

The First Report on the Japanese CTO PCI Expert Registry

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*on behalf of
Japanese Board of CTO Interventional Specialist*

Japanese CTO-PCI Registry

Currently,

‘Retrograde Summit General Registry’

and

‘Japanese CTO PCI Expert Registry’

are being conducted in Japan.

Japanese CTO PCI Expert Registry

- The Japanese Board of CTO Interventional Specialists was established in 2013 to accumulate quantitative data to identify issues such as stagnation in the development of CTO-PCI techniques
- Starting from 2014, Japanese CTO PCI Expert Registry began establishing a database of CTO-PCI performed by certified expert physicians who have a certain level of CTO-PCI skills
- Patients are enrolled by certified expert operators.
- Procedure success is adjudicated by a Corelab

Registry Overview

| | Retrograde Summit | | Japanese CTO PCI Expert Registry |
|---------------------------------|---|------------------|---|
| | Registry | General Registry | |
| Pts. Enrollment | Jan. 2009~ Dec. 2013 | Jan. 2014~ | Jan. 2014~ |
| Participants As of Jun. 2015 | 56 of Japanese Centers | 40 of | 42 of Japanese Expert physicians |
| Criteria for Participants | <ul style="list-style-type: none"> Centers approved by Retrograde Summit Cases treated by Expert are excluded | | <ul style="list-style-type: none"> More than 300 cases of experience of CTO-PCI More than 50 cases of CTO-PCI per year Recommendation from two or more steering committee member |
| Core lab | None | | Adjudication of Indication and Procedure Success |
| Organization | Retrograde Summit | | Japanese Board of CTO interventional specialist |
| Chairman | Habara (initiated by Tsuchikane) | | Tsuchikane (initiated by Katoh, late Mitsudo) |

