

Clinical Outcomes After TEER in Japan: Updated National Data From the OCEAN-Mitral Registry

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Potential conflicts of interest

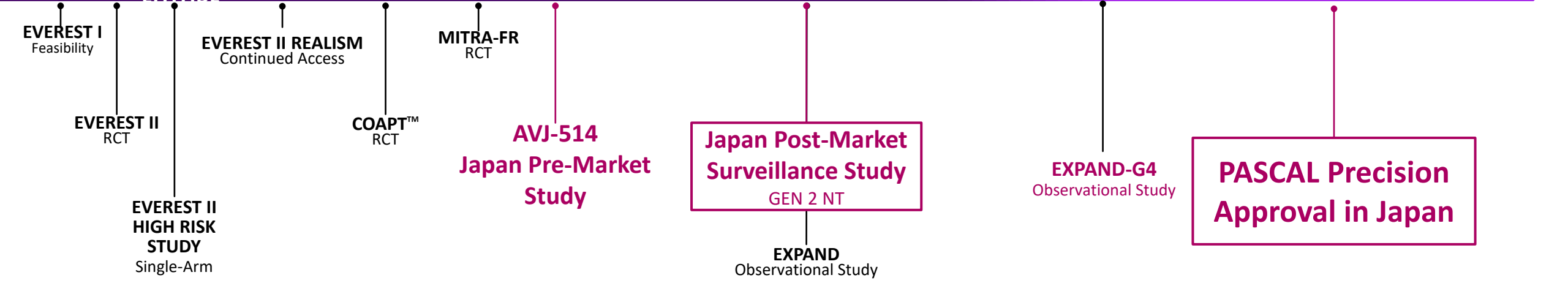
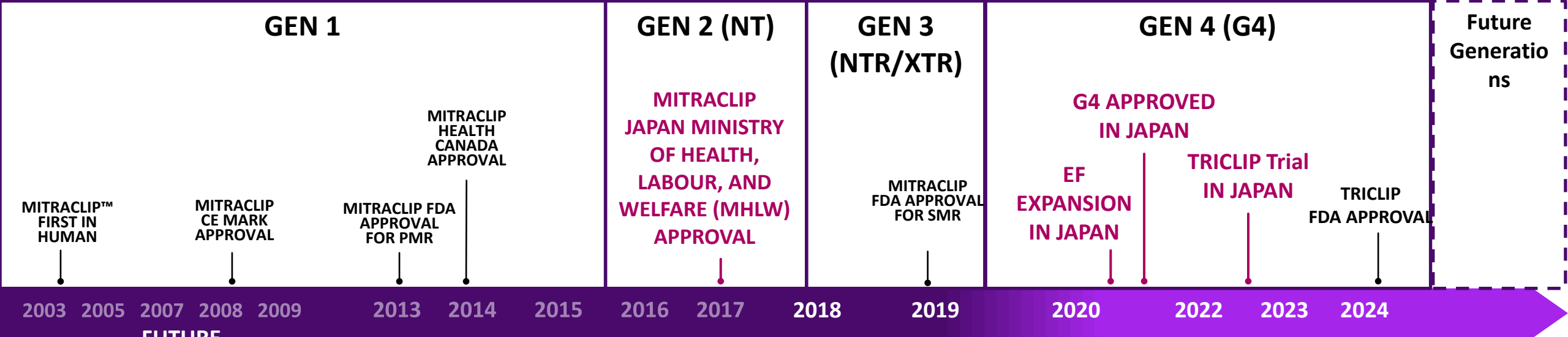
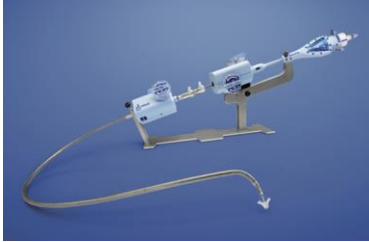
Speaker's name : Shunsuke Kubo

I have the following potential conflicts of interest to declare:

Clinical Proctor : Boston Scientific, Abbott Medical

Honoraria or consultation fees : Boston Scientific, Abbott Medical

TEER History in Japan



Indication of TEER in Japan

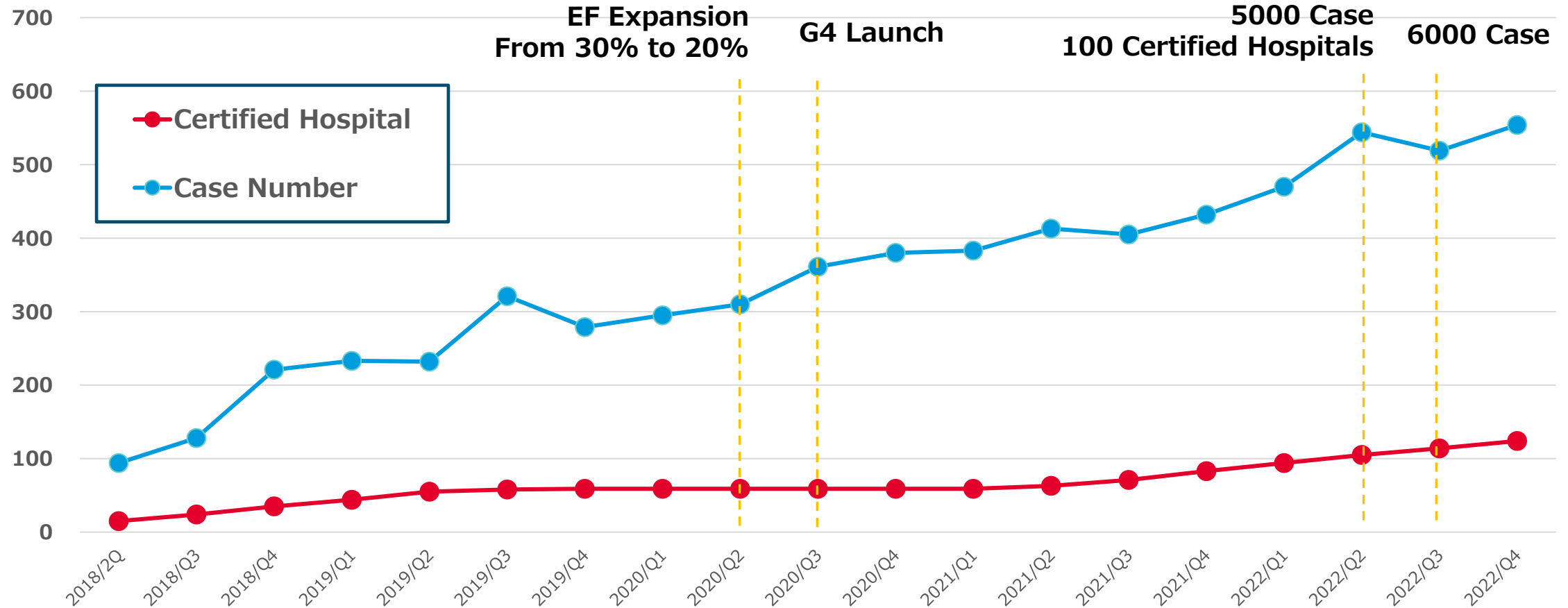
TEER was approved for high surgical risk patients with symptomatic severe MR (**grade 3+ or 4+ at rest or exercise**) with **LV ejection fraction more than 20%**.

Exclusion criteria...

