



Interventional Cardiology Update

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APCTO club

What are the changes to Interventional Cardiology?

- Absorbable Scaffolds.
- Transcatheter Aortic Valve replacement (TAVI).
- Left Atrial Appendage Occluders (LAAO).
- Mitraclip.
- CTO Algorithms.

Absorbable Scaffolds

- Stents carry a 0.3% per year thrombosis rate. Implication for future bleeding episode or surgery.
- Long stents can fracture after time.
- If you have restenosis inside a stent, then putting layer upon layer of stents can increase risk of stent fracture and restenosis.
- Coronary artery disease is occurring in younger and younger patients and the disease is more and more extensive.

BVS.

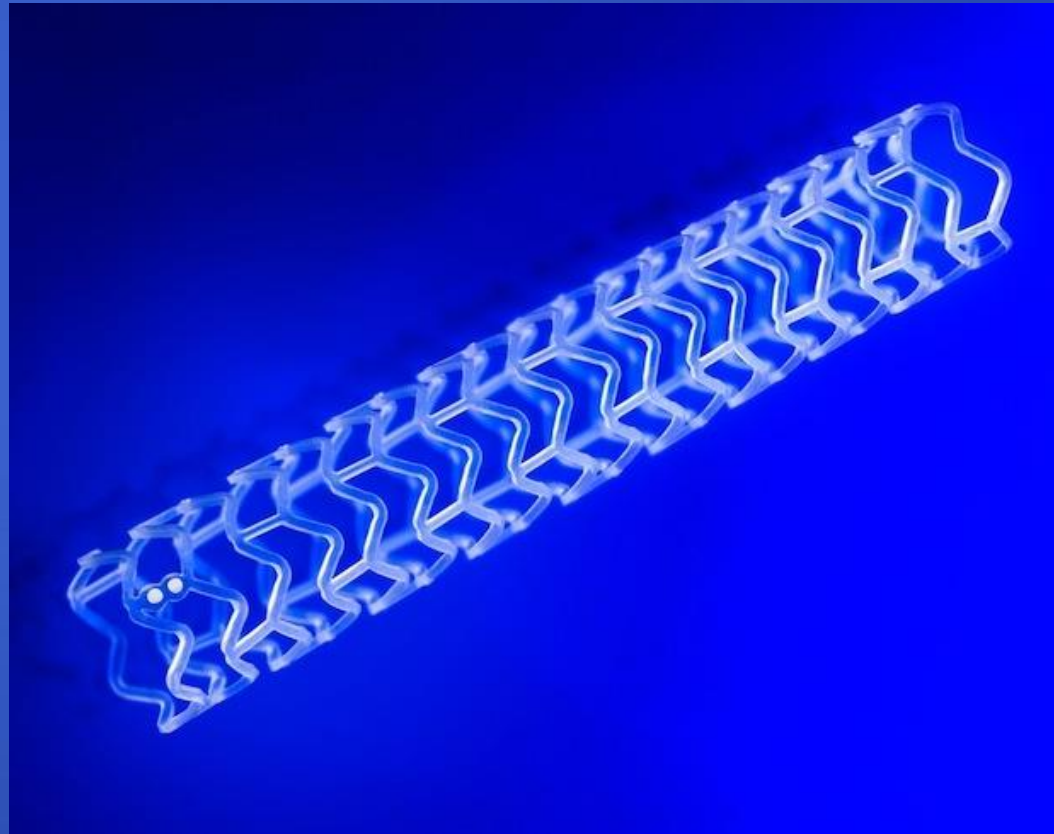
Same Efficacy as Drug eluting Stents

Maybe slightly increased risk of Thrombosis.

But after 3 years complete absorbed Scaffold.

In theory no long term stent thrombosis risks.

Less deliverable and less robust.



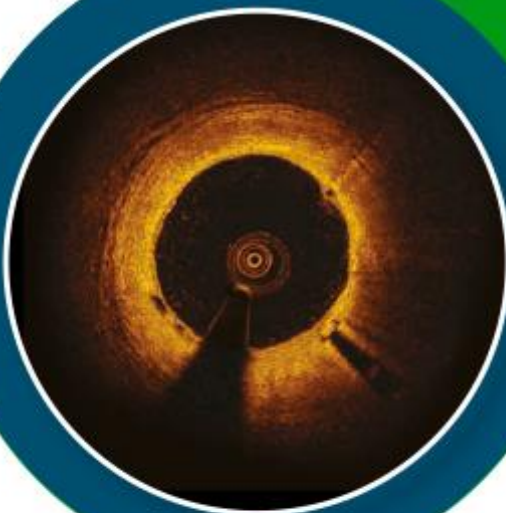
BASELINE⁶



6 MONTHS⁶



2 YEARS⁶



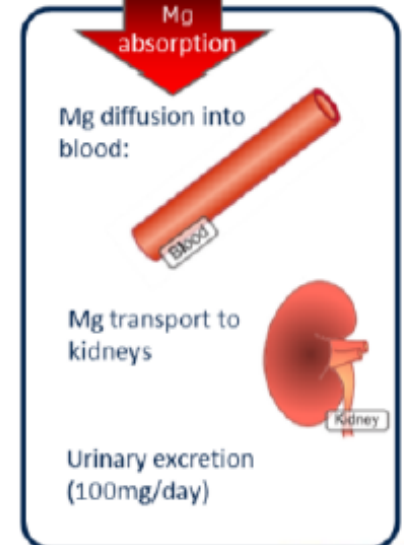
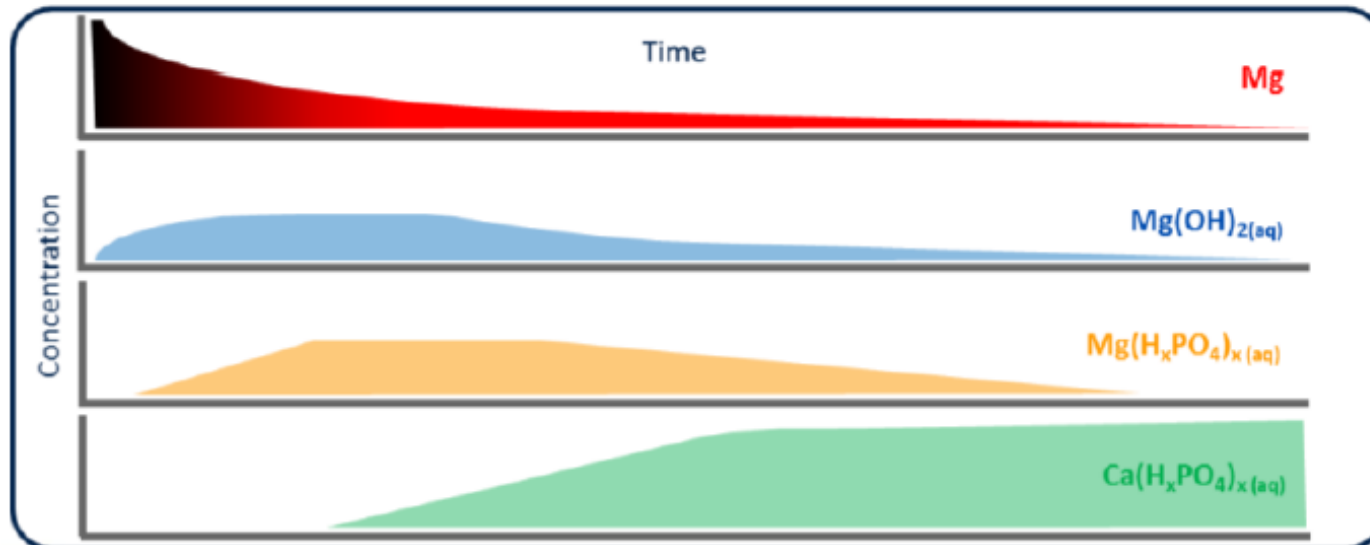
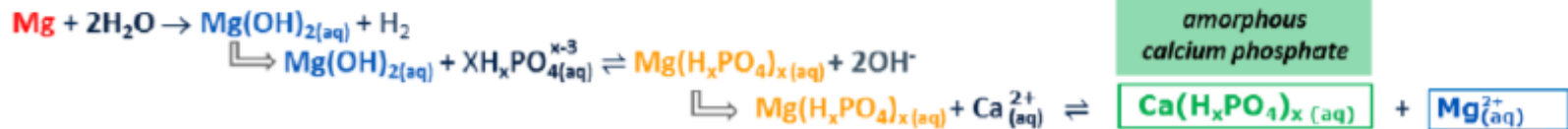
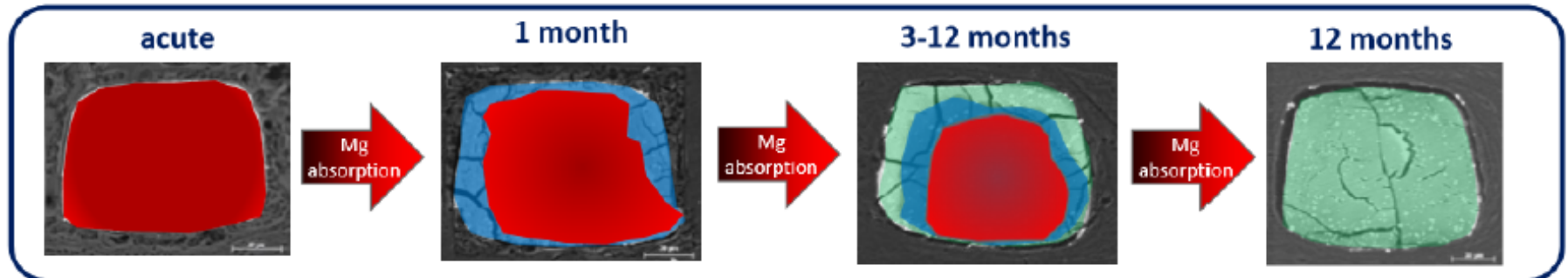
Use of BVS

