proportion of TF approach



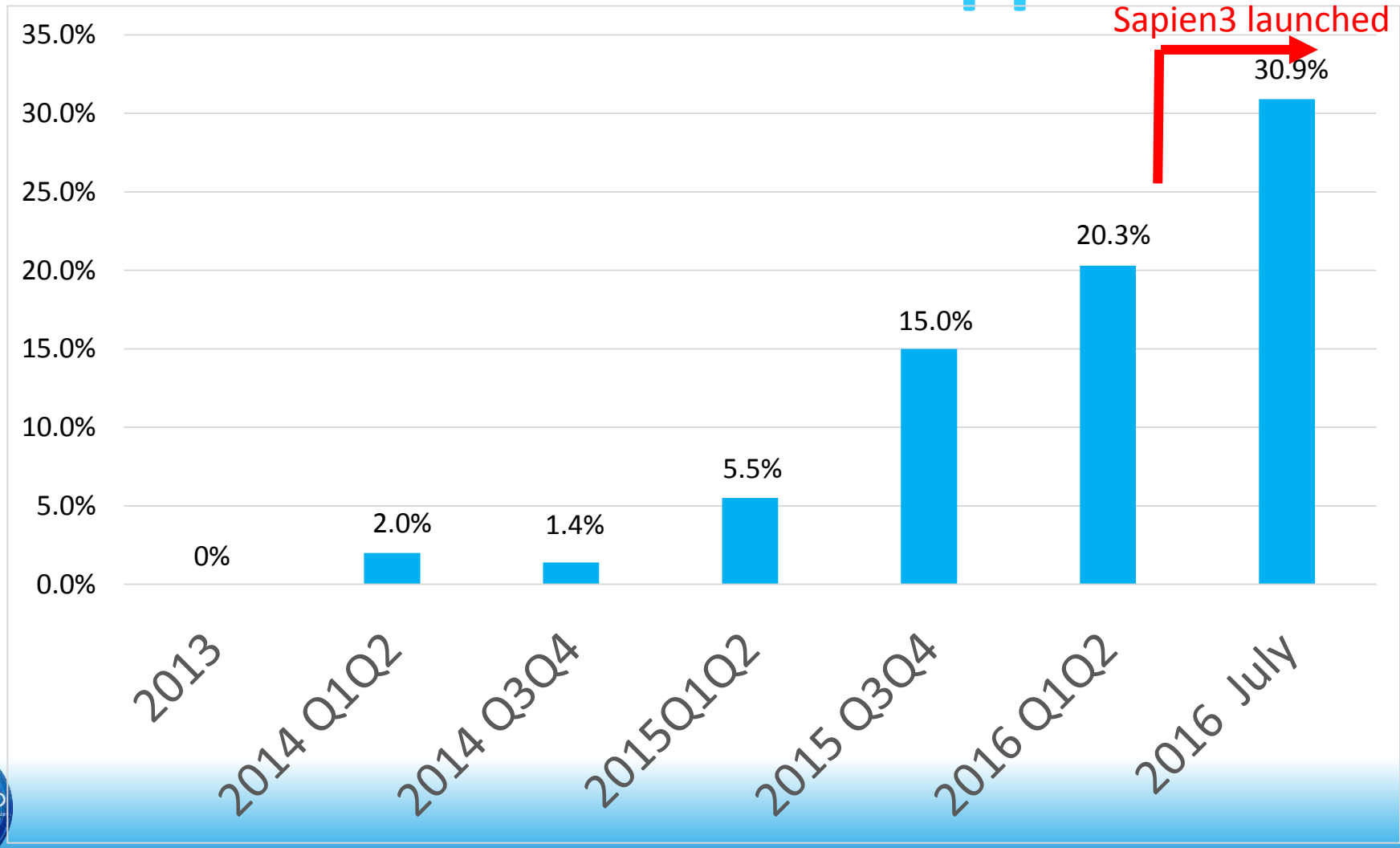
Shirai et al. CVIT 2017

Fully percutaneous approach



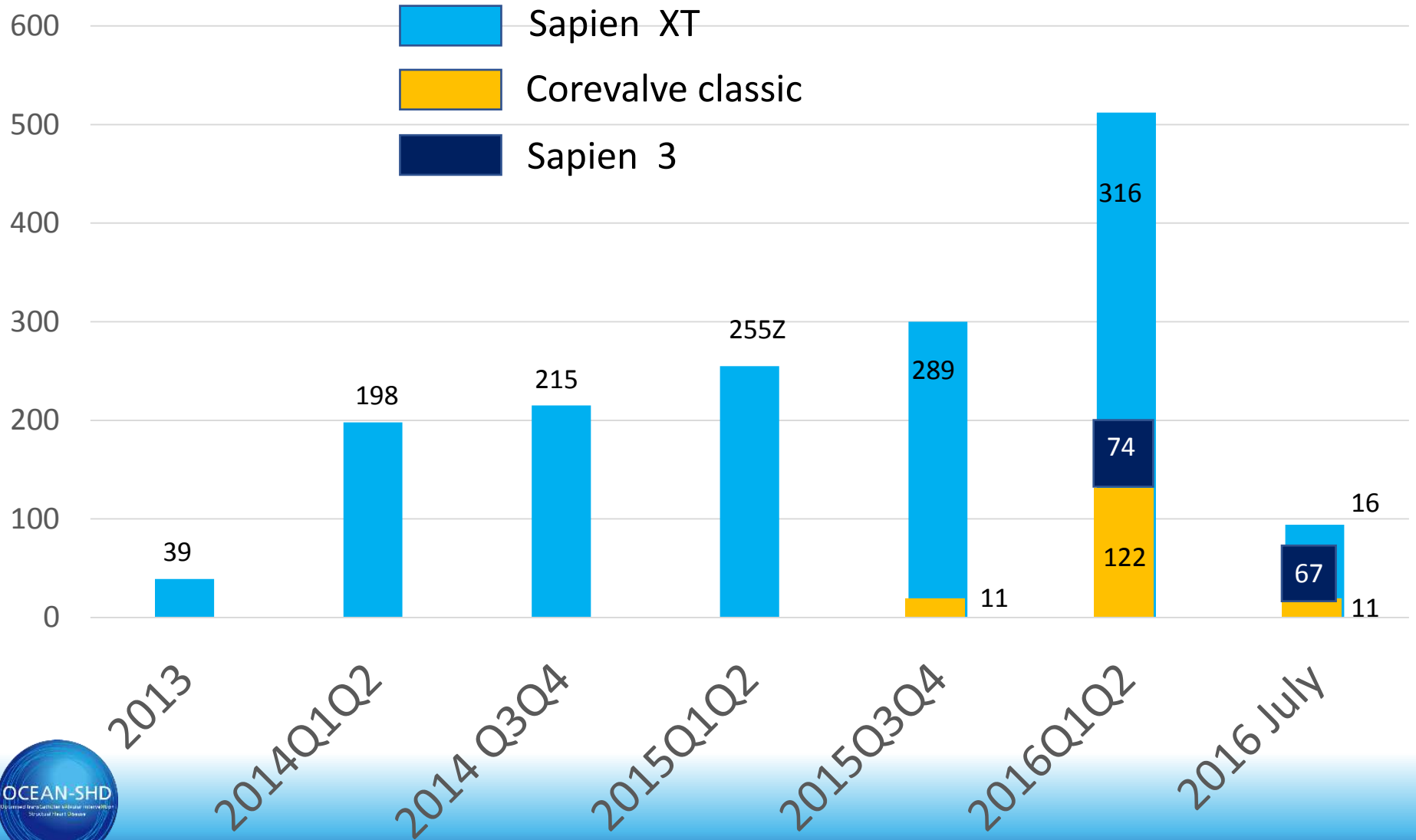
Shirai et al. CVIT 2017

Local anesthesia in patients treated with TF approach



Shirai et al. CVIT 2017

Valve selection



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30-day mortality

Patient	N=1613
Overall	**28/1613 (1.7%)**
Edwards Sapien XT	22/1328 (1.7%)
Edwards Sapien 3	**2/141 (1.4%)**
Medtronic CoreValve	4/144 (2.8%)
Approach	
TF	**20/1283 (1.6%)**
non TF	8/330 (2.4%)