- Functional MR patients under suboptimal GDMT
- Acute worsened MR
- **Catecholamine dependent (supported is OK)**
- **Under support device such as ECMO and Impella**

DATA PERIOD : 2018.04.01 ~ 2022.12.31

Change in Case number and Certified Hospital in Japan



(Q1: Jan – Mar, Q2: Apr – Jun, Q3: Jul – Sep, Q4: Oct – Dec)

Proprietary and confidential — do not distribute

*This data is based on Abbott Medical Japan LLC own aggregate results.
Please note that there may be some deviation from the actual data.*

OCEAN-Mitral Registry from OCEAN-SHD family

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

- ・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

近畿地方

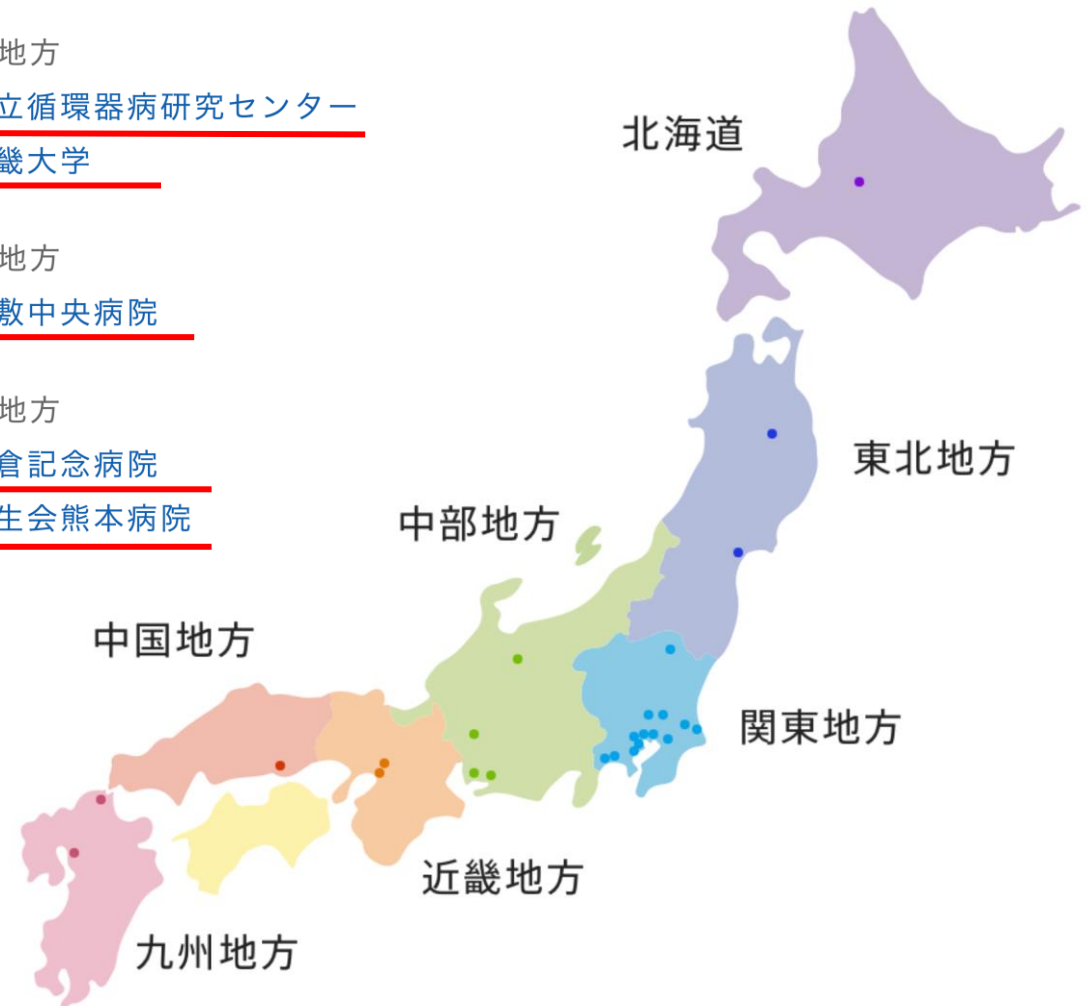
- ・国立循環器病研究センター
- ・近畿大学

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



A total of 21 centers participated

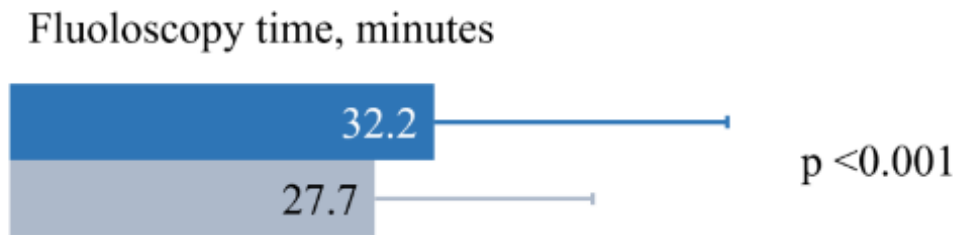
Baseline Characteristics (n = 2150)

Age	80 (73-85)	Body size area, m ²	1.5 (1.4-1.7)
Male	1209 (56.2)	Prior myocardial infarction	502 (23.3)
Hypertension	1452 (67.5)	ACE-I/ARB/ARNI	1371 (63.9)
Diabetes	579 (26.9)	β blocker	1614 (75.1)
Atrial fibrillation	1368 (63.7)	MR etiology	
Hemodialysis	113 (5.3)	Primary MR	639 (29.7)
CRT therapy	232 (10.3)	Secondary MR	1617 (75.2)
Prior open heart surgery	298 (13.9)	Atrial FMR	419 (19.5)
STS score (MVR)	9.1 (5.8-14.1)	LVDd, mm	57 (50-64)
BNP, pg/mL	342 (170-675)	LVDs, mm	43 (33-54)
eGFR, ml/min/1.73m²	38 (26-51)	LA diameter, mm	49 (44-55)
HF hospitalization < 1 year	1541 (71.7)	LVEF, %	43 (31-61)
NYHA class		EROA, cm ²	0.35 (0.25-0.47)
II	744 (34.6)	Mitral valve area, cm ²	5.1 (4.2-6.2)
III	1047 (48.7)	Moderate/severe TR	766 (35.6)
IV	312 (14.5)	TRPG, mmHg	33 (25-44)

Data were presented as Median (interquartile range) or n (%)

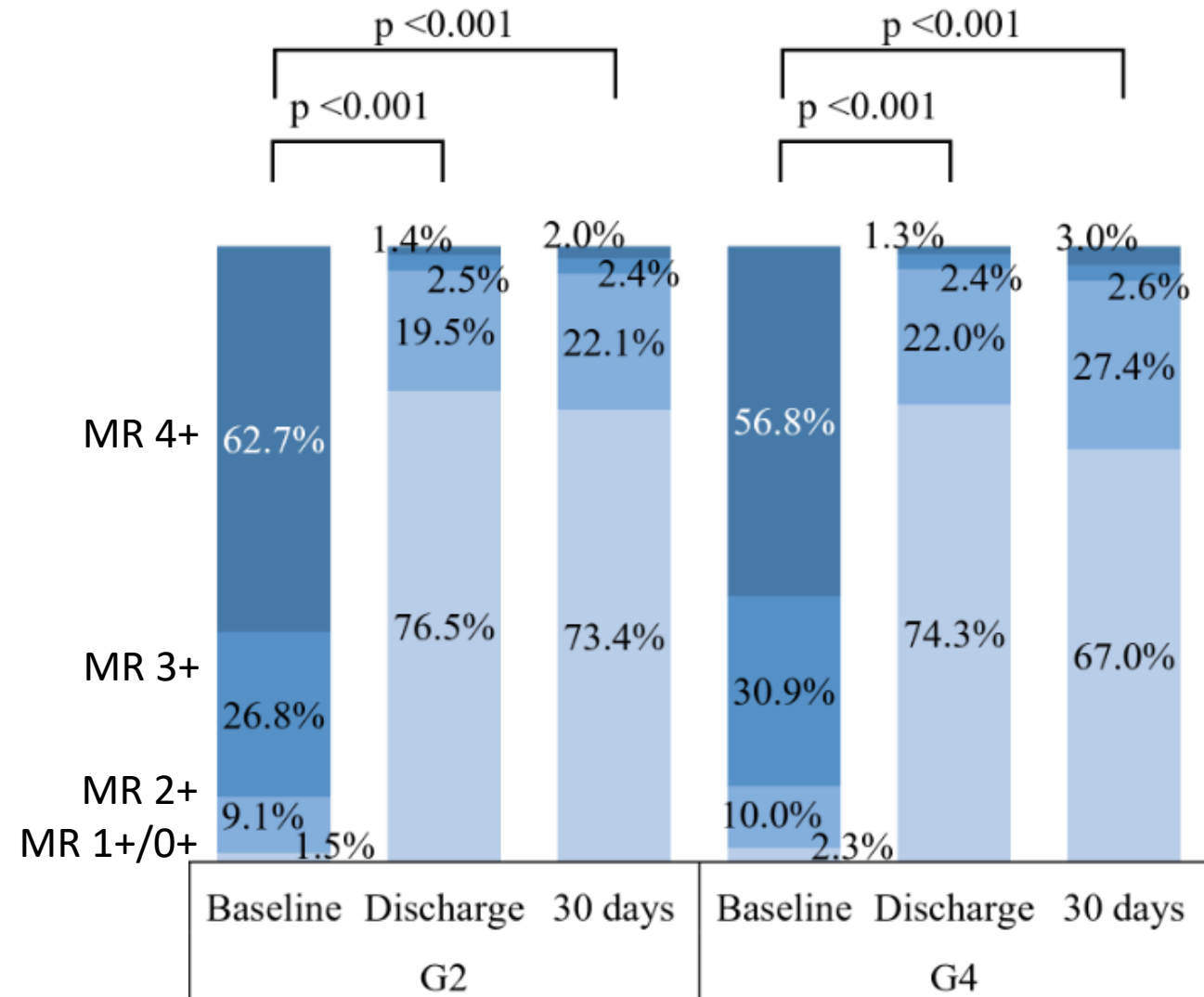
TABLE 2 Procedural Outcomes (N = 2,150)