- Young patients (age < 70).
- Bifurcation – especially two scaffold.
- Patients who may need surgery in 3-4 years or more.
- ISR? Need data.
- Easier lesions.



Biotronik Magnesium Scaffold

Magnesium Absorption Process



Background

Evolution of the BIOTRONIK Magnesium Scaffold

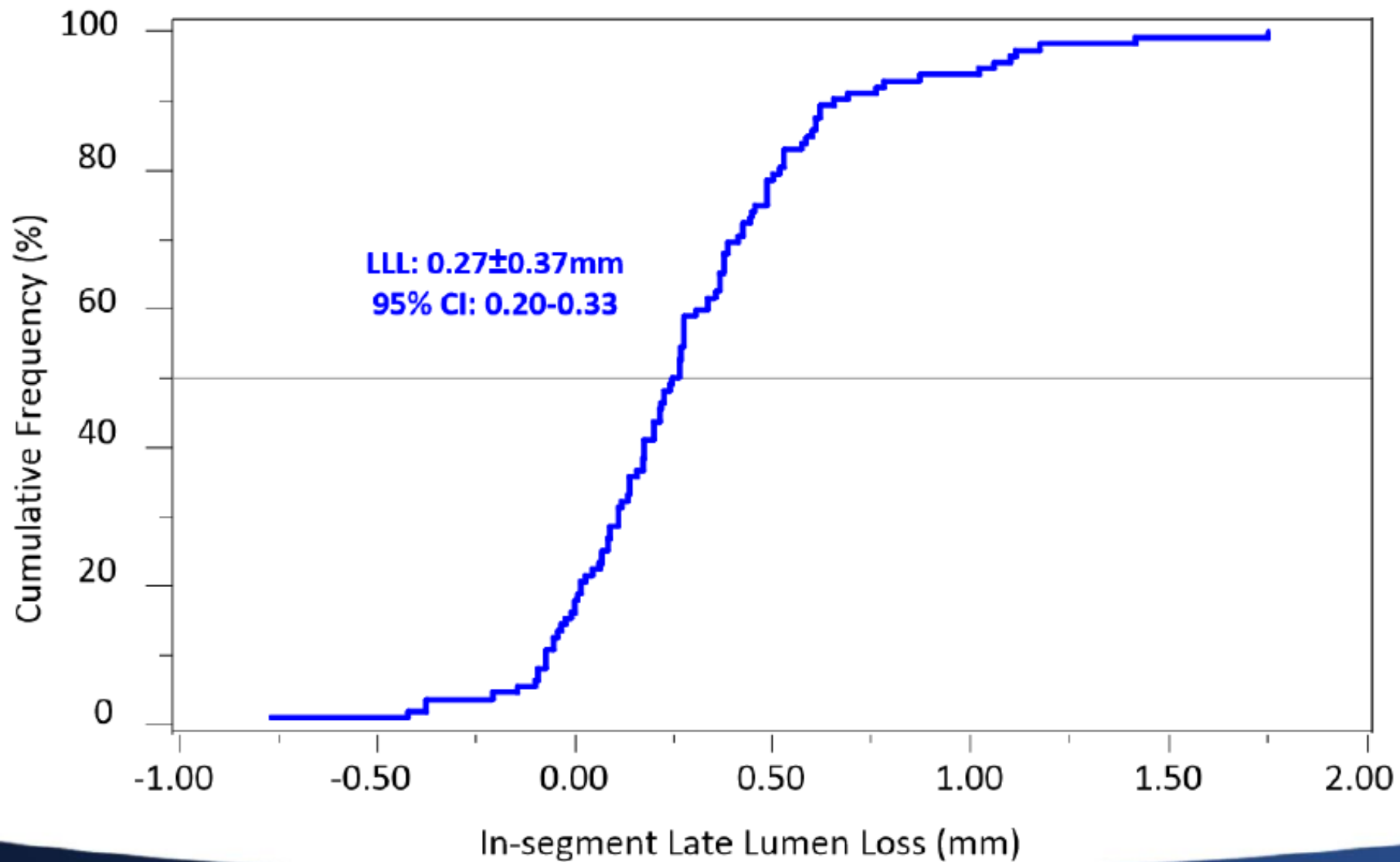


| | Device generation | DREAMS 2G |
|----------|--|---|
| Design | Sizes (mm) | ∅ 2.5, 3.0 & 3.5 Length: 15, 20, 25 |
| | Backbone | Refined Mg alloy |
| | Strut thickness/width | 120/120 μm (∅ 2.5) 150/150 μm (∅ 3.0 & 3.5) |
| | Markers | Ta-composite |
| | Coating - drug | PLLA/SIR |
| | Crossing profile in mm | 1.75 |
| Kinetics | Drug elution kinetics | like Orsiro |
| | Absorption period in month | ≈12 (Mg) |
| Results | In-segment Late Lumen Loss (mm) | 0.27±0.37 |
| | In-scaffold Late Lumen Loss (mm) | 0.44±0.36 |
| | TLF* (%) | 3.3 |
| | Definite or Probable Scaffold Thrombosis (%) | 0.0 |

*Composite of cardiac death, target vessel myocardial infarction, clinically driven target lesion revascularization and CABG

Primary Endpoint

In-segment Late Lumen Loss at 6-month



Dreams

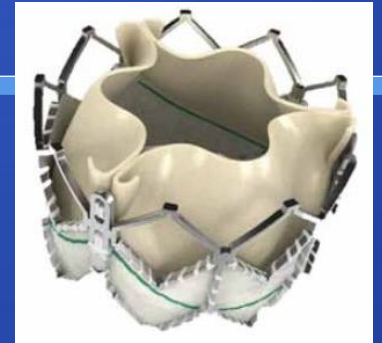
- Faster reabsorption 12 months.
- Better performance.
- Late loss similar to Drug eluting stents.