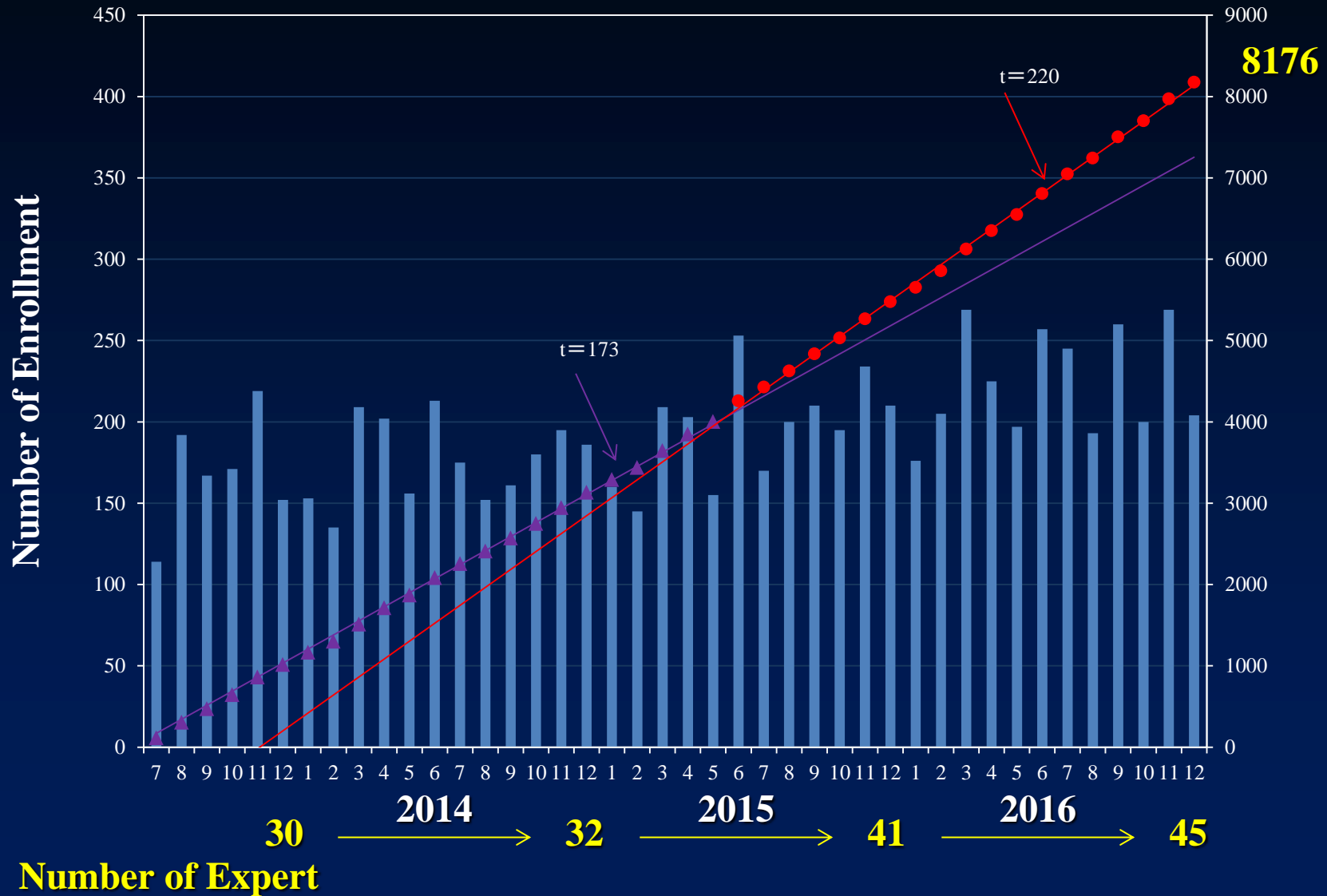
Data Unification

- The database for Retrograde Summit general registry has already been modified to collect same dataset as Japanese CTO PCI Expert Registry
- The outcome from both Retrograde Summit General Registry and Japanese CTO PCI Expert Registry will be compared and reported in the near future

Features of Expert Registry

- Officially started from January 2014, will end in December 2022
- All clinical data including patient background data and details of the procedures are input via an electronic capture system
- Pre-procedural CAG and CTA (optional), and procedural angiograms and IVUS images are sent as DICOM data to an independent core laboratory
- Annual clinical follow-up data are collected for 5 years (only in domestic pts)

Patient Enrollment



**The Initial Outcomes from
Japanese CTO PCI Expert Registry
2014-2015**

Patient Enrollment

The enrolled CTO-PCI procedure; **n=4205** procedures
the number of target CTO lesion in each procedure
(1 lesion : n=4148, 2 lesions : n=57)

CTO-PCI **outside** Japan
n=1359

CTO-PCI in Japan
n=2846

2 CTO lesions in one procedure: n=30

N= 2816

Inadequate anatomical indication : n=62
sub-total lesion: n=104 ,
non-CTO lesion: n=1, unanalyzable n=4

N=2645

Inappropriate data of pt. /lesion
background: n=49

N=2596

Definitions

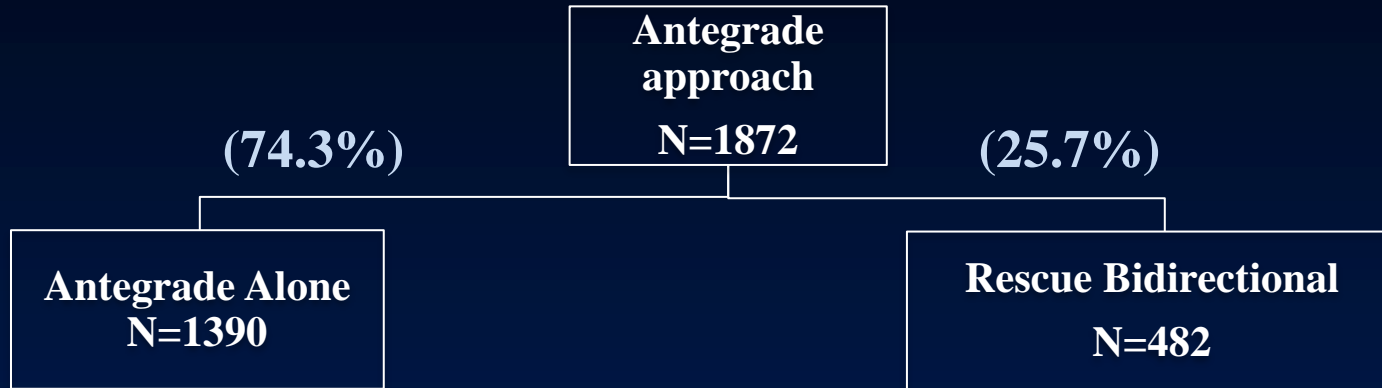
- The procedure was defined here as **bidirectional approach (BA)** where an attempt was made to cross the collateral channel for retrograde revascularization techniques.
- Cases were divided into 3 groups based on **ITT** principle; primary antegrade approach (**PAA**), primary BA (**PBA**), and rescue BA (**RBA**).
- PAA included rescue BA and re-switched antegrade approach.
- No antegrade dissection and reentry device was used.