Clip generation		
G2	1,532/2,150 (71.3)	
G4	618/2,150 (28.7)	
Number of clips		
G2	1.46 ± 0.53	
G4 ^a	1.30 ± 0.50	



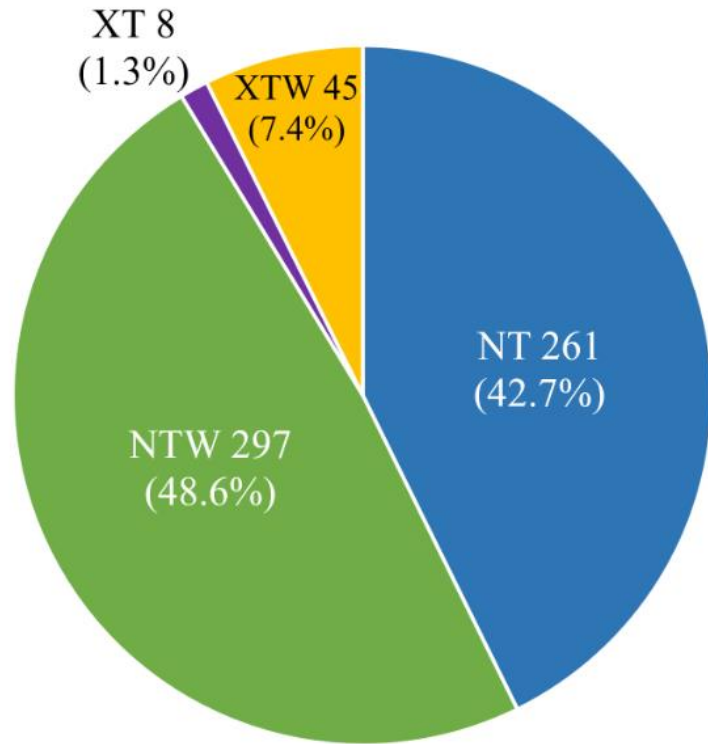
■ G2 ■ G4

Impact of MitraClip G4

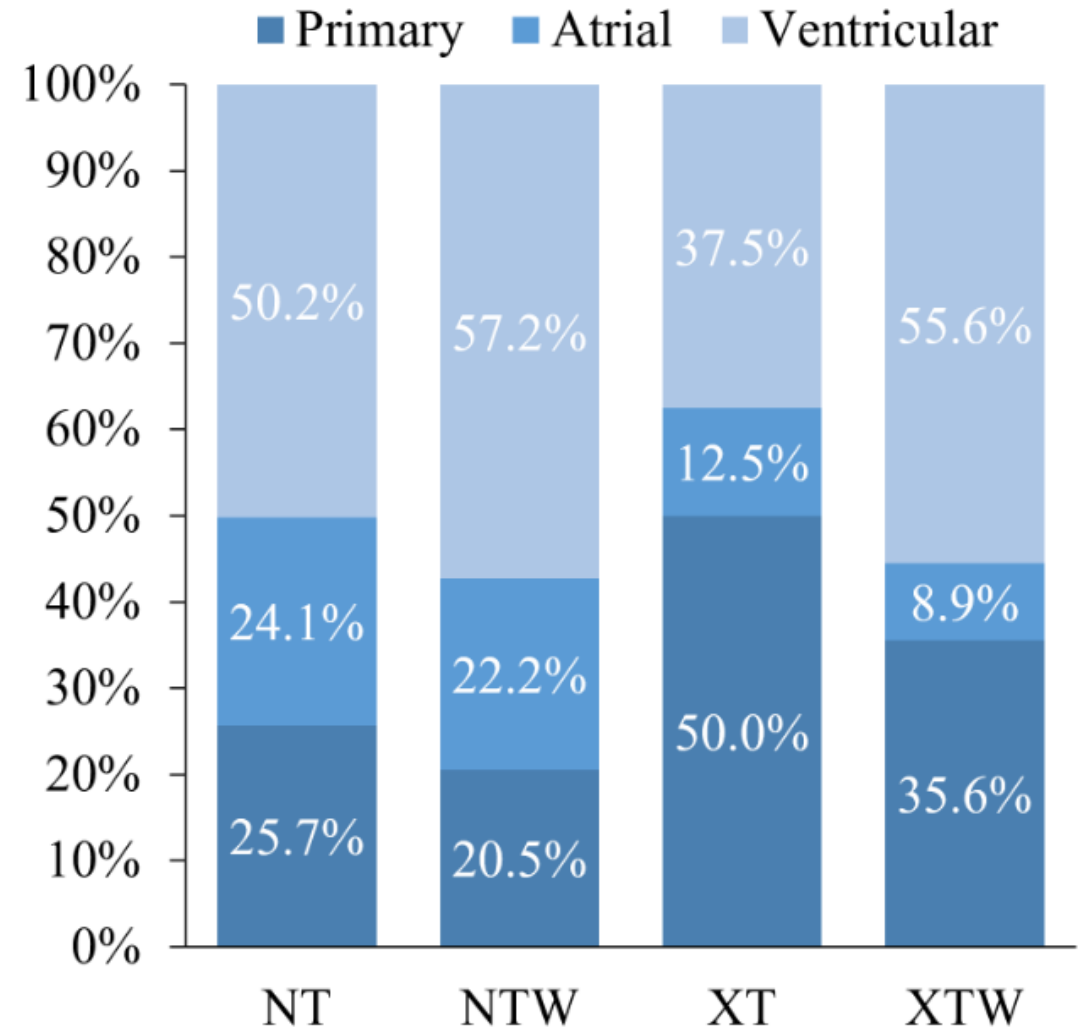


- MitraClip G4 improved the procedure quality, but the degree of MR reduction was not different.