The future.

- Scaffolds are not going to answer all the problems of coronary artery disease intervention. BUT
- Absorbable scaffolds will dominate the market.
- Multiple companies will produce multiple products.
- Gradual increase of use in different subgroups e.g. CTO.



TAVI



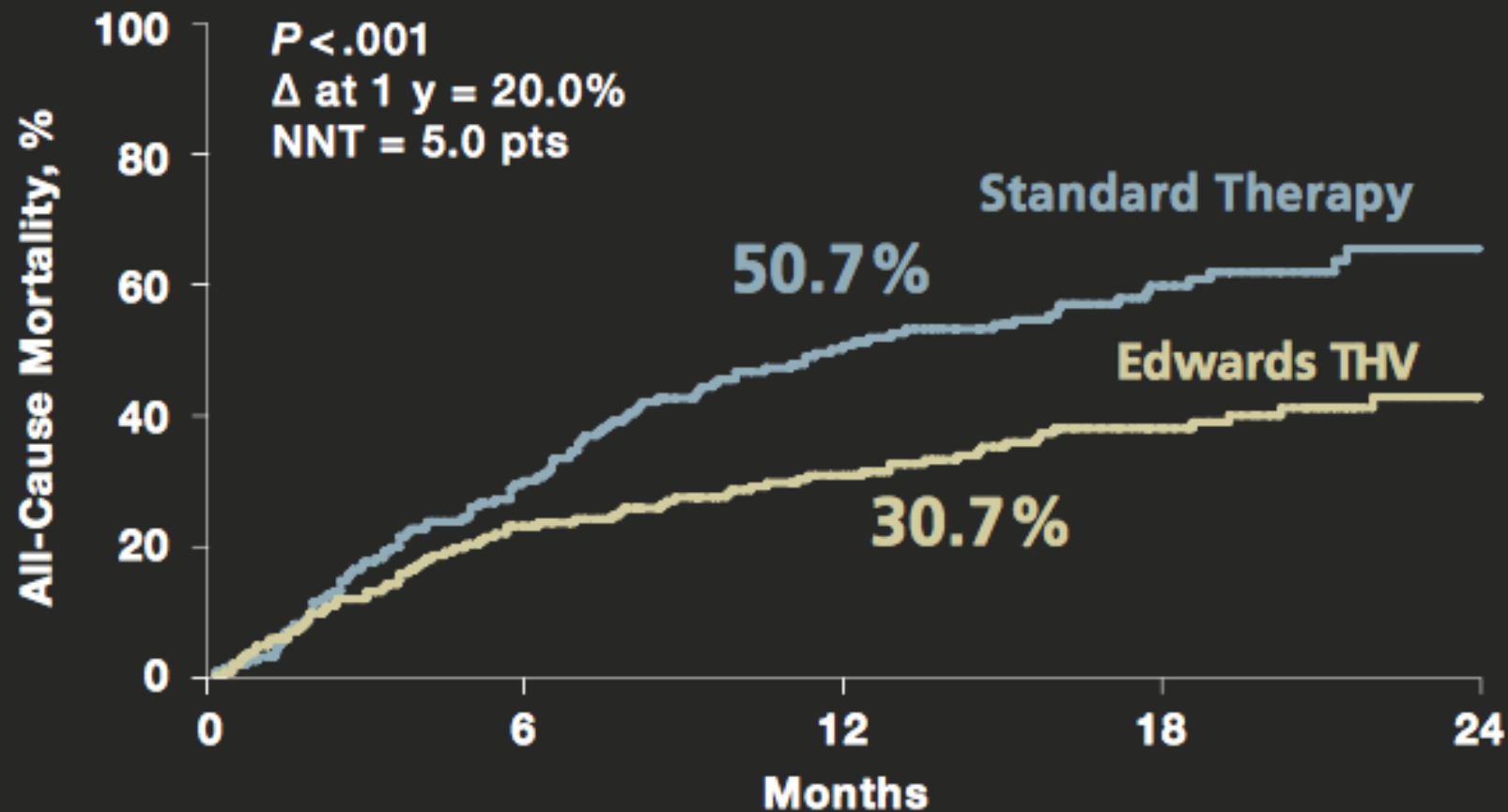
Severe Aortic Stenosis

- Many patients are too old, too frail, too high surgical risk to undergo surgical AVR.
- Many patients in Asia refuse surgical AVR.
- These patients do badly when treated medically.
- Percutaneous minimally invasive aortic valve replacement would benefit these cases.
- There are now many of such valves with good data to support its use.

TAVI vs Medical therapy

- For inoperable patients.