| | Overall | PAA | PBA | PAA vs. PBA |
|--------------------|-----------|-----------|-----------|-------------|
| | N=2596 | N=1872 | N=724 | P-value |
| | | 72.1% | 27.9% | |
| Age | 66.9±10.9 | 66.8±10.9 | 66.9±10.7 | 0.863 |
| BMI | 24.7±3.8 | 24.7±3.8 | 24.6±3.8 | 0.413 |
| LVEF | 54.8±12.9 | 54.9±12.9 | 54.6±12.8 | 0.458 |
| eGFR | 64.9±29.0 | 65.1±30.2 | 64.3±25.7 | 0.458 |
| Male gender, % | 86.1 | 85.1 | 88.4 | 0.018 |
| Hypertension, % | 78.5 | 78.0 | 80.8 | 0.12 |
| Dyslipidemia, % | 77.5 | 76.1 | 82.1 | 0.001 |
| Diabetes, % | 44.9 | 44.9 | 45.8 | 0.35 |
| Current smoking, % | 54.4 | 58.0 | 62.3 | 0.057 |
| OMI, % | 51.0 | 51.7 | 51.3 | 0.895 |
| Prior CABG, % | 7.9 | 7.4 | 9.4 | 0.105 |
| Prior PCI, % | 63.2 | 61.8 | 67.5 | 0.007 |
| Reattempt, % | 20.6 | 15.1 | 34.8 | <0.0001 |
| Syntax score | 15.9±8.6 | 16.0±8.4 | 15.6±8.9 | 0.062 |
| J-CTO score | 2.0±1.1 | 1.9±1.1 | 2.4±1.1 | <0.0001 |
| Target vessel, % | | | | <0.0001 |
| LAD | 30.9 | 32.9 | 25.7 | |
| LCX | 17.1 | 20.4 | 8.6 | |
| LMT | 0.6 | 0.6 | 0.6 | |
| RCA | 51.5 | 46.2 | 65.2 | |

| | Overall | PAA | PBA | PAA vs. PBA |
|---------------------------------------|----------------|------------|------------|--------------------|
| | N=2596 | N=1872 | N=724 | P-value |
| In-stent occlusion, % | 13.6 | 16.9 | 5.1 | <0.0001 |
| Distal run off (<3.0mm), % | 65.0 | 64.9 | 67.2 | 0.274 |
| CTO length (≥20mm), % | 60.5 | 57.0 | 69.6 | <0.0001 |
| Side branch at proximal cap, % | 34.1 | 34.8 | 32.0 | 0.181 |
| Collateral filling, % | | | | <0.0001 |
| Contralateral | 50.7 | 47.6 | 58.8 | |
| Ipsilateral | 13.3 | 15.9 | 6.6 | |
| Both | 35.2 | 35.5 | 34.4 | |
| None | 0.7 | 1.0 | 0.1 | |
| Lesion calcification, % | 52.3 | 50.5 | 56.9 | 0.003 |
| Proximal tortuosity, % | 50.7 | 49.1 | 49.3 | 0.108 |
| Tortuosity of CTO lesion, % | 24.6 | 21.6 | 32.5 | <0.0001 |
| Morphology of proximal cap, % | | | | 0.002 |
| Blunt | 23.7 | 23.6 | 23.9 | |
| No stump | 19.1 | 17.7 | 22.7 | |
| Tapered/tunnel | 56.7 | 58.3 | 52.3 | |

| | Overall | PAA | PBA | PAA vs. PBA |
|-------------------------------------|-------------|-------------|-------------|-------------|
| | N=2596 | N=1872 | N=724 | P-value |
| GW success, % | 92.0 | 92.9 | 90.1 | 0.016 |
| Technical success, % | 89.9 | 91.0 | 87.3 | 0.006 |
| Procedural success, % | 88.8 | 90.3 | 85.0 | <0.0001 |
| Procedure time | 160.4±89.6 | 143.8±81.9 | 201.5±94.4 | <0.0001 |
| Contrast volume | 230.8±105.9 | 224.7±104.5 | 245.8±108.0 | <0.0001 |
| In hospital death, % | 0.2 | 0.2 | 0.4 | 0.362 |
| MI, % | 1.2 | 0.8 | 2.0 | 0.018 |
| Acute stent thrombosis, % | 0.2 | 0.2 | 0.1 | 1.000 |
| Stroke, % | 0.2 | 0.2 | 0.3 | 0.628 |
| Emergent CABG, % | 0 | 0 | 0 | |
| Emergent PCI | 0.2 | 0.2 | 0.1 | 1.000 |
| Coronary embolism, % | 0.2 | 0.1 | 0.6 | 0.06 |
| Coronary perforation (tamponade), % | 0.4 | 0.2 | 0.9 | <0.0001 |
| Complications of puncture site, % | 1.3 | 1.2 | 1.4 | 0.844 |
| CIN, % | 1.7 | 1.2 | 3.1 | 0.031 |