Clip Selection of MitraClip G4

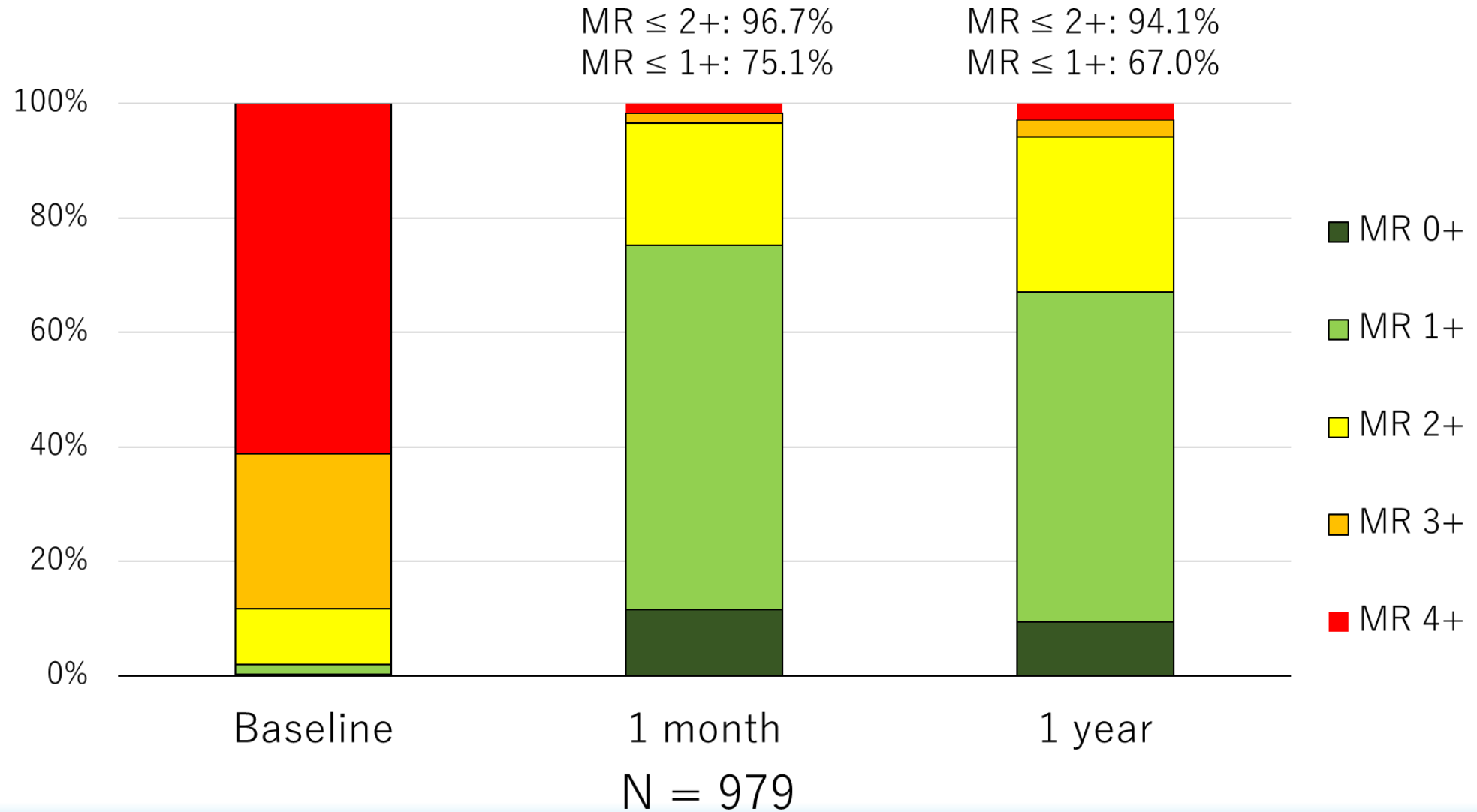


- Longer clip type was more commonly used in primary MR.
- Due to initial stage of MitraClip G4 in Japan, XT series were rarely used.



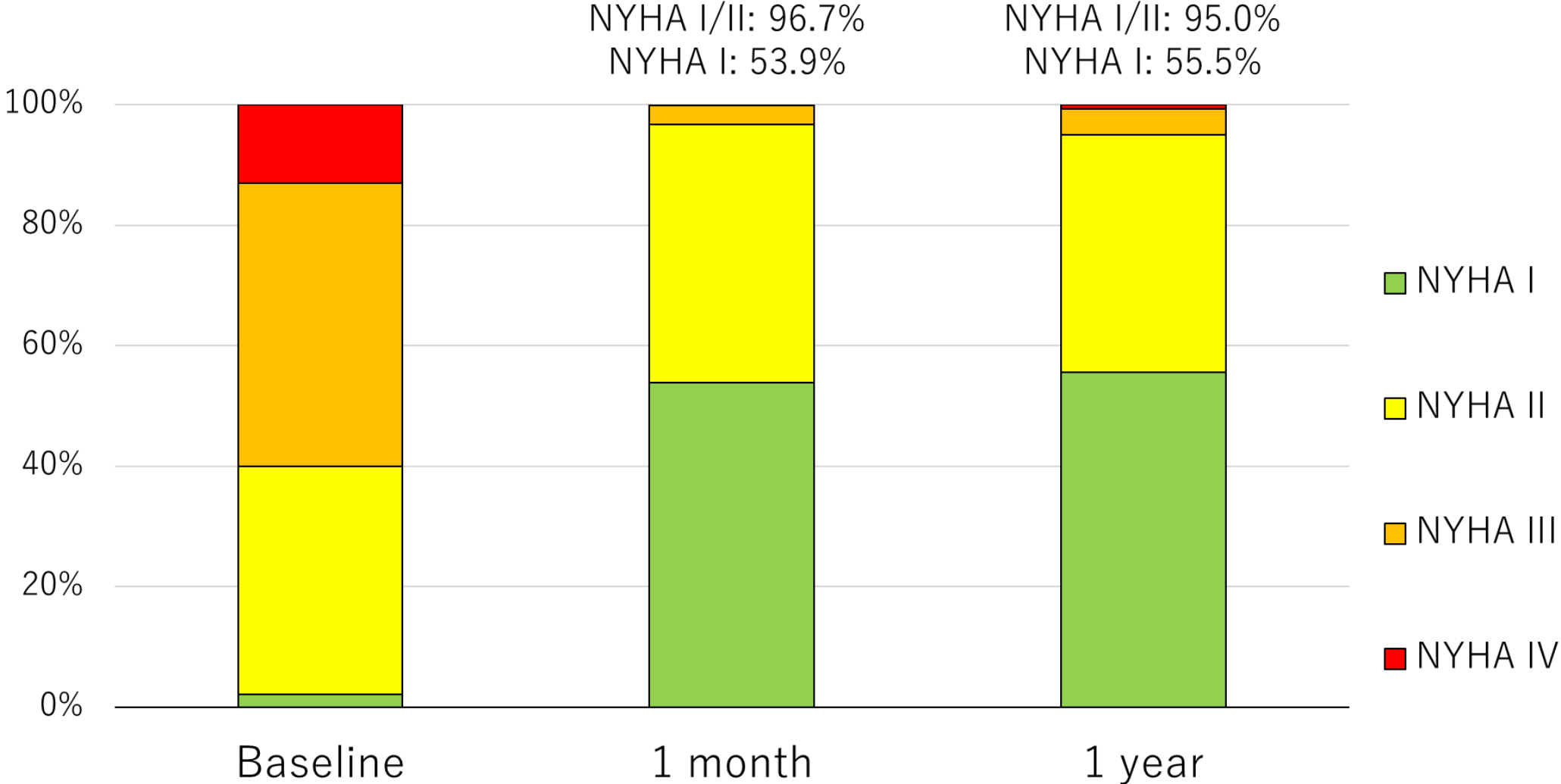
Now, XT series is a 1st choice clip for any types of MR.

Serial MR Severity



MR reduction was durable at 1 year.