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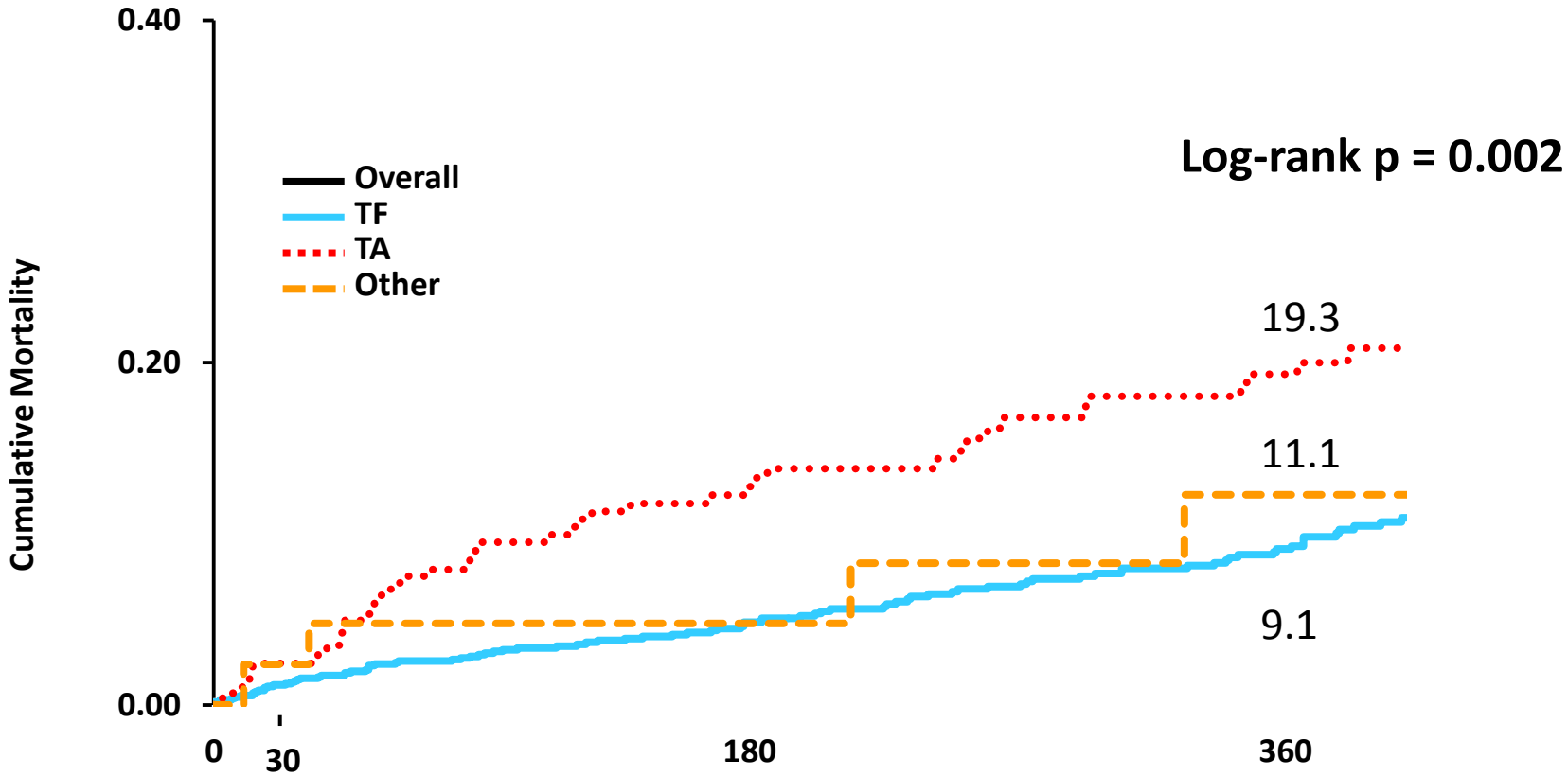