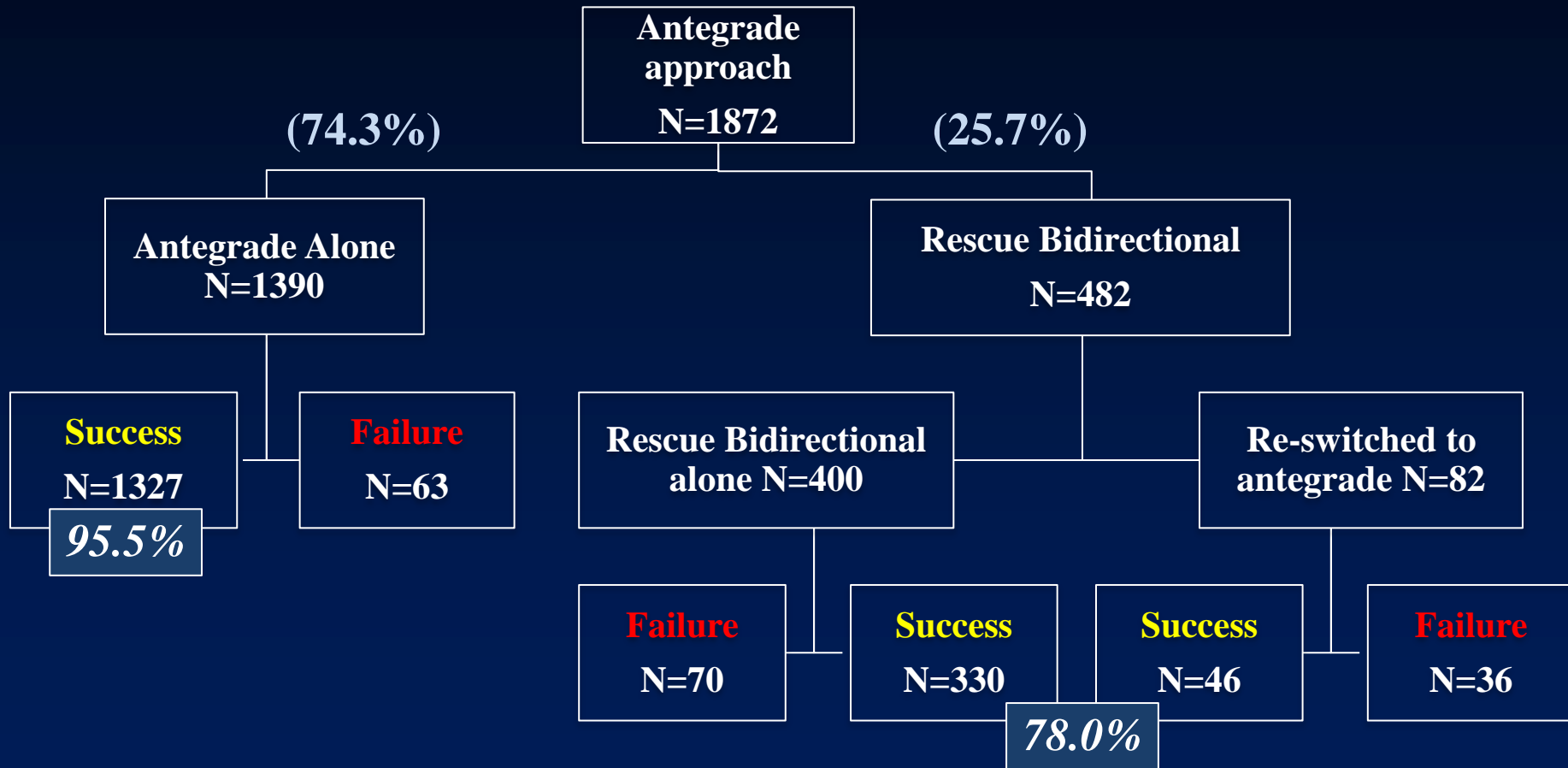
Primary Antegrade



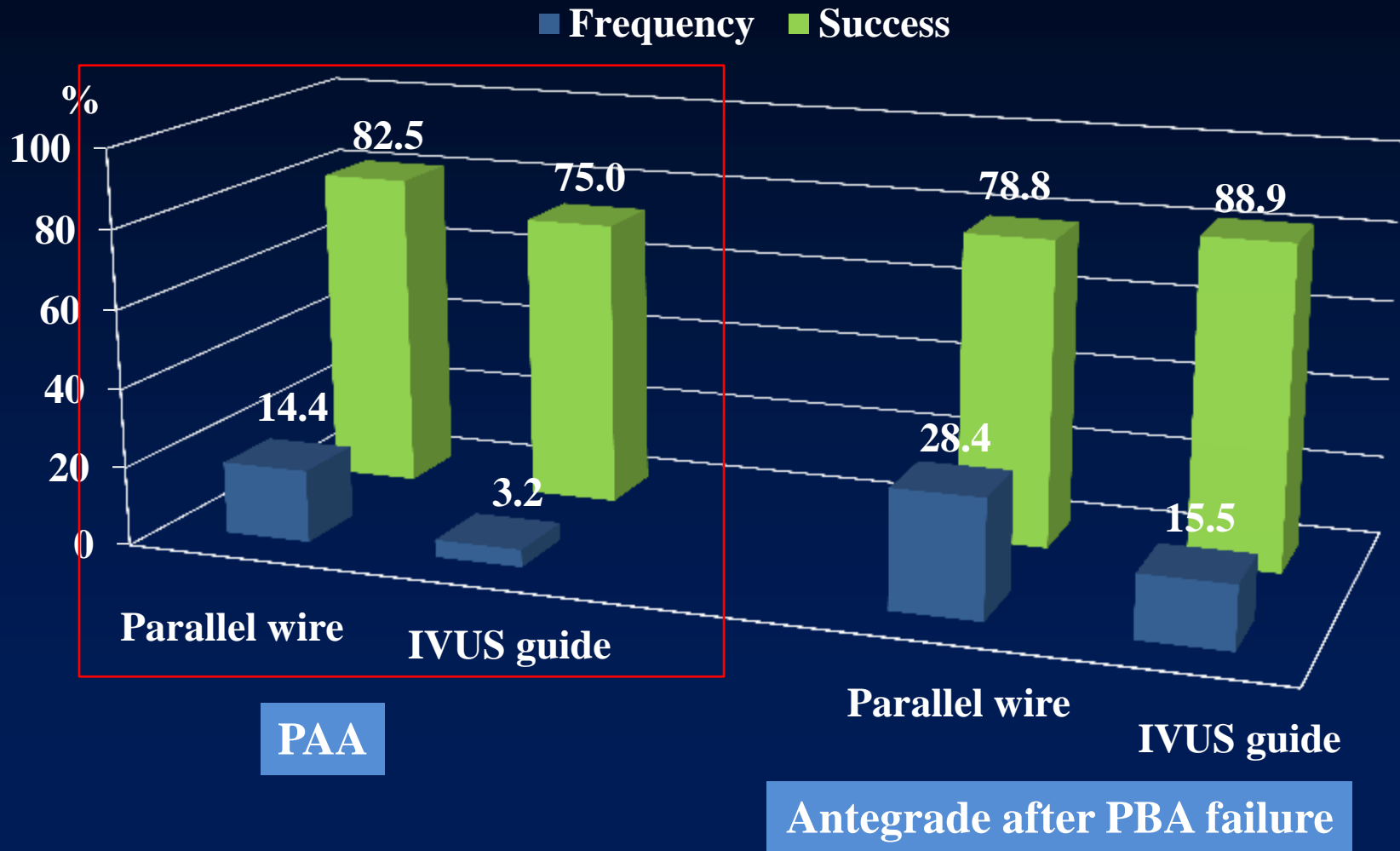
| | Antegrade alone | RBA | Ant vs. RBA |
|--------------------|-----------------|-----------|-------------|
| | N=1390 | N=482 | P-value |
| Age | 67.1±11.0 | 66.2±10.8 | 0.171 |
| BMI | 24.6±3.7 | 24.8±3.9 | 0.370 |
| LVEF | 55.0±13.0 | 54.6±12.8 | 0.434 |
| eGFR | 64.5±30.8 | 66.6±28.4 | 0.277 |
| Male gender, % | 84.1 | 88.2 | 0.031 |
| Hypertension, % | 77.6 | 78.0 | 0.784 |
| Dyslipidemia, % | 75.2 | 77.8 | 0.166 |
| Diabetes, % | 44.7 | 44.5 | 0.434 |
| Current smoking, % | 51.9 | 57.1 | 0.137 |
| OMI, % | 49.7 | 55.0 | 0.120 |
| Prior CABG, % | 6.6 | 9.6 | 0.096 |
| Prior PCI, % | 59.9 | 65.5 | 0.025 |
| Syntax score | 16.1±8.5 | 15.8±8.1 | 0.797 |
| J-CTO score | 1.7±1.1 | 2.2±1.1 | <0.0001 |
| Target vessel, % | | | <0.0001 |
| LAD | 33.9 | 29.9 | |
| LCX | 22.9 | 13.3 | |