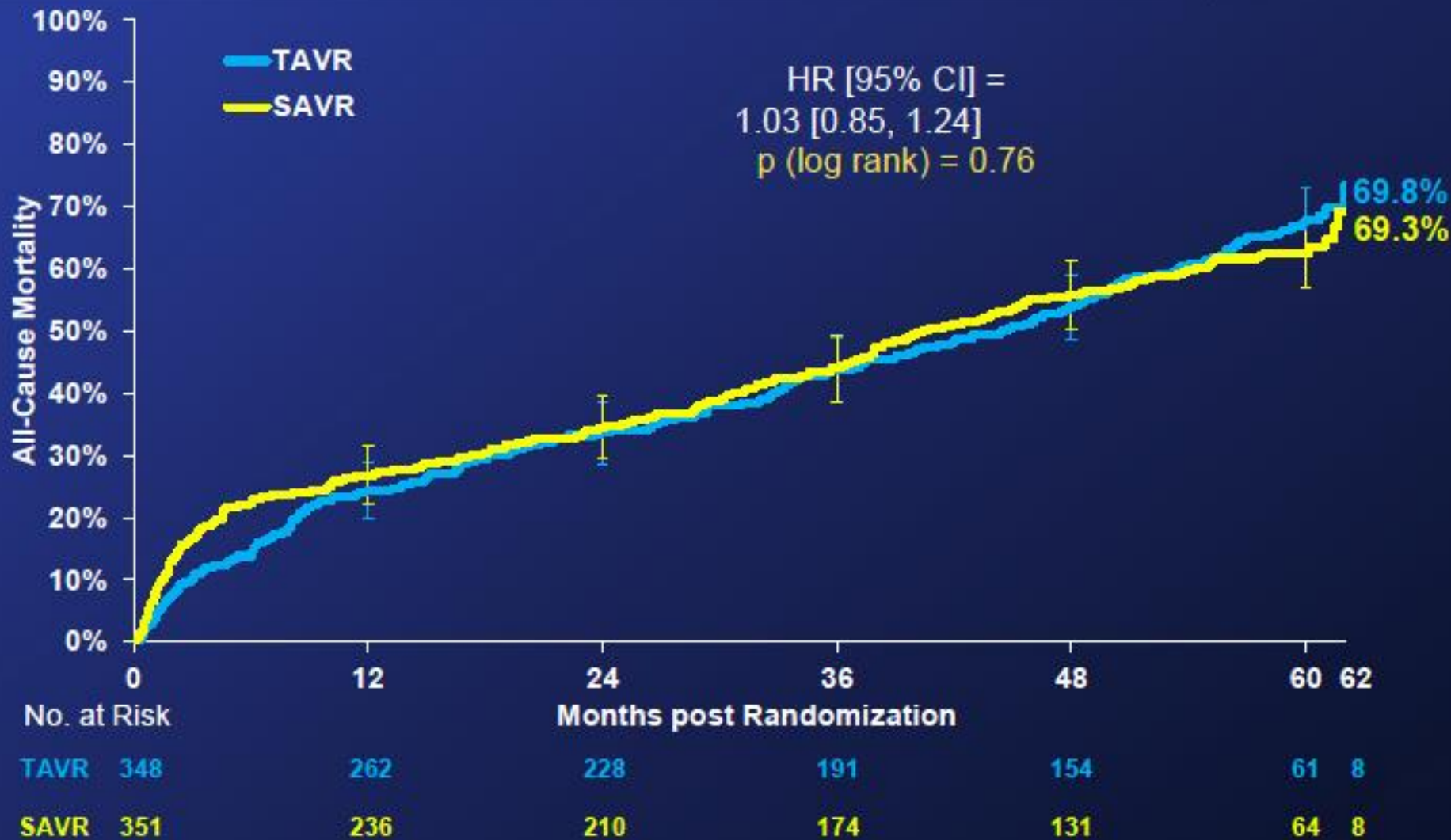
CO-PRIMARY ENDPOINT: ALL-CAUSE MORTALITY^{4,5}



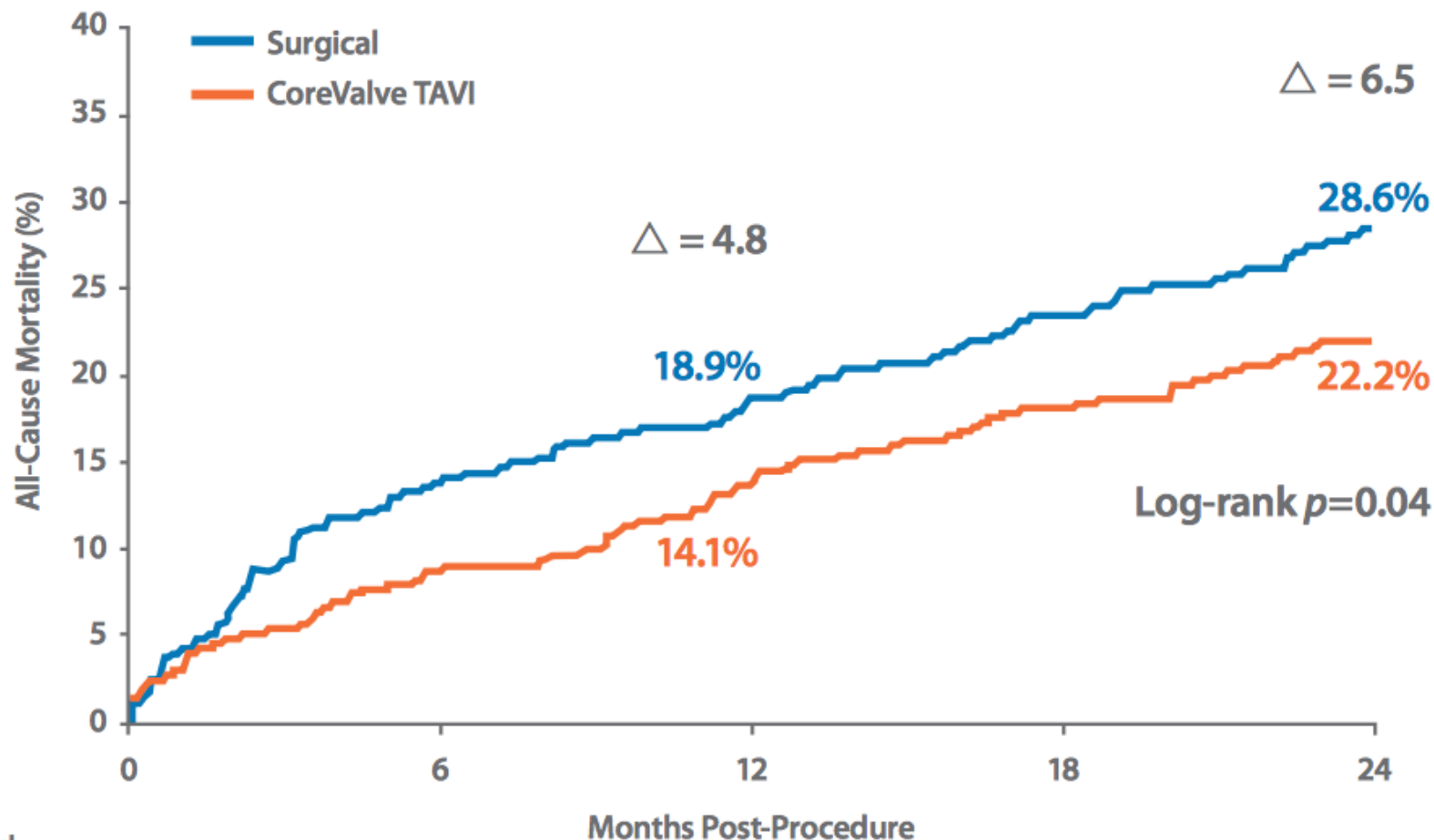
TAVI vs Surgical AVR

- For High risk OT patients.

All-Cause Mortality (ITT) Pooled Approaches



CoreValve® US PIVOTAL TRIAL | All-Cause Mortality



No. at Risk

Transcatheter
Surgical

391
359

378
343

354
304

334
282

219
191

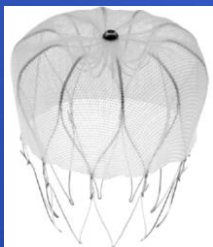
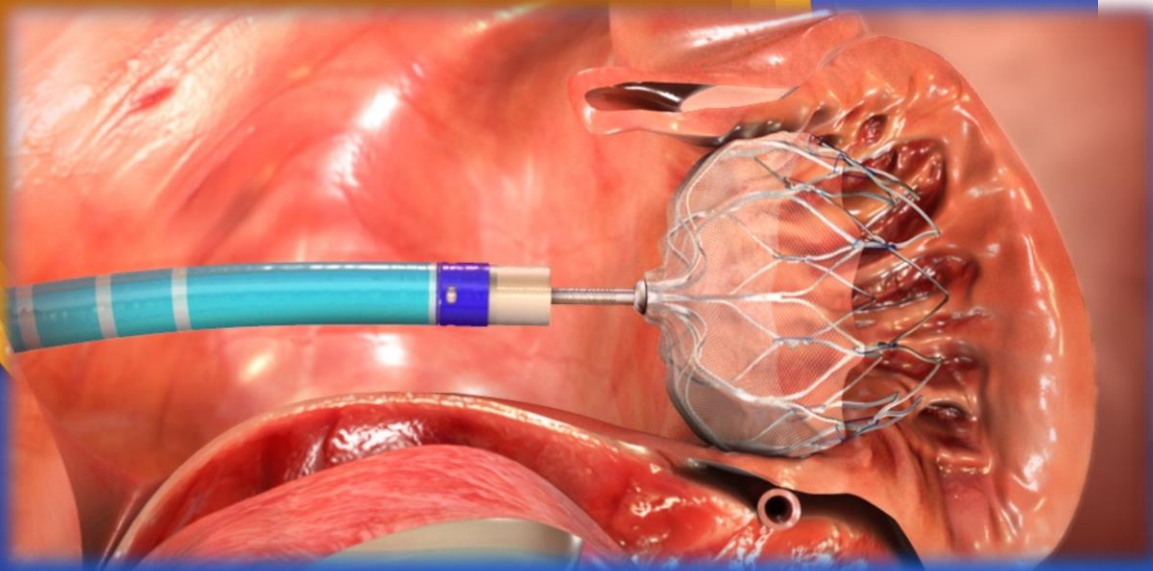
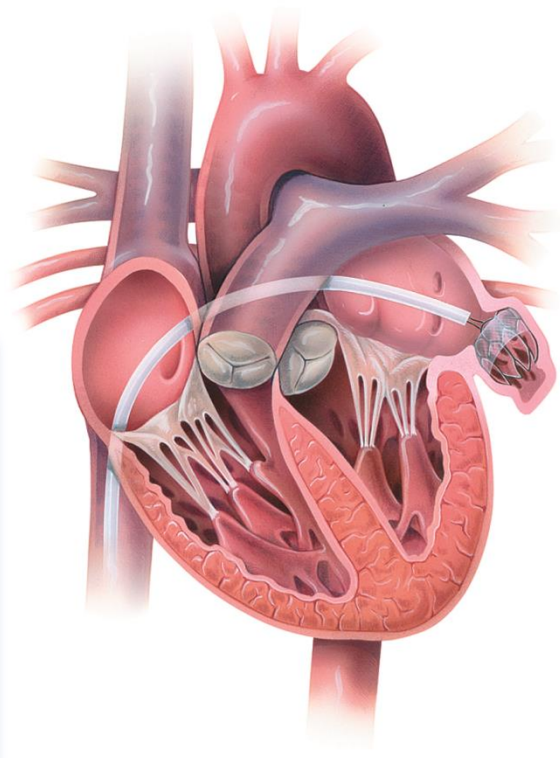
TAVI summary

