

Zilver PTX Japan 5-year Results for Paclitaxel-Eluting Stent Treatment of Femoropopliteal Artery Disease

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On behalf of the Investigators

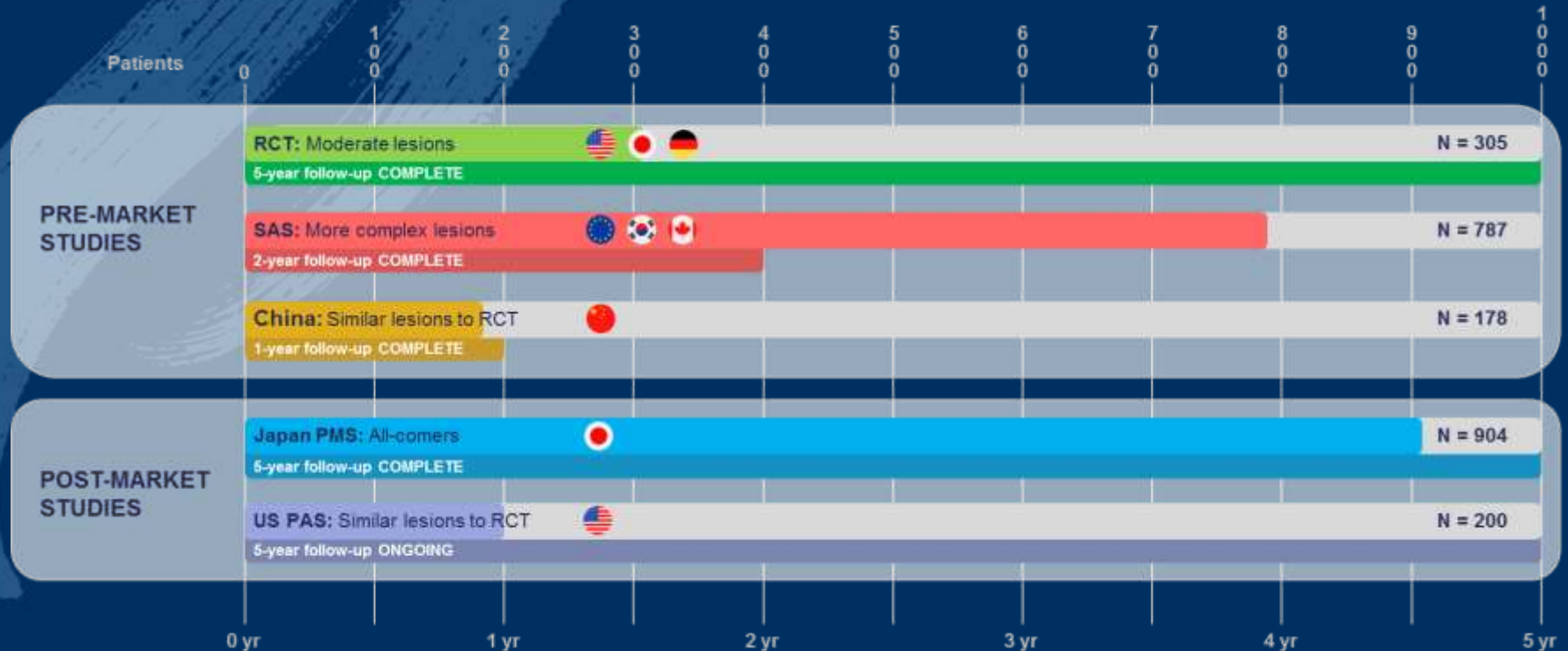
Disclosure

Speaker name: Hiroyoshi Yokoi

I have the following potential conflicts of interest to report:

- Consulting
 - Employment in industry
 - Stockholder of a healthcare company
 - Owner of a healthcare company
 - Other(s): COOK
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- I do not have any potential conflict of interest