| LMT | 0.6 | 0.4 | |
| RCA | 42.6 | 56.4 | |

| | Antegrade alone | RBA | Ant vs. RBA |
|---------------------------------------|------------------------|------------|--------------------|
| | N=1390 | N=482 | P-value |
| Reattempt, % | 12.7 | 22.2 | <0.0001 |
| In-stent occlusion, % | 20.2 | 7.3 | <0.0001 |
| Distal run off (<3.0mm), % | 64.2 | 65.1 | 0.762 |
| CTO length (≥20mm), % | 53.5 | 67.2 | <0.0001 |
| Side branch at proximal cap, % | 35.5 | 33.0 | 0.325 |
| Collateral filling, % | | | <0.0001 |
| Contralateral | 46.6 | 50.4 | |
| Ipsilateral | 18.4 | 8.9 | |
| Both | 33.8 | 40.5 | |
| None | 1.2 | 0.2 | |
| Lesion calcification, % | 48.8 | 55.4 | 0.013 |
| Proximal tortuosity, % | 49.2 | 49.0 | 0.836 |
| Tortuosity of CTO lesion, % | 18.7 | 29.9 | <0.0001 |
| Morphology of proximal cap, % | | | 0.008 |
| Blunt | 24.6 | 20.7 | |
| No stump | 16.0 | 22.6 | |
| Tapered/tunnel | 59.1 | 56.2 | |