- Superior Treatment compared to medical therapy in severe AS patients who are inoperable.
- Superior Treatment option compared to surgical AVR in extreme risk patients.
- Superior Treatment option compared to surgical AVR in high risk patients.

Superior treatment

Costs \$260,000 HKD.

左心耳封堵術



AF Stroke prevention

- Many patients taking warfarin for stroke prevention.
- NOAC development.
- But ... still many patients cannot take NOAC/ warfarin due to bleeding – diverticulosis, haemorrhoids, AVM.
- LAAO.

WATCHMAN Clinical History

over 2000 patients with 4800 patients years follow-up

Pilot

- Early feasibility with > 6 years of follow up

n=66

PROTECT-AF

- Superior to warfarin for primary efficacy, CV death, and all-cause mortality at 4 years (1)

n=707

CAP Registry

- Significantly improved safety results. (2)

n=566

ASAP

- Expected rate of stroke reduced by 77% in patients contraindicated to warfarin. (3)

n=150

PREVAIL

- Improved success and procedural safety confirm with new and experienced operators. (4)

n=461

CAP₂

- Currently enrolling up to 750 patients at ~60 sites

N=750

1. Reddy, et al. JAMA.

2014; 312:1988-1998

2. Reddy, et al. Circulation.

2011;123:417-424

3. Reddy, et al. JACC.

2013;61:2551-6

4. Holmes, et al. JACC

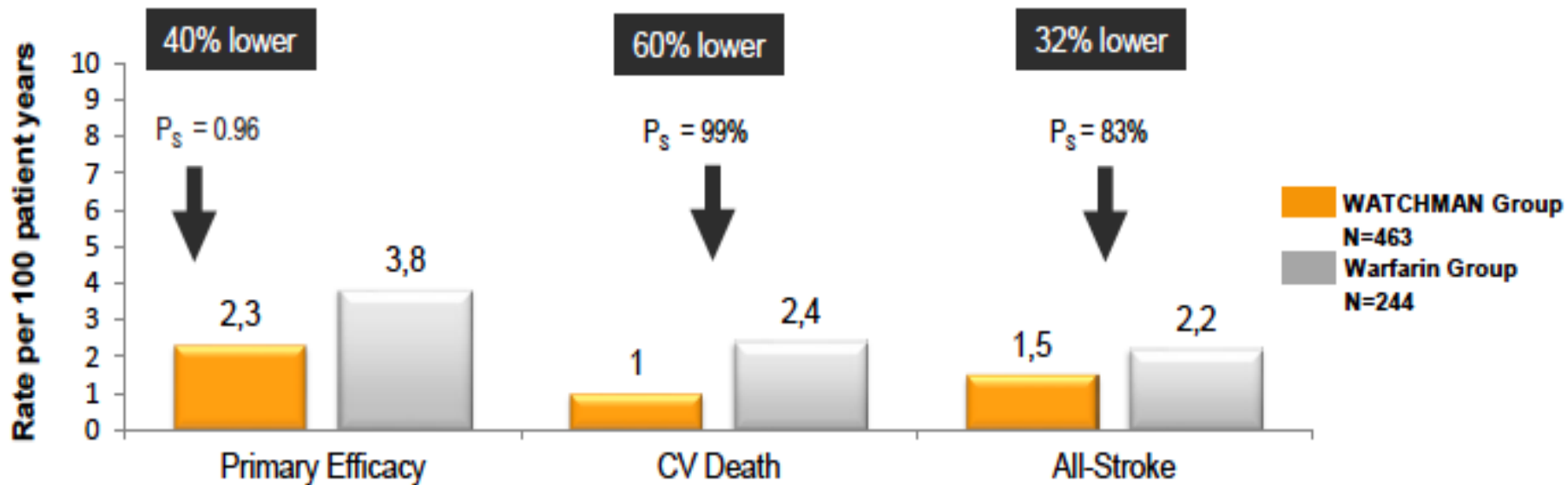
2014;64:1-12

PROTECT AF

RCT, n 707; 4 Yrs.

| | WATCHMAN Observed Rate per 100 pt-yrs | Warfarin Observed Rate per 100 pt-yrs | % Reduction (vs Warfarin) | |
|------------------------|--|--|------------------------------|--------------|
| Primary Endpoint | 2.3 | 3.8 | 40% | SUPERIOR |
| CV Death | 1.0 | 2.4 | 60% | SUPERIOR |
| All-Stroke | 1.5 | 2.2 | 32% | NON-INFERIOR |
| Hemorrhagic Stroke | 0.2 | 1.1 | 85% | SUPERIOR |
| Fatal/Disabling Stroke | 0.5 | 1.2 | 63% | SUPERIOR |