Serial NYHA Class



N = 1010

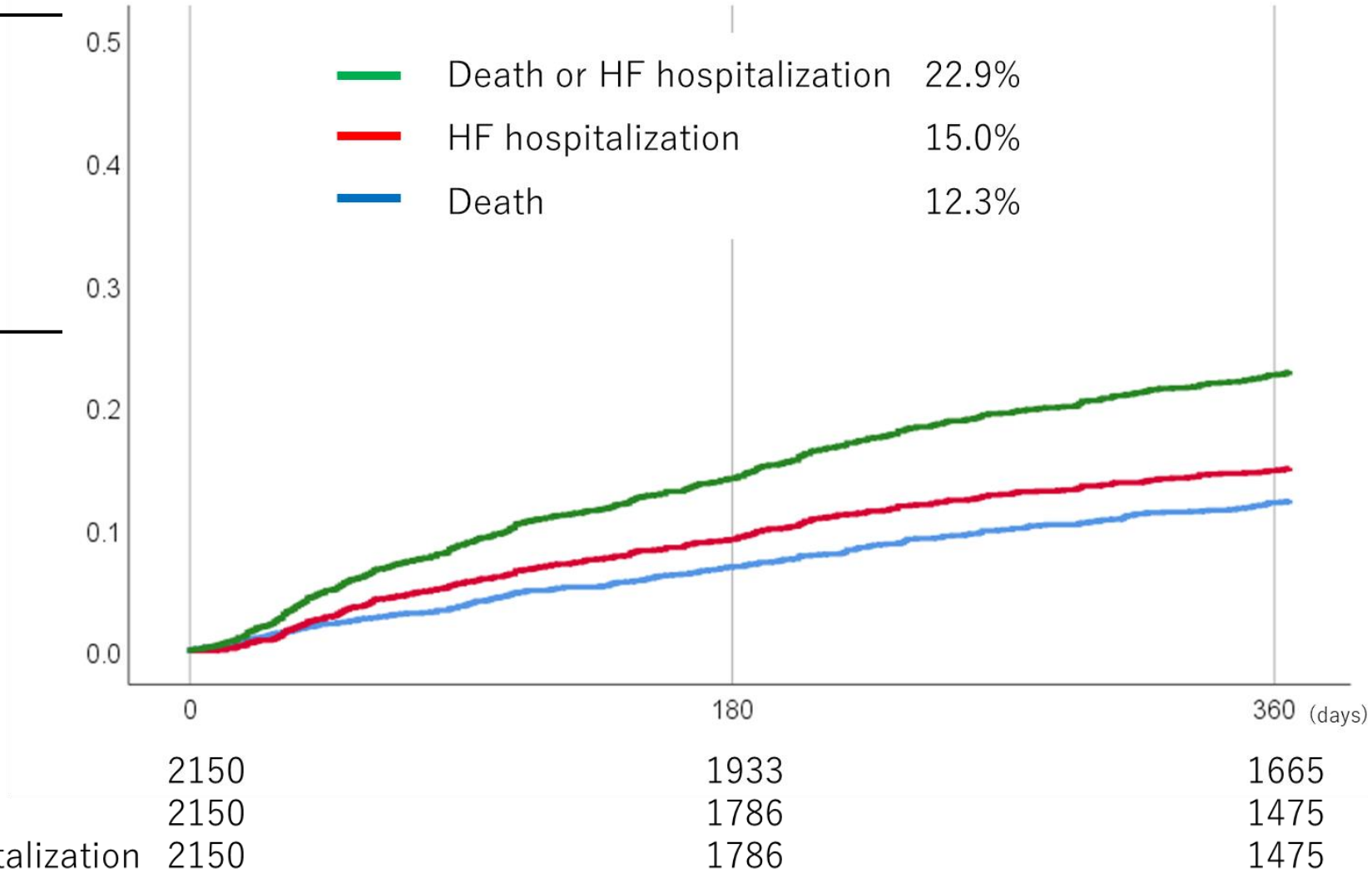
NYHA class dramatically improved at 1 month and durable at 1 year.



One-Year Outcomes

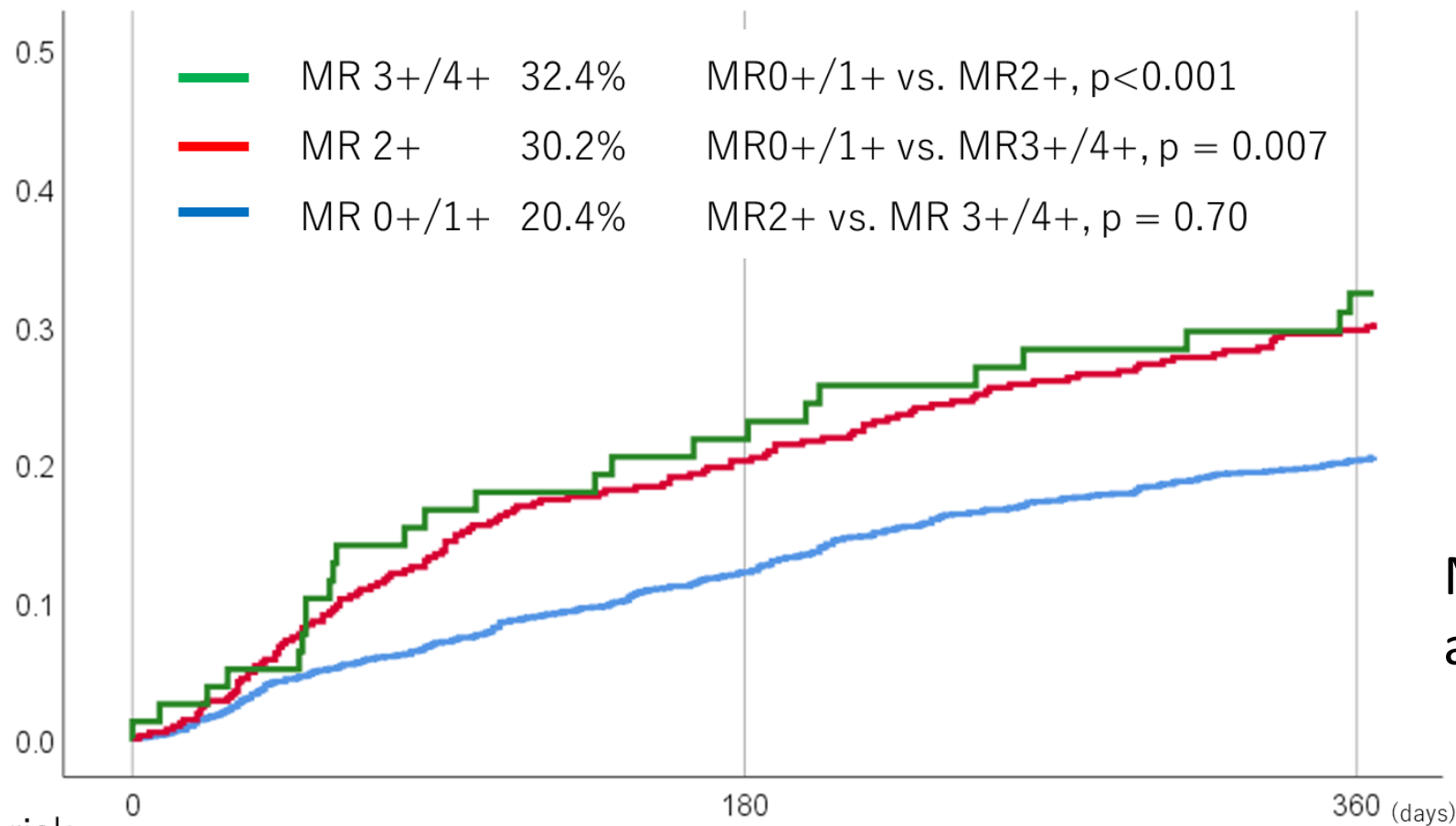
Other adverse events	
Cardiovascular death	7.9%
Non-cardiovascular death	4.8%
Single leaflet device attachment	1.7%
Leaflet tear	1.2%
Mitral valve re-intervention	2.4%

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



1-year results were favorable and better than registries of Western countries.