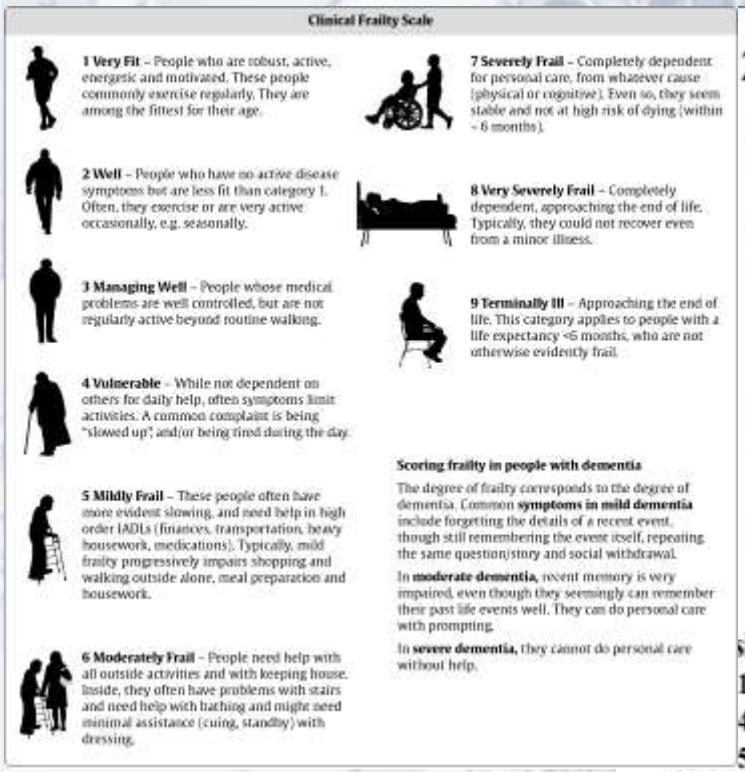
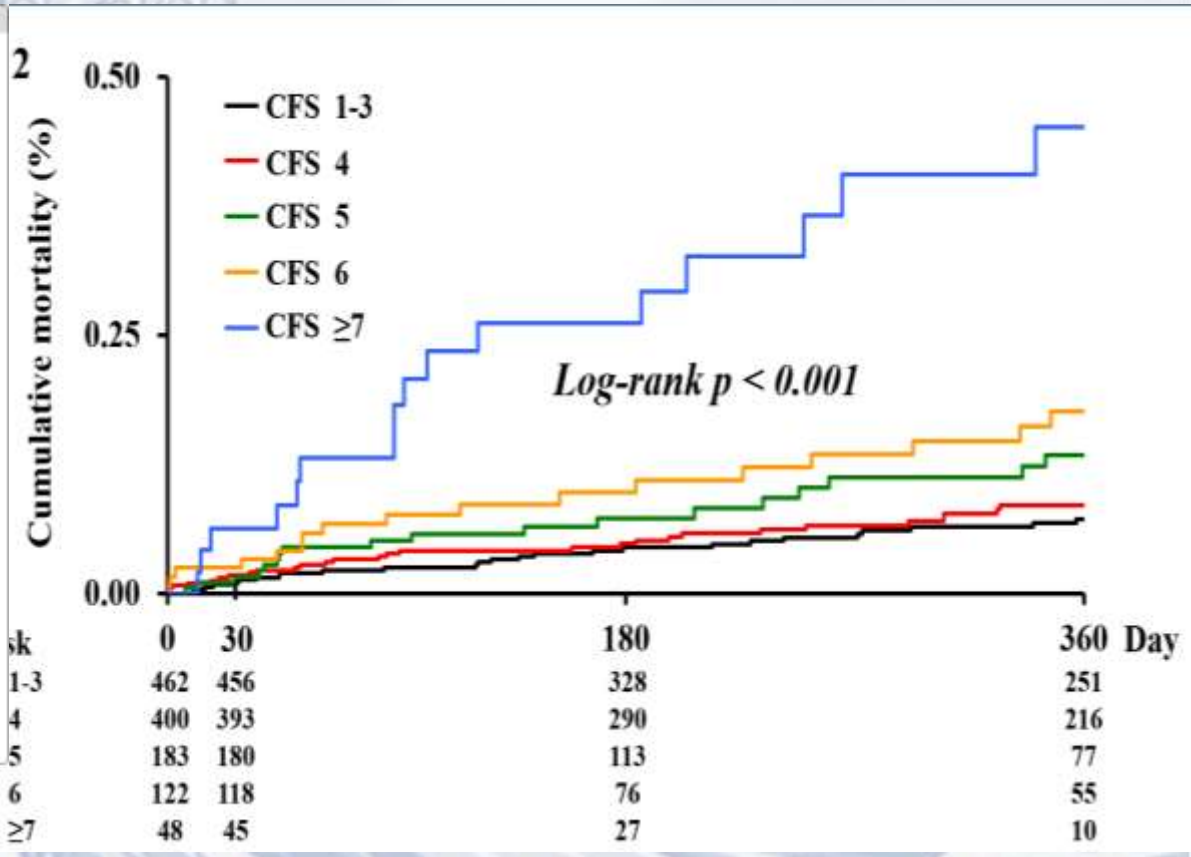
All cause mortality