Events in PROTECT AF trial at 2,621 patient years



LAAO summary

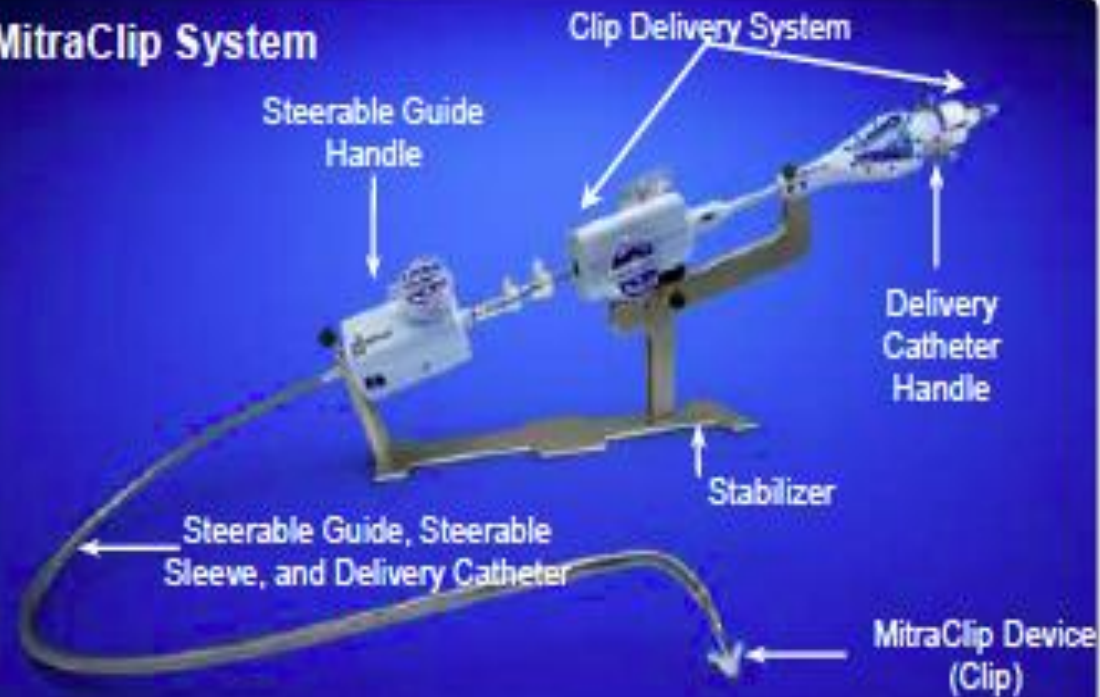
- Superior treatment option compared to warfarin for bleeding risks.
- Non-inferior treatment option compared to warfarin for stroke prevention.
- Superior treatment option compared to warfarin for disabling stroke.
- Superior treatment option compared to warfarin for quality of life.
- Superior treatment option compared to warfarin for CV death.

MitraClip System



MitraClip Device
(Clip)

MitraClip System



Mitraclip

- No option MR patient who is too high risk for OT.
- Aim to improve quality of life.
- Reduction of MR.

European Registries

| Reference | n | Mean Age | LogEuro | Procedure Mortality | 30Day Mortality | MR 1-2+ Pre | MR 1-2+ Post | 1 Year Mortality |
|------------------|------|----------|---------|---------------------|-----------------|-------------|--------------|------------------|
| Auricchio [22] | 51 | 70±9 | 30±19 | 2 % | 4.2 % | 0 | 84 % | 18 % |
| Neuss [25] | 157 | 74±10 | 22±17 | | 7 % | 0 | 100 % | 24 % |
| Grasso [26] | 117 | 72±11 | 13±13 | | 1.1 % | 0 | 100 % | 14 % |
| Surder [27] | 100 | 77±18 | 17±19 | 1 % | 5 % | 0 | 93 % | 20 % |
| Maisano [16] | 567 | 74±10 | 23±18 | 0 | 3.4 % | 2.3 % | 91 % | 17.3 % |
| Schillinger [20] | 1064 | 75 | 23 | 2.8 % | 5.7 % | 4.3 % | 74 % | |

- **51 – 1064 patients**
- **High Logistic EuroSCORE**
- **Low Procedural Mortality**
- **Low 30 day Mortality**
- **Most had reduction of MR to 1-2+**
- **1 year Mortality 14 – 24%**

Safety Outcomes

Site Reported – 30 Days and 12 months

ACCESS-EU Phase I

| Safety Outcomes | 30 Days | | | 12 Months | | |
|------------------------|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | All Patients (N = 567) | FMR Patients (n = 393) | DMR Patients (n = 117) | All Patients (N = 567) | FMR Patients (n = 393) | DMR Patients (n = 117) |
| Death | 3.4% (19/567) | 2.8% (11/393) | 6.0% (7/117) | 17.3% (98/567) | 17.0% (67/393) | 17.1% (20/117) |
| Stroke | 0.7% (4/567) | 0.5% (2/393) | 0.9% (1/117) | 1.1% (6/567) | 1.0% (4/393) | 0.9% (1/117) |
| Myocardial infarction | 0.7% (4/567) | 0.8% (3/393) | 0.9% (1/117) | 1.4% (8/567) | 1.8% (7/393) | 0.9% (1/117) |
| Renal failure | 4.8% (27/567) | 5.1% (20/393) | 2.6% (3/117) | 8.8% (49/567) | 9.4% (37/393) | 6.0% (7/117) |
| Respiratory failure | 0.7% (4/567) | 1.0% (4/393) | 0% (0/117) | 0.9% (5/567) | 1.0% (4/393) | 0.0% (0/117) |
| Need for resuscitation | 1.8% (10/567) | 2.3% (9/393) | 0.9% (1/117) | 2.1% (12/567) | 2.8% (11/393) | 0.9% (1/117) |
| Cardiac tamponade | 1.1% (6/567) | 1.0% (4/393) | 0.9% (1/117) | 1.2% (7/567) | 1.0% (4/393) | 0.9% (1/117) |
| Bleeding complications | 3.9% (22/567) | 3.8% (15/393) | 3.4% (4/117) | 4.8% (27/567) | 4.6% (18/393) | 3.4% (4/117) |

- Low Mortality 30 days – 3.4%, 12 months 17.3%
- Low Complication rates

Mitraclip summary

- V effective therapeutic option for NYHA 4 heart failure patients with severe MR.