Global Clinical Program for Zilver PTX



More than 2400 patients included in current Zilver PTX clinical program

5-year Follow-up for Japan PMS

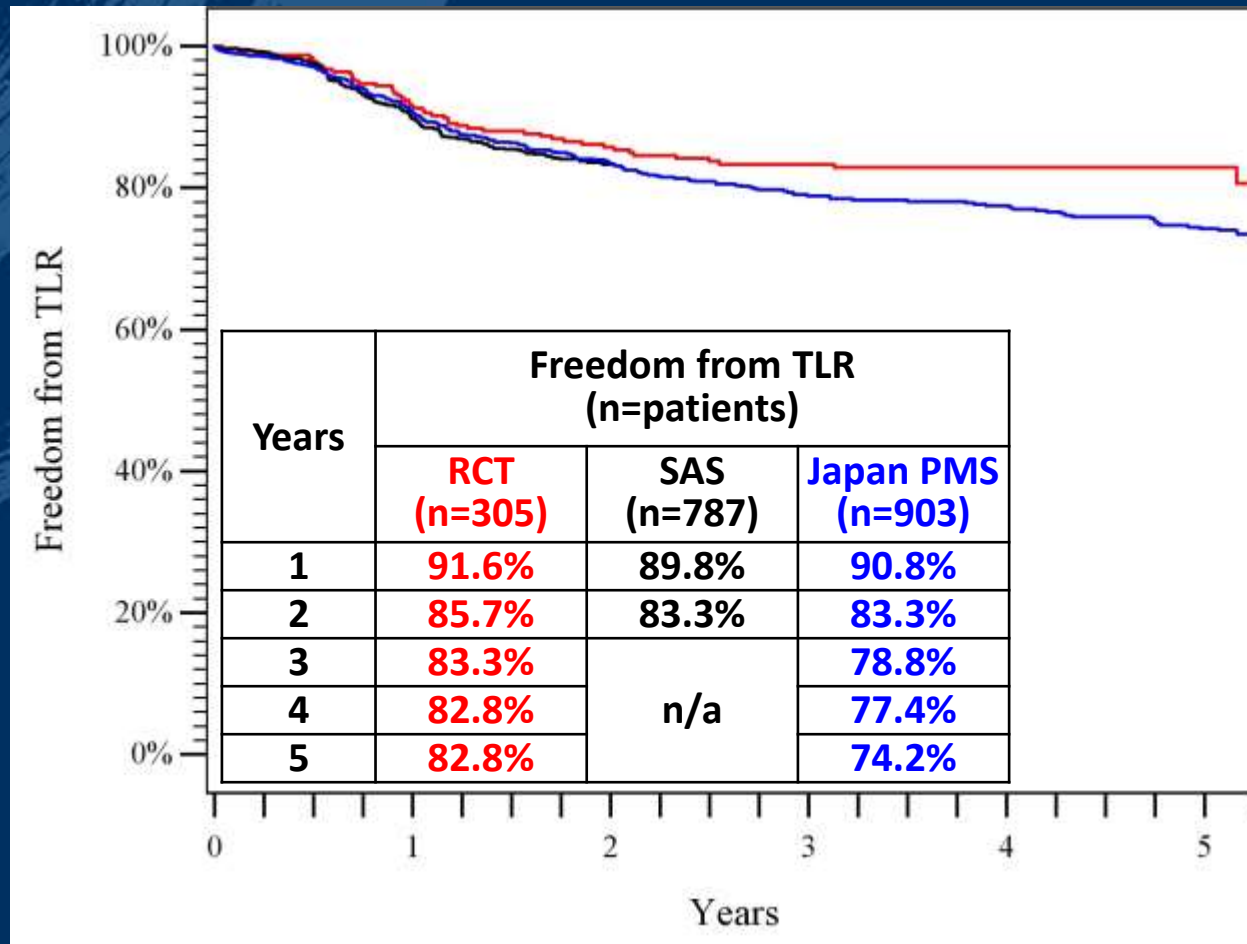
- 904 patients with 1080 lesions treated with 1877 Zilver PTX stents
 - 411 patients completed 5-year follow-up
 - 493 patients exited study through 5 years (~10% per year)
 - 226 lost to follow-up through 5 years (25%)
 - 82 withdrawals through 5 years (9%)
 - 185 deaths through 5 years (20%)
 - None adjudicated as device or procedure related
 - Follow-up and exit rates very similar to those observed in RCT

Patient Demographics and Lesion Characteristics

Patient Characteristics	Zilver PTX Japan PMS
Patients	904
Age (years)	74 ± 9
Male	70%
Diabetes	59%
High cholesterol	61%
Hypertension	85%
Pulmonary disease	8%
Renal disease	44%
Renal failure (eGFR < 60 and/or “on dialysis”)	36%

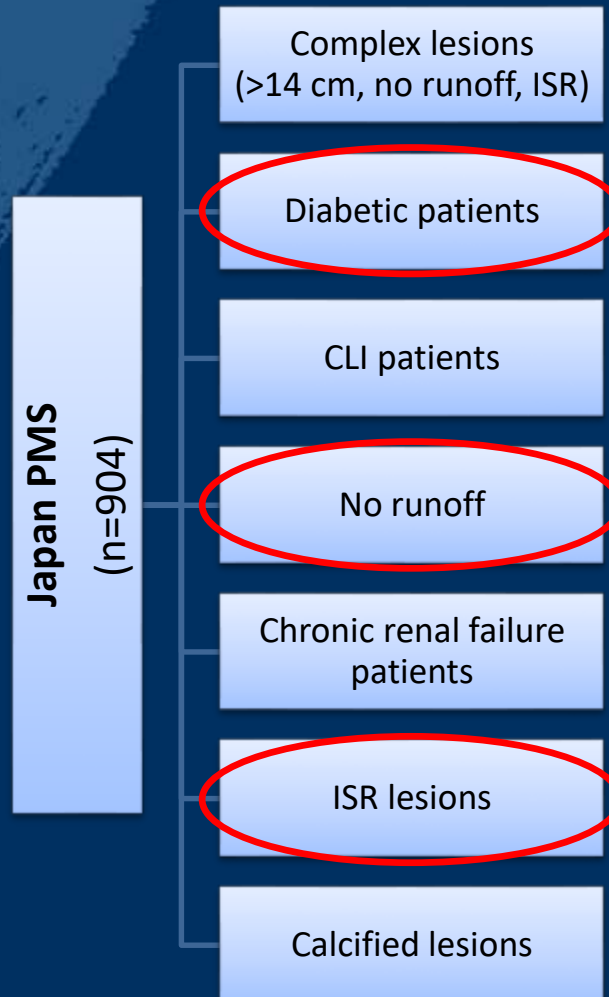
Lesion Characteristics	Zilver PTX Japan PMS	
Lesions	1080	
Lesion length (cm)	14.6 ± 9.6	
Diameter stenosis (%)	92 ± 11	
Total occlusions	42%	
In-stent restenosis	19%	
Rutherford 4-6 (CLI)	21%	
Patent runoff vessels	0	7%
	1	32%
	2	33%
	3	29%

Freedom from TLR