No. at Risk				
Overall	1613	1583	989	687
TF approach	1283	1261	789	544
TA approach	288	281	174	123
Other approach	42	41	29	22

Clinical frailty score predicts mortality after TAVR





Shimura, Yamamoto et al. Circulation in press

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,
Masanori Yam
Takahide Arai,
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 Yashima[4], MD;
ichi Fukuda[4], MD, PhD;

ELSEVIER

Impact of preparat
risk of acute corona
valve implantation

Masanori Yamamoto [a,b,*]
Yusuke Watanabe [c], Norio Tada [d], Kensuke Takagi [e], Motoharu Araki [f], Shinichi Shirai [g], Kentaro Hayashida [h]

lvular

oshitake Yamada [e],
zu [f], Masahiro Jinzaki [e],

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[i]

y 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

22 papers accepted

>20 projects ongoing

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OCEAN-SHD family (2016)

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OCEAN-SHD family (Feb 2017)

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Keio experience: 475 cases (Oct 2013 - July 2017)

Sapien XT : 218
Sapien 3 : 200

Lotus:18

CoreValve :15
Evolut R : 24

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Keio experience

N = 475	Value
Conversion to open chest surgery	**0**
30-day mortality	**5 (1.1%)**
Cerebral infarction, n (%)	5 (1.1%)
Major vascular complications	**18 (4.4%)**
New PM implantation, n (%)	34 (7.2%)
Coronary obstruction, n (%)	4 (0.9%)