CTO

Hybrid

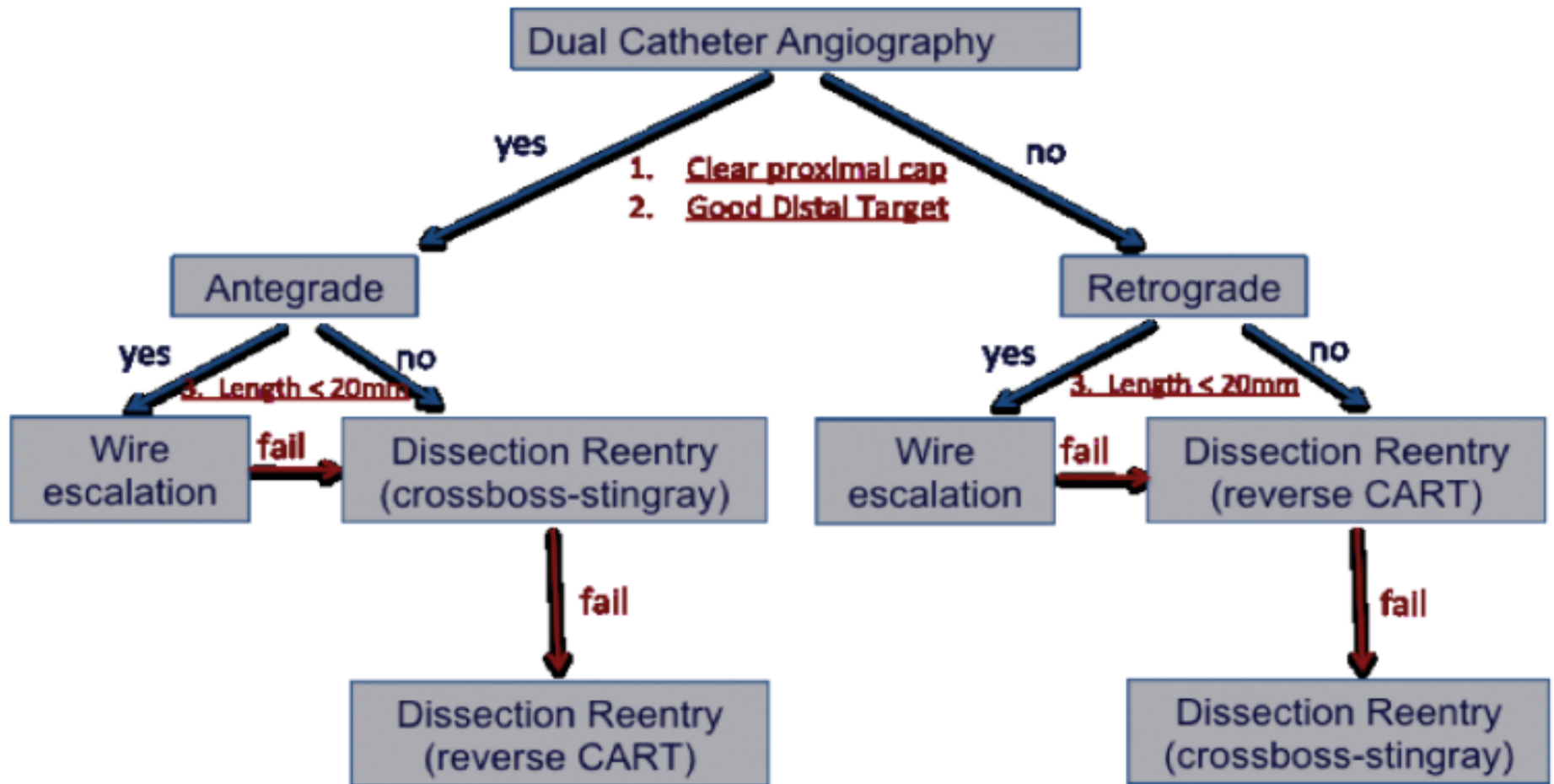


Figure 2. The hybrid algorithm. Reprinted with permission from Grantham JA, Thompson CA. Chronic total occlusion angioplasty: indications appropriateness, and strategy. In: Thompson CA, ed. Textbook of Cardiovascular Intervention. London, UK: Springer-Verlag London; 2014:289–297.

Hybrid Algorithm

Good vs Bad

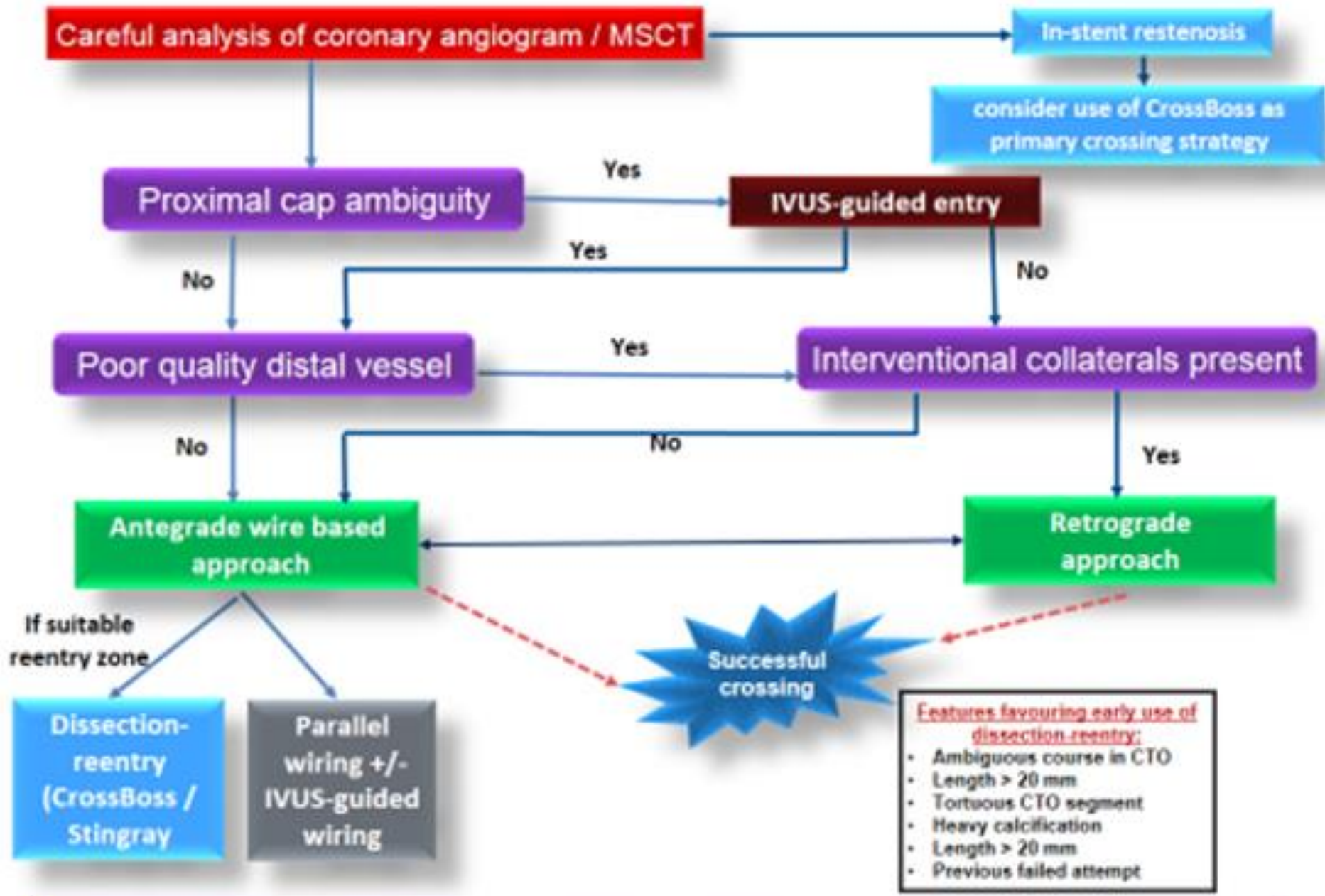
- First systematic algorithm for CTO PCI.
 - Dual injection compulsory.
 - Contrast and radiation limits.
 - Switch method / avoid stuck in failure mode.
 - Crossboss Stingray included.
 - Proctoring style allows trainee to be first operator.
 - Effective proctoring
- Length is main determinant of CTO approach.
 - No IVUS use.
 - Crossboss stingray not available or very expensive in Asian countries and with ADR there is no hybrid algorithm.
 - Overuse of dissection reentry (debate over the quality of CTO PCI).

From Left to Right: Eugene B Wu (Hong Kong); Ge Lei (Shanghai); Jie Qian (Beijing); Scott Harding (New Zealand); Chen Ji Yan (GuangZhou); Sidney Lo (Australia); Etsuo Tsuchikane (Japan); Osamu Katoh (Japan); Soo Teik Lim (Singapore); Paul Kao (Taiwan).