Impact of Residual MR on Death/HF Hospitalization



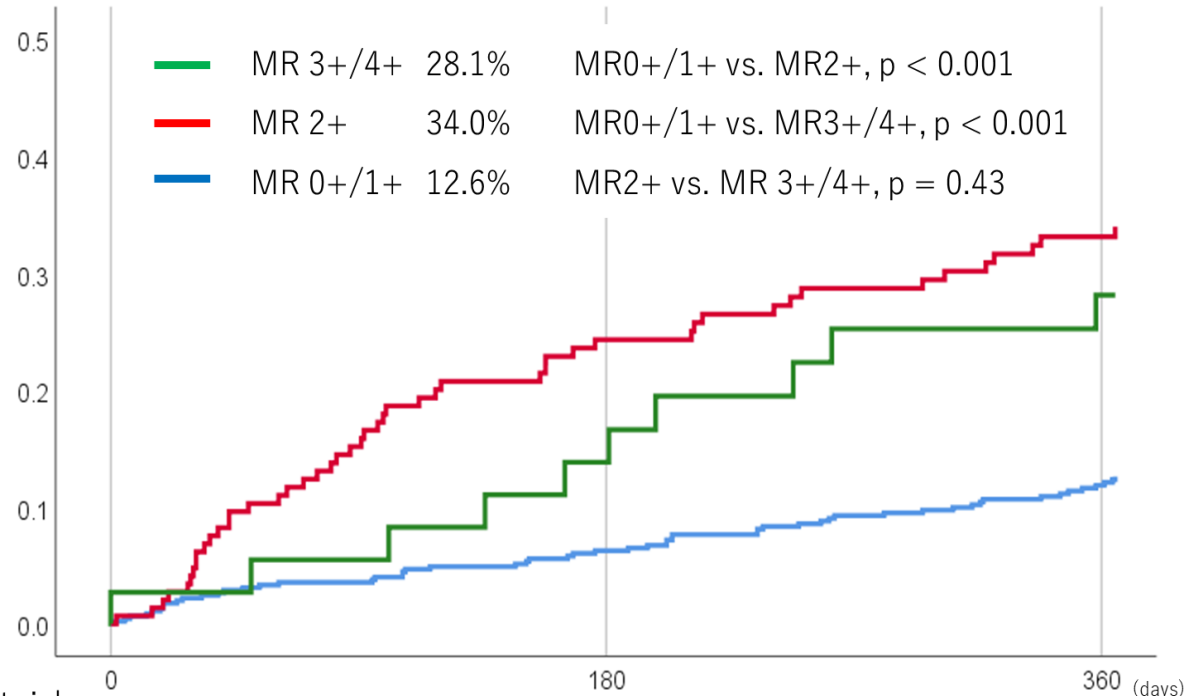
MR should be reduced as much as possible.

No. at risk	0	180	360 (days)
MR 0+/1+	1630	1387	1158
MR 2+	440	338	269
MR 3+/4+	80	61	48



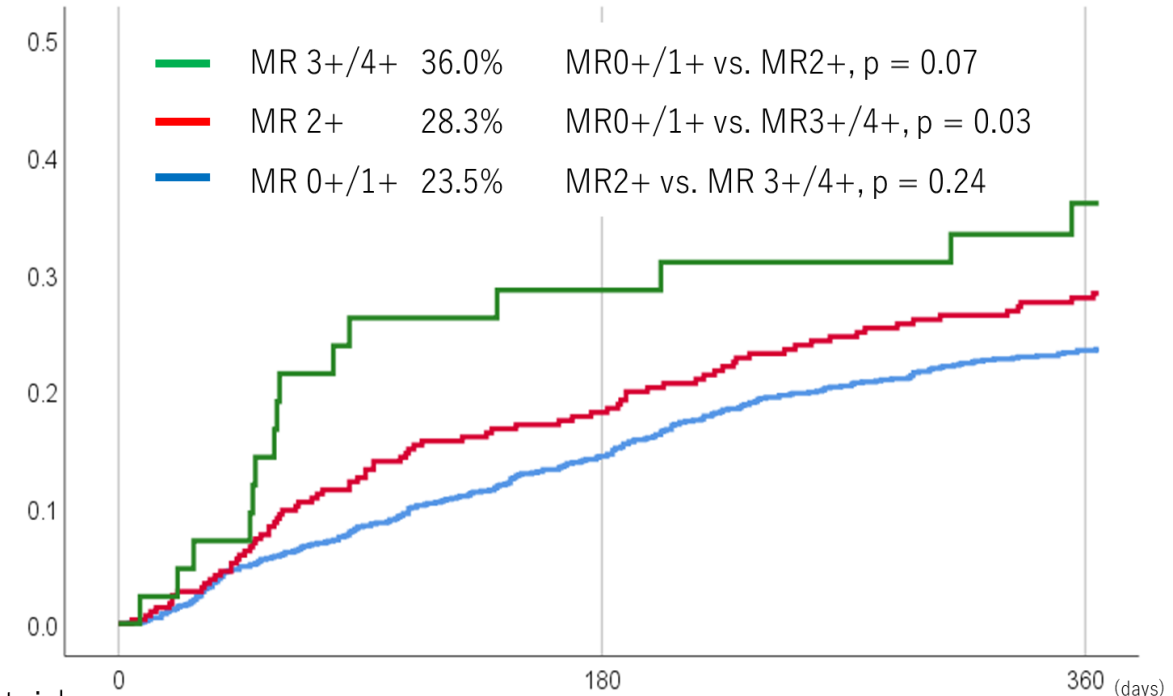
Impact of Residual MR according to MR Etiology

Primary MR



No. at risk	0	180	360 (days)
MR 0+/1+	455	412	359
MR 2+	147	105	82
MR 3+/4+	37	31	24

Secondary MR



No. at risk	0	180	360 (days)
MR 0+/1+	1175	975	799
MR 2+	293	233	187
MR 3+/4+	43	30	24



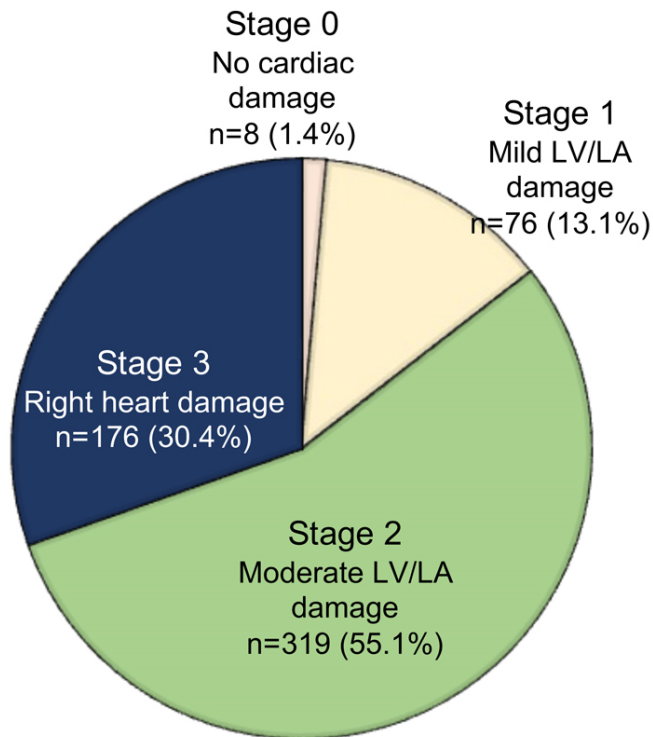
Adverse effects of residual MR were more strongly observed in primary MR