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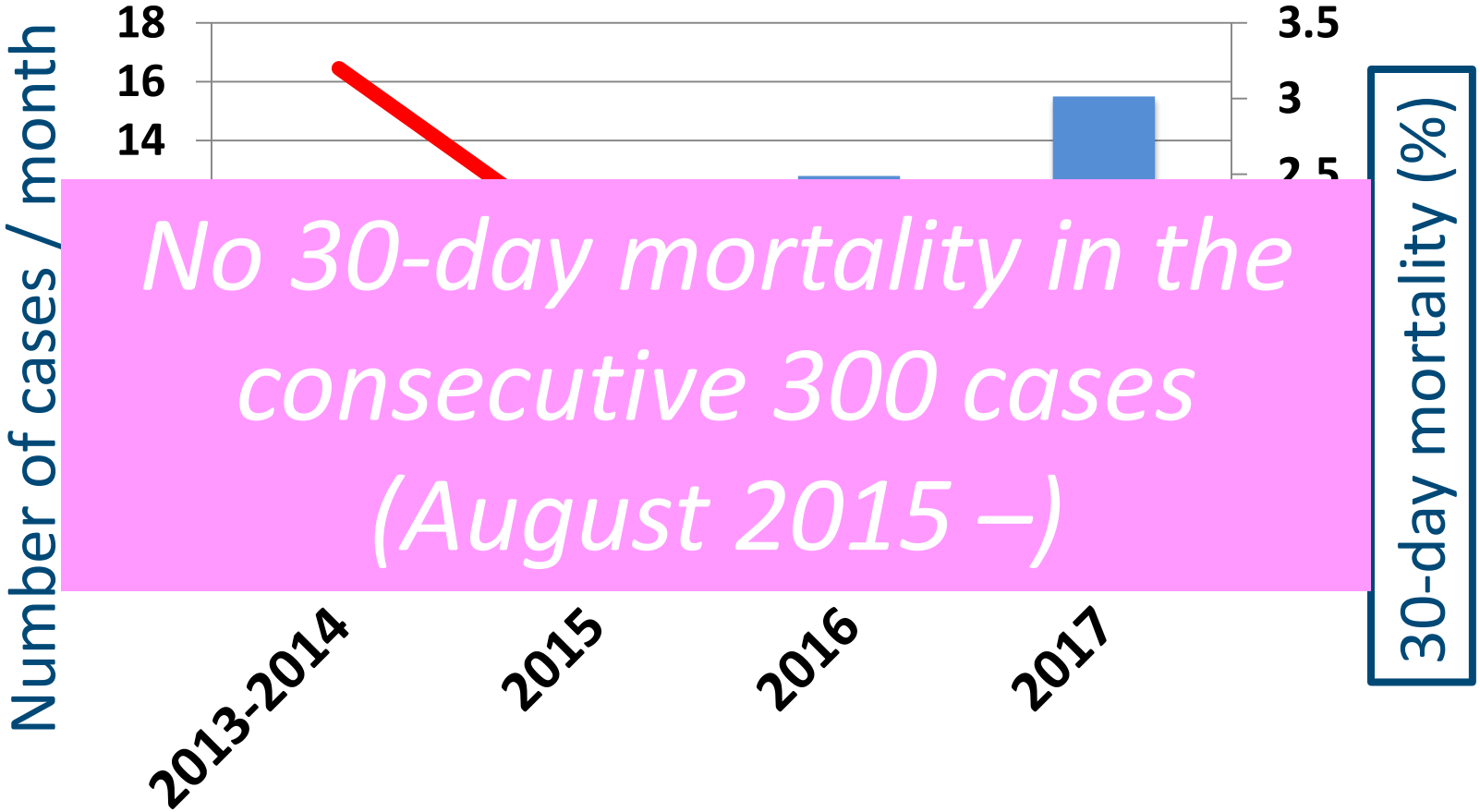
30-day mortality and procedural volume



No 30-day mortality in the consecutive 300 cases (August 2015 –)