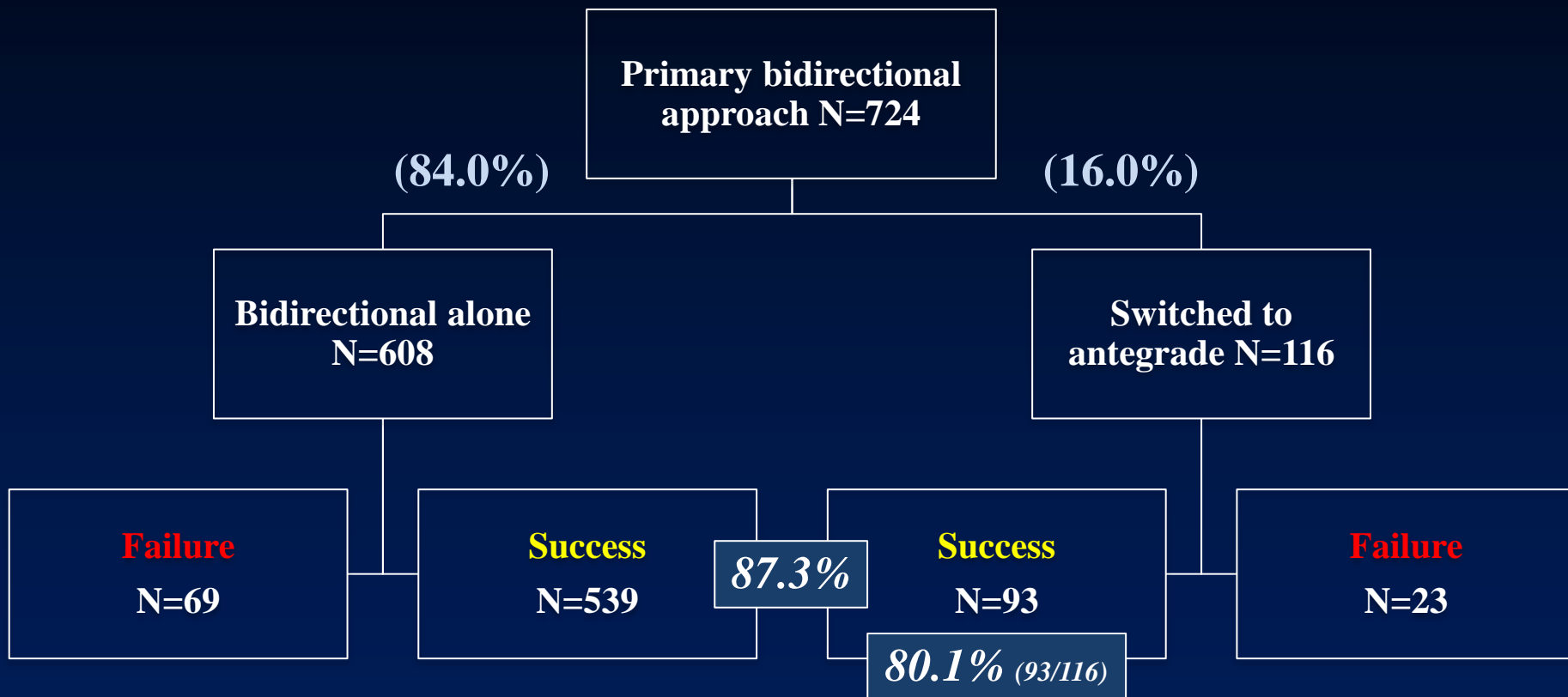
Primary Antegrade



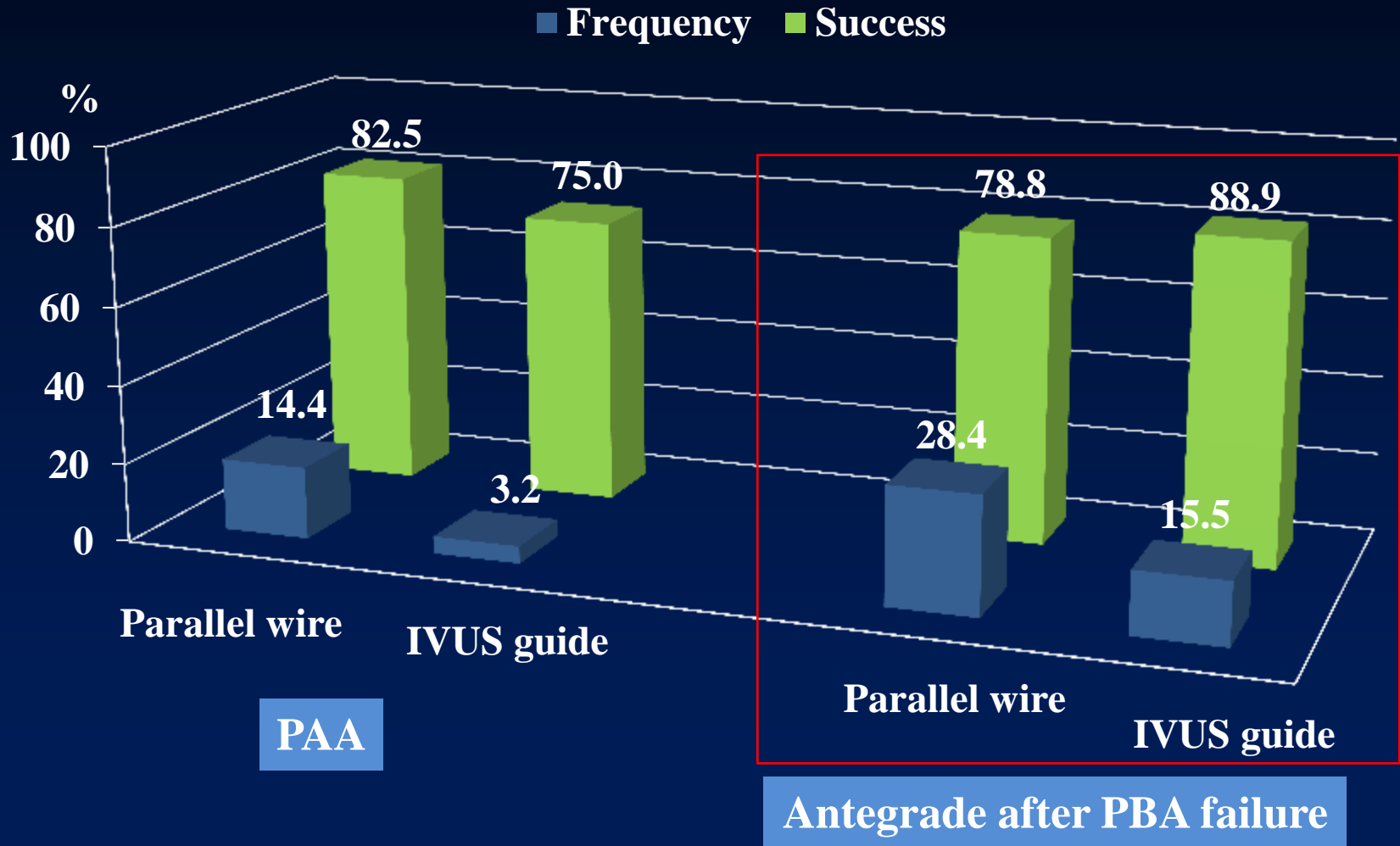
Parallel Wiring and IVUS Guidance



Primary Bidirectional



Parallel Wiring and IVUS Guidance



| | RBA | PBA | RBA vs. PBA |
|--------------------|-----------|-----------|-------------|
| | N=482 | N=724 | P-value |
| Age | 66.2±10.8 | 66.9±10.7 | 0.289 |
| BMI | 24.8±3.9 | 24.6±3.8 | 0.227 |
| LVEF | 54.6±12.8 | 54.6±12.9 | 0.982 |
| eGFR | 66.6±28.4 | 64.3±25.7 | 0.286 |
| Male gender, % | 88.2 | 88.4 | 0.927 |
| Hypertension, % | 78.0 | 80.5 | 0.449 |
| Dyslipidemia, % | 77.8 | 81.9 | 0.175 |
| Diabetes, % | 44.5 | 45.5 | 0.906 |
| Current smoking, % | 57.1 | 57.4 | 0.915 |
| OMI, % | 55.0 | 50.8 | 0.320 |
| Prior CABG, % | 9.6 | 9.4 | 0.972 |
| Prior PCI, % | 66.5 | 67.2 | 0.948 |
| Syntax score | 15.8±8.1 | 15.6±8.9 | 0.182 |
| J-CTO score | 2.2±1.1 | 2.4±1.1 | 0.001 |
| Target vessel, % | | | 0.007 |
| LAD | 29.9 | 25.7 | |
| LCX | 13.3 | 8.6 | |
| LMT | 0.4 | 0.5 | |
| RCA | 56.4 | 65.2 | |

| | RBA | PBA | RBA vs. PBA |
|---------------------------------------|------------|------------|--------------------|
| | N=482 | N=724 | P-value |
| Reattempt, % | 22.2 | 34.8 | <0.0001 |
| In-stent occlusion, % | 7.3 | 5.1 | 0.137 |
| Distal run off (<3.0mm), % | 65.1 | 66.4 | 0.793 |
| CTO length (≥20mm), % | 67.2 | 69.6 | 0.729 |
| Side branch at proximal cap, % | 33.0 | 32.0 | 0.754 |
| Lesion calcification, % | 55.4 | 56.9 | 0.635 |
| Proximal tortuosity, % | 49.0 | 49.3 | 0.401 |
| Tortuosity of CTO lesion, % | 29.9 | 32.5 | 0.644 |
| Morphology of proximal cap, % | | | 0.303 |
| Blunt | 20.7 | 23.9 | |
| No stump | 22.6 | 22.7 | |
| Tapered/tunnel | 56.2 | 52.3 | |
| Collateral used, % | | | 0.801 |
| Sepal | 66.3 | 69.0 | |
| Epicardial | 24.7 | 23.4 | |
| Arterial | 6.4 | 5.2 | |
| Graft | 2.7 | 2.4 | |

| | RBA | PBA | RBA vs. PBA |
|--|-------------|-------------|--------------------|
| | N=482 | N=724 | P-value |
| Failed collateral crossing, % | 20.2 | 16.0 | 0.062 |
| GW success, % | 80.3 | 90.1 | <0.0001 |
| Technical success, % | 78.0 | 87.3 | <0.0001 |
| Procedural success, % | 76.5 | 85.0 | <0.0001 |
| Procedure time | 218.0±79.8 | 201.5±94.4 | <0.0001 |
| Contrast volume | 279.5±123.9 | 245.8±108.0 | <0.0001 |
| In hospital death, % | 0 | 0.4 | 0.296 |
| MI, % | 1.4 | 2.0 | 0.688 |
| Acute stent thrombosis, % | 0 | 0.1 | 1.000 |
| Stroke, % | 0.7 | 0.3 | 0.370 |
| Emergent CABG, % | 0 | 0 | |
| Emergent PCI | 0.2 | 0.1 | 1.000 |
| Coronary embolism, % | 0 | 0.6 | 0.171 |
| Coronary perforation (tamponade), % | 0.4 | 0.9 | 0.295 |
| Complications of puncture site, % | 1.2 | 1.4 | 0.796 |
| CIN, % | 2.4 | 3.1 | 0.72 |

Predictors of Failure in PBA

| PBA | | | |
|-----------------------------|-------|-------------|---------|
| Univariate analysis | | | |
| | OR | CI | P-value |
| Prior CABG | 1.87 | 1.024-3.416 | 0.042 |
| Dyslipidemia | 0.565 | 0.349-0.915 | 0.02 |
| Side branch at proximal cap | 2.086 | 1.373-3.167 | 0.001 |
| Tortuosity of CTO | 1.813 | 1.191-2.760 | 0.006 |
| Severe lesion calcification | 2.876 | 1.622-5.101 | <0.0001 |
| | | | |
| | | | |
| | | | |
| multivariate analysis | | | |
| | OR | CI | p-value |
| Severe lesion calcification | 3.264 | 1.739-6.125 | <0.0001 |
| Tortuosity of CTO | 1.699 | 1.075-2.686 | 0.023 |
| Side branch at proximal cap | 2.399 | 1.524-3.776 | <0.0001 |
| Dyslipidemia | 0.535 | 0.322-0.889 | 0.016 |

Predictors of Failure in RBA

| RBA | | | |
|-----------------------------|-------|-------------|---------|
| Univariate analysis | | | |
| | OR | CI | P-value |
| Sex | 0.328 | 0.180-0.598 | <0.001 |
| BMI | 1.604 | 1.024-2.511 | 0.039 |
| Diabetes | 1.720 | 1.097-2.698 | 0.018 |
| eGFR<60 | 0.630 | 0.401-0.988 | 0.044 |
| In-stent occlusion | 2.780 | 1.329-5.814 | 0.007 |
| Lesion>20mm | 1.722 | 1.039-2.855 | 0.035 |
| Tortuosity of CTO | 1.734 | 1.087-2.765 | 0.021 |
| Severe lesion calcification | 4.242 | 2.074-8.677 | <0.0001 |
| multivariate analysis | | | |
| | OR | CI | p-value |
| Severe lesion calcification | 2.711 | 1.188-6.185 | 0.018 |
| Sex | 0.302 | 0.155-0.590 | <0.0001 |
| BMI | 1.807 | 1.084-3.012 | 0.023 |
| | | | |

Summary

- Japanese experts frequently chose the bidirectional approach as the primary strategy (27.9%), especially for more complex CTO lesions, with a technical success rate of about 90%.
- For intermediate CTO lesions (J-CTO score < 2), experts mainly performed the antegrade approach alone, with a very high success rate (more than 95%).
- However, for RBA, the success rate decreased to less than 80%.
- The experts frequently used the parallel wiring and IVUS-guided penetration in antegrade approach, with high technical success (75.0%–88.9%).
- Severe lesion calcification was a strong predictor of failure.

Conclusion

CTO-PCI performed by highly experienced experts achieved a high technical success rate and a low rate of major complications.

18th CTO Club



June 2-3, 2017, Nagoya, Japan

www.cct.gr.jp/ctoclub