Cardiac Damage and TEER Outcomes in DMR

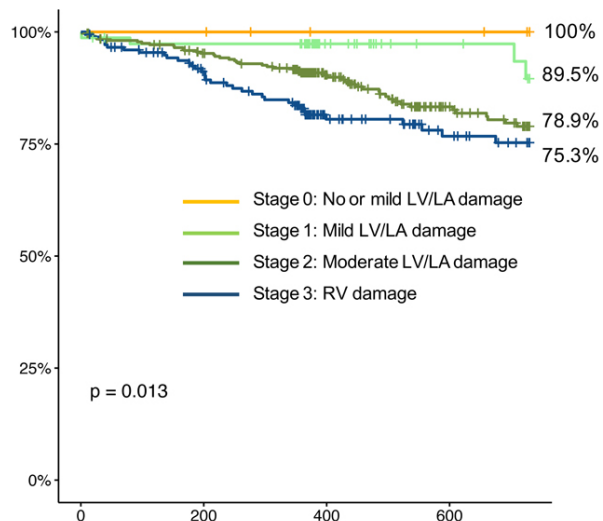
Patients undergoing M-TEER
for **degenerative MR**
n=579



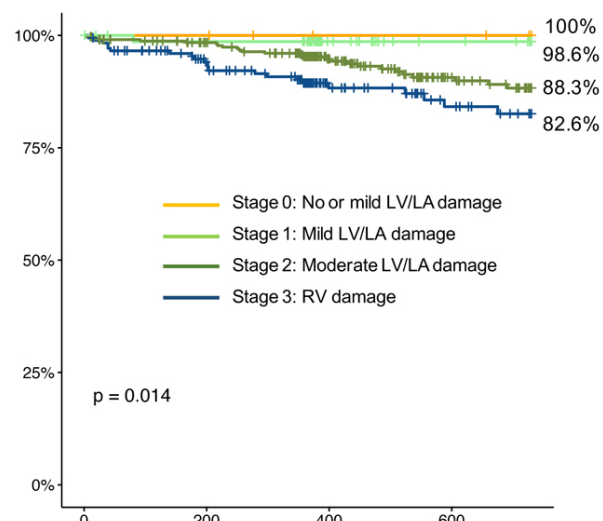
Staging of cardiac damage



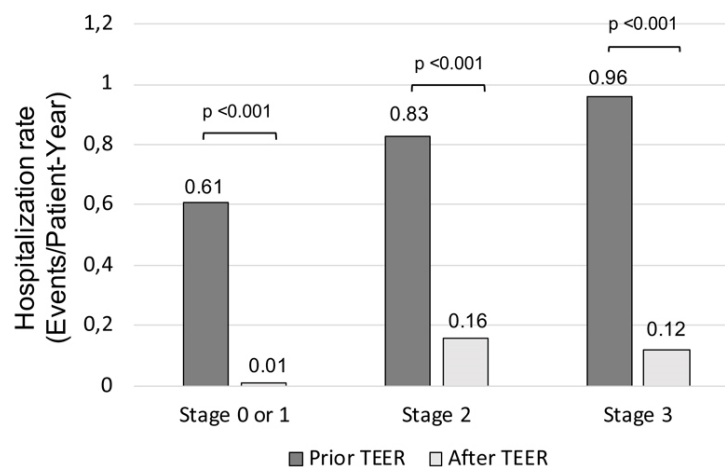
All-cause death



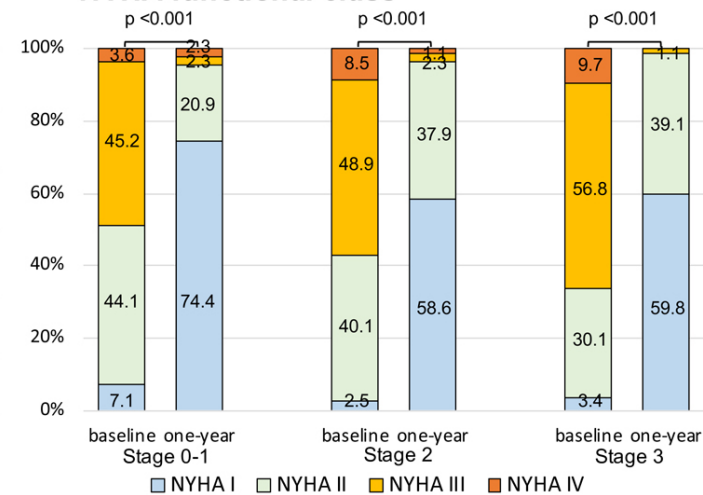
Cardiovascular death



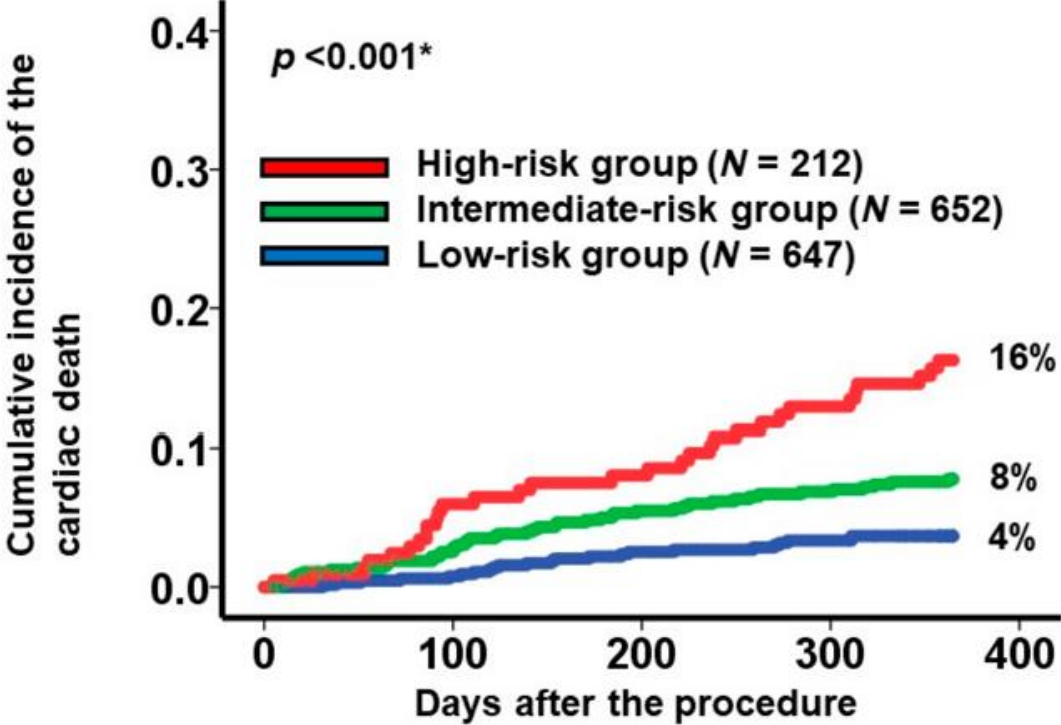
Heart failure rehospitalization



NYHA functional class



Predictors of Adverse Events in FMR after TEER



High-risk:	212	186	172	160	135
Intermediate-risk:	652	596	561	532	465
Low-risk:	647	629	603	587	510

Number of HF admission

Plasma BNP level

Intravenous catecholamines

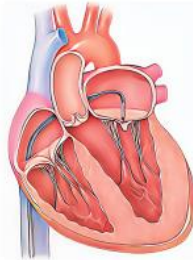
Imamura T, et al. J Clin Med. 2024;13(3):851.