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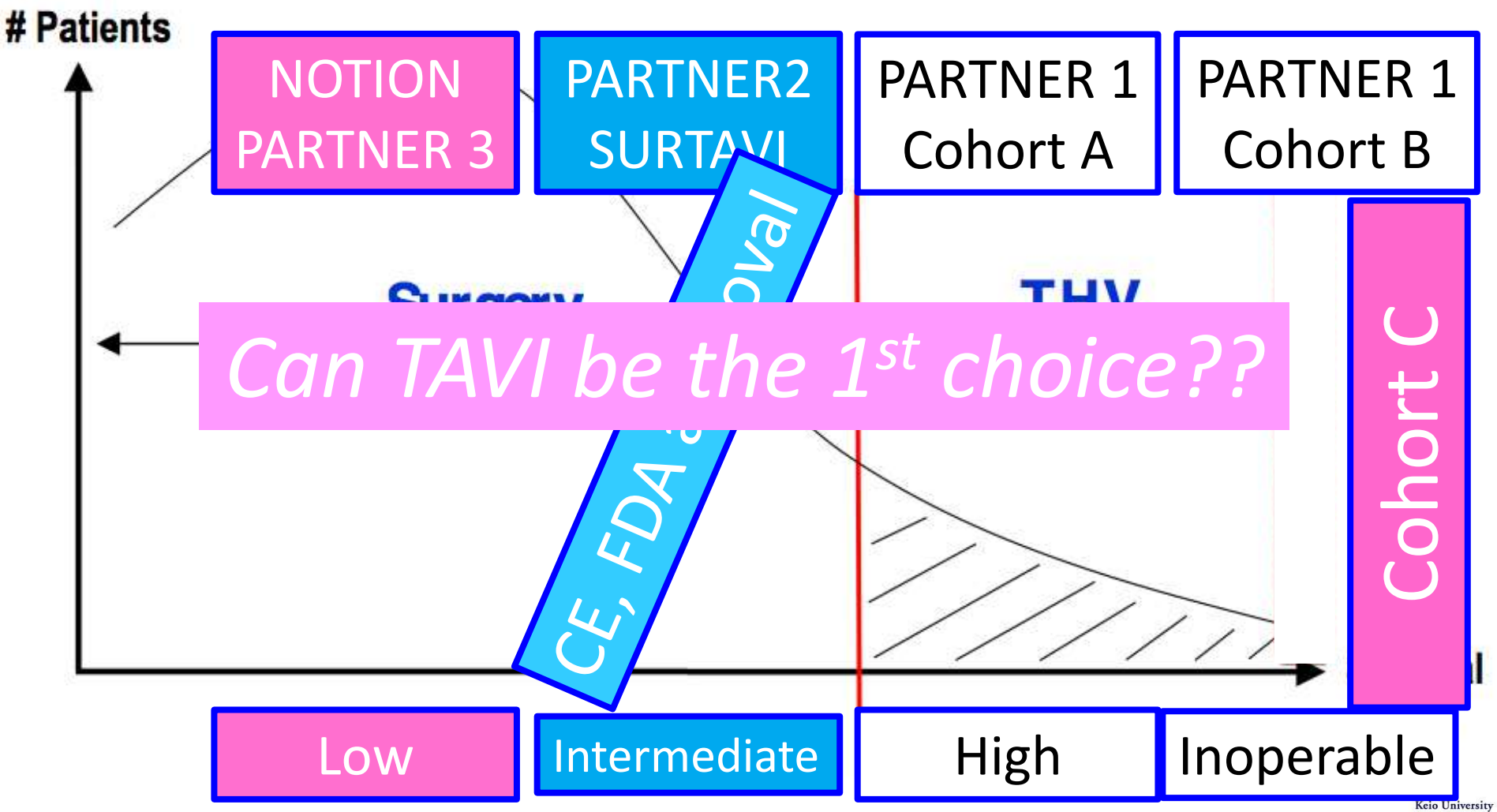
Indication for TAVI



Can TAVI be the 1st choice??