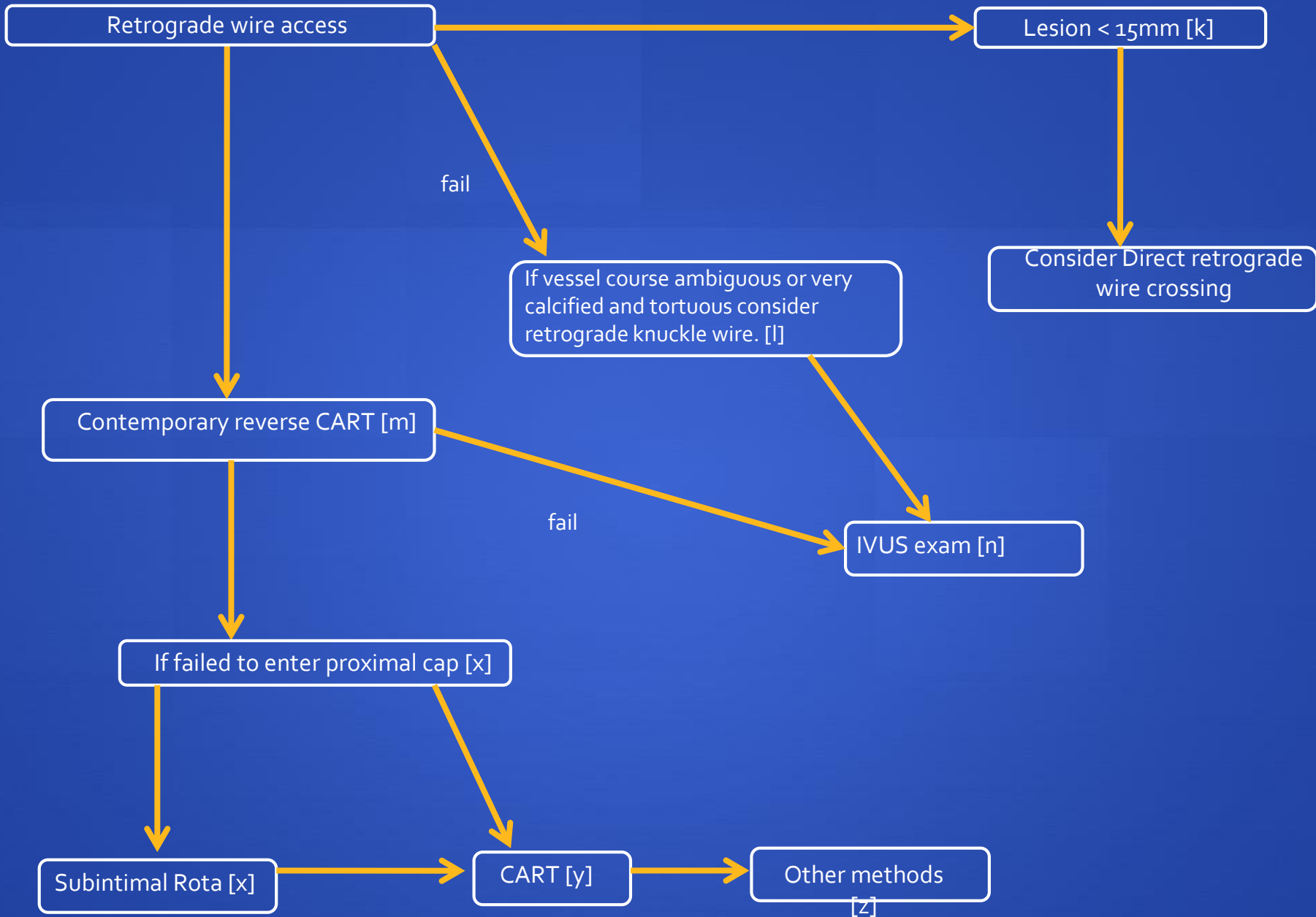
CTO Club

*The 16th Seminar of
Angioplasty of Chronic Total Occlusions*





Consider stopping if > 3 hr; 3.7x eGFR ml contrast; Air Kerma > 5 Gy unless procedure well advanced.



Retrograde wire access

Lesion < 15mm [k]

fail

If vessel course ambiguous or very calcified and tortuous consider retrograde knuckle wire. [l]

Consider Direct retrograde wire crossing

Contemporary reverse CART [m]

fail

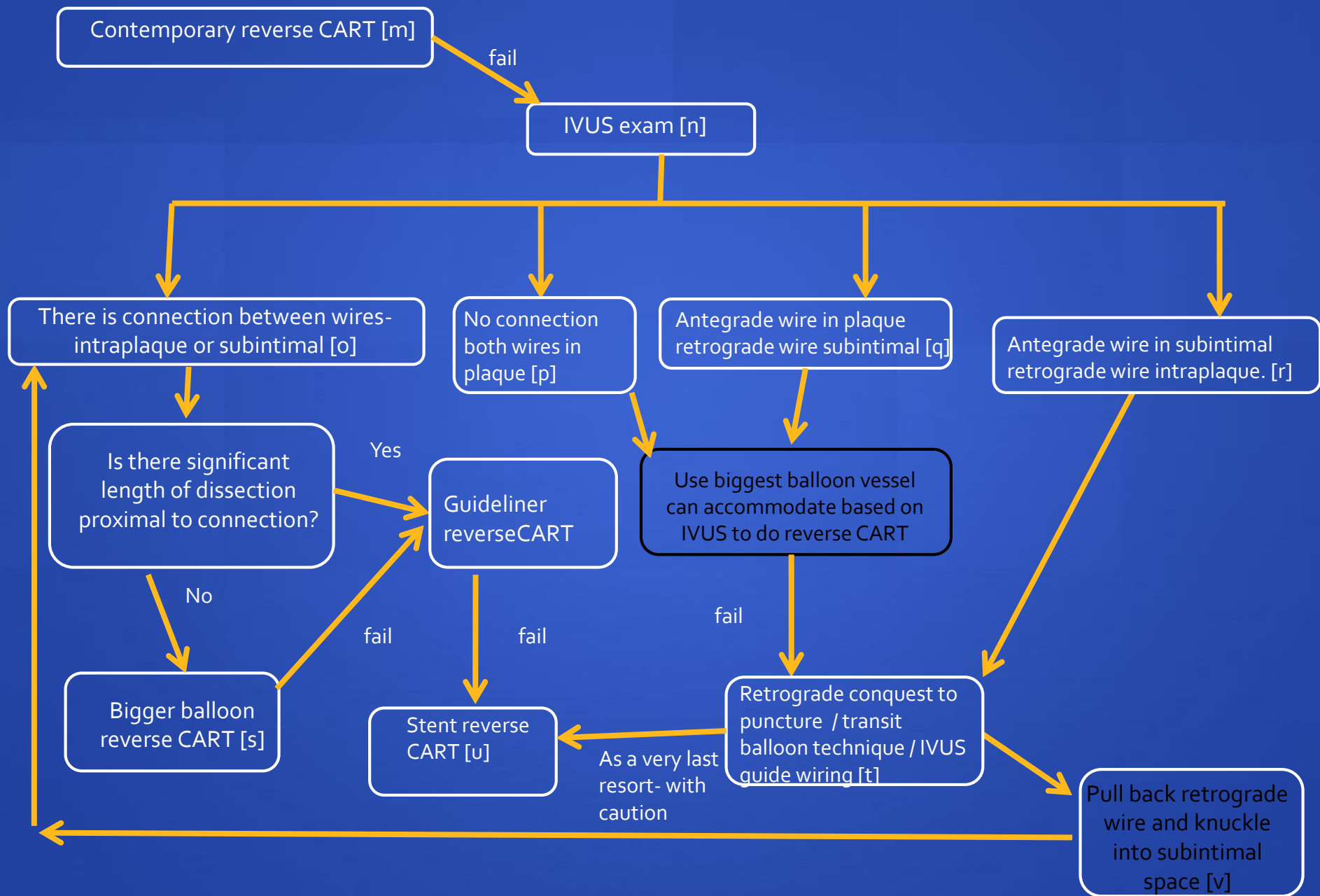
IVUS exam [n]

If failed to enter proximal cap [x]

Subintimal Rota [x]

CART [y]

Other methods [z]



Main difference

- Uses the strengths of Asia style CTO PCI: IVUS, New generation wires, Parallel wiring.
- Incorporates the crossboss stingray methods.
- Highly knowledge based detailed teaching about retrograde channel crossing instead of channel surfing.
- Highly knowledge based detailed teaching about reverse CART.

CTO algorithm

- Method of proctoring.
- Method of improving success rates.
- Registry to follow the impact of such algorithm is underway.

Future of Intervention

- More “off the radar” “forgotten” cases can be treated with structural heart intervention.
- More and more valvular lesions will be treated in such a way -> already first in man percutaneous mitral valve replacements have been done.
- Absorbable dominance of stent world -> already five new absorbable scaffolds are appearing in the market in next year.
- More knowledge based teaching of intervention at the frontier of interventional cardiology.

Thank you