Clinical Impact of LVEF Worsening after TEER

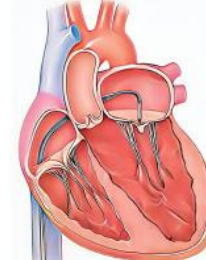
TEER patients for severe MR in the OCEAN registry
(n=2,019)

pEF (n=1,470)



Preserved LVEF after TEER

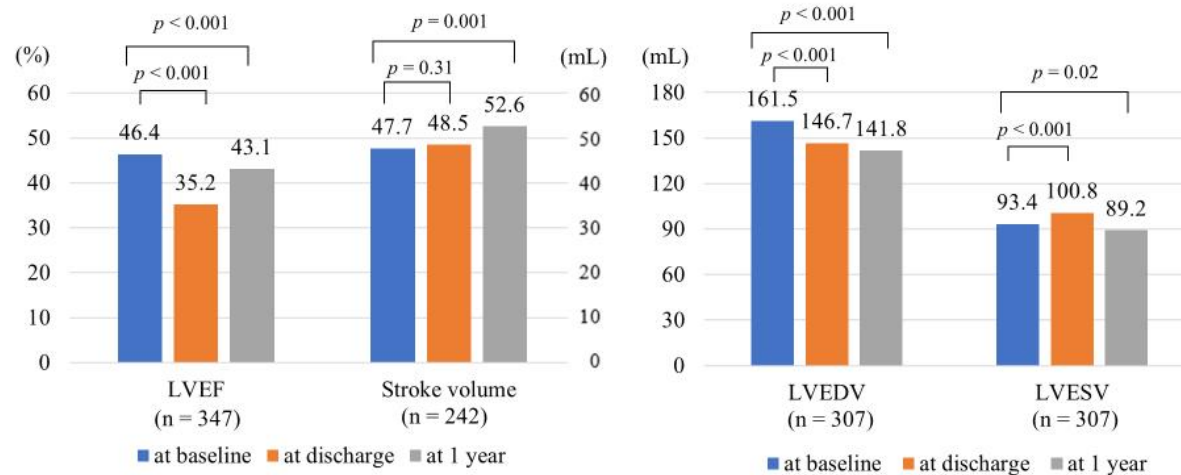
wEF (n=649)



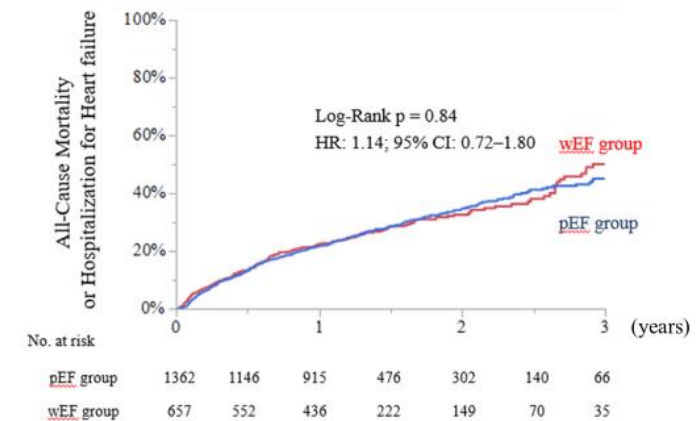
Worsened LVEF after TEER
(a relative decrease of >12.9%)

Predictors of wEF		
Overall	PMR	SMR
LVEDV		
LVEF	LVEF	LVESV
BNP	Stroke volume	BNP
Moderate or severe AR	The degree of MR reduction ≥ 3	Previous CRT
		Procedural time

Serial changes in LVEF and LV volume of wEF



Long-term outcomes of wEF and pEF



OCEAN-Mitral 6 Published, Ongoing >50 proposals

JACC: ASIA
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[Journal of the American Heart Association](#)

ORIGINAL RESEARCH

Short-Term Outcomes Following Transcatheter Edge-to-Edge Repair



One-Year Outcomes and Their Relationship to Residual Mitral Regurgitation After Transcatheter Edge-to-Edge Repair With

Review > [Cardiovasc Interv Ther](#) (IF: 1.11; Q3). 2023 Jan;38(1):28-38. doi: 10.1007/s12928-022-00898-4. Epub 2022 Dec 5.

Data of >3700 patients with >2000 MitraClip G4 Coming Soon!

ture

Edge-to-Edge Repair for Functional Mitral Regurgitation

Hirofumi Hioki, MD^{a,*}, Yusuke Watanabe, MD^a, Akihisa Kataoka, MD^b, Ken Kozuma, MD^a, Shinichi Shirai, MD^b, Toru Naganuma, MD^c, Masahiro Yamawaki, MD^d, Yusuke Enta, MD^c, Shingo Mizuno, MD^f, Hiroshi Ueno, MD^g, Yohei Ohno, MD^h, Yoshifumi Nakajima, MDⁱ, Masaki Izumo, MD^j, Hiroki Botta, MD^k, Kazuhisa Kodama, MD^l, Junichi Yamaguchi, MD^m, Shunsuke Kubo, MDⁿ, Makoto Amaki, MD^o, Masahiko Asami, MD^p, Mike Kazuki Mizutani, MD^q, Shinya Okazaki, MD^r, Daisuke Hachinohe, MD^s, Toshia Yuya Adachi, MD^t, Masanori Yamamoto, MD^{u,w,x}, and Kentaro Hayashida, MD
OCEAN-Mitral Investigators

Circulation: Cardiovascular Interventions

ORIGINAL ARTICLE

Cardiac Damage in Degenerative Mitral Regurgitation Treated With Transcatheter Mitral Edge-to-Edge Repair

Atsushi Sugiura^a, MD, PhD^{*}; Masanori Yamamoto, MD, PhD^{*}; Miike Saji^b, MD, PhD; Masahiko Asami^c, MD; Yusuke Enta^d, MD; Masaki Nakashima^e, MD; Shinichi Shirai^f, MD; Masaki Izumo^g, MD, PhD; Shingo Mizuno, MD; Yusuke Watanabe^h, MD, PhD; Makoto Amaki, MD, PhD; Kazuhisa Kodama, MD, PhD; Junichi Yamaguchiⁱ, MD, PhD; Yoshifumi Nakajima, MD; Toru Naganuma, MD, PhD; Hiroki Botta, MD; Yohei Ohno^j, MD, PhD; Masahiro Yamawaki, MD, PhD; Hiroshi Ueno^k, MD, PhD; Kazuki Mizutani^l, MD, PhD; Yuya Adachi, MD; Toshiaki Otsuka^m, MD, PhD; Shunsuke Kubo, MD; Georg Nickenig, MD; Kentaro Hayashidaⁿ, MD, PhD; on behalf of the OCEAN-Mitral Investigators

Article

Predictive Factors of Cardiac Mortality Following TEER in Patients with Secondary Mitral Regurgitation

Teruhiko Imamura^{1,*}, Shuhei Tanaka¹, Ryuichi Ushijima¹, Nobuyuki Fukuda¹, Hiroshi Ueno¹, Koichiro Kinugawa¹, Shunsuke Kubo², Masanori Yamamoto^{3,4,5}, Mike Saji^{6,7}, Masahiko Asami⁸, Yusuke Enta⁹, Masaki Nakashima⁹, Shinichi Shirai¹⁰, Masaki Izumo¹¹, Shingo Mizuno¹², Yusuke Watanabe¹³, Makoto Amaki¹⁴, Kazuhisa Kodama¹⁵, Junichi Yamaguchi¹⁶, Yoshifumi Nakajima¹⁷, Toru Naganuma¹⁸, Hiroki Botta¹⁹, Yohei Ohno²⁰, Masahiro Yamawaki²¹, Kazuki Mizutani²², Toshiaki Otsuka²³, Kentaro Hayashida²⁴ and on behalf of the OCEAN-Mitral Investigators



Summary

- Initial results of TEER with MitraClip in Japan were excellent compared with results from other countries.
- MitraClip G4 system had an impact on procedural quality, but the effect of MR reduction was under investigation.
- Our OCEAN-Mitral registry suggested that we have to reduce MR as much as possible irrespective of mitral valve anatomy.
- OCEAN-Mitral registry is ready to create a lot of evidence in the future like the OCEAN-TAVI registry.