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PARTNER III Trial Design

Symptomatic Low Operative Risk Severe AS Patients
Heart team agrees the patient has a risk of operative mortality < 2% (e.g., STS <4)

n=1300

65 5 3 1

1:1 Randomization

TAVR (SAPIEN 3) (n=~650)

SAVR (Surgical Bioprosthetic Valve) (n= ~650)

CT Imaging Sub-Study (n=200)

CT Imaging Sub-Study (n=200)

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

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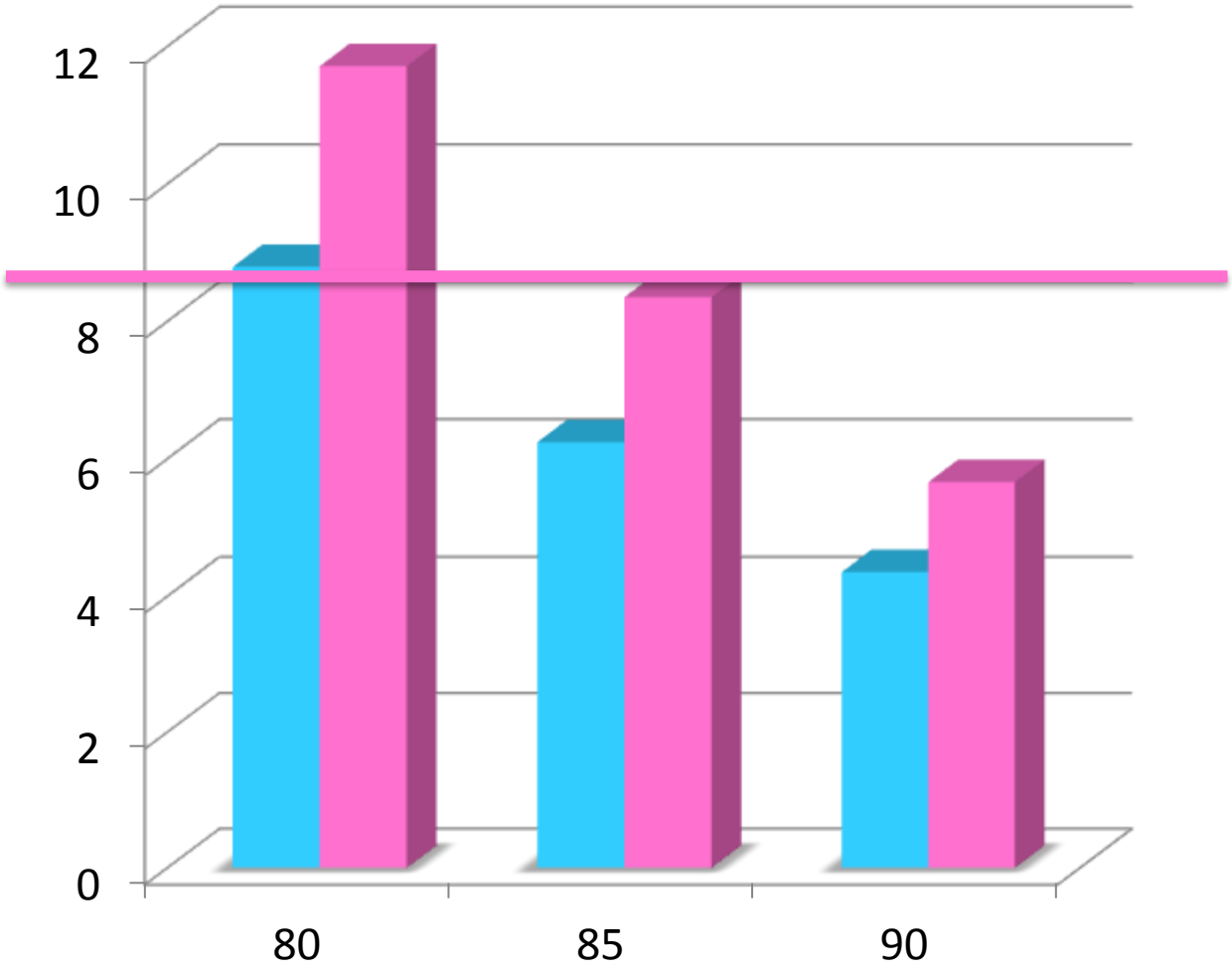
Life expectancy of Japanese patients



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PCR
tokyo valves

March 30th-April 1st, 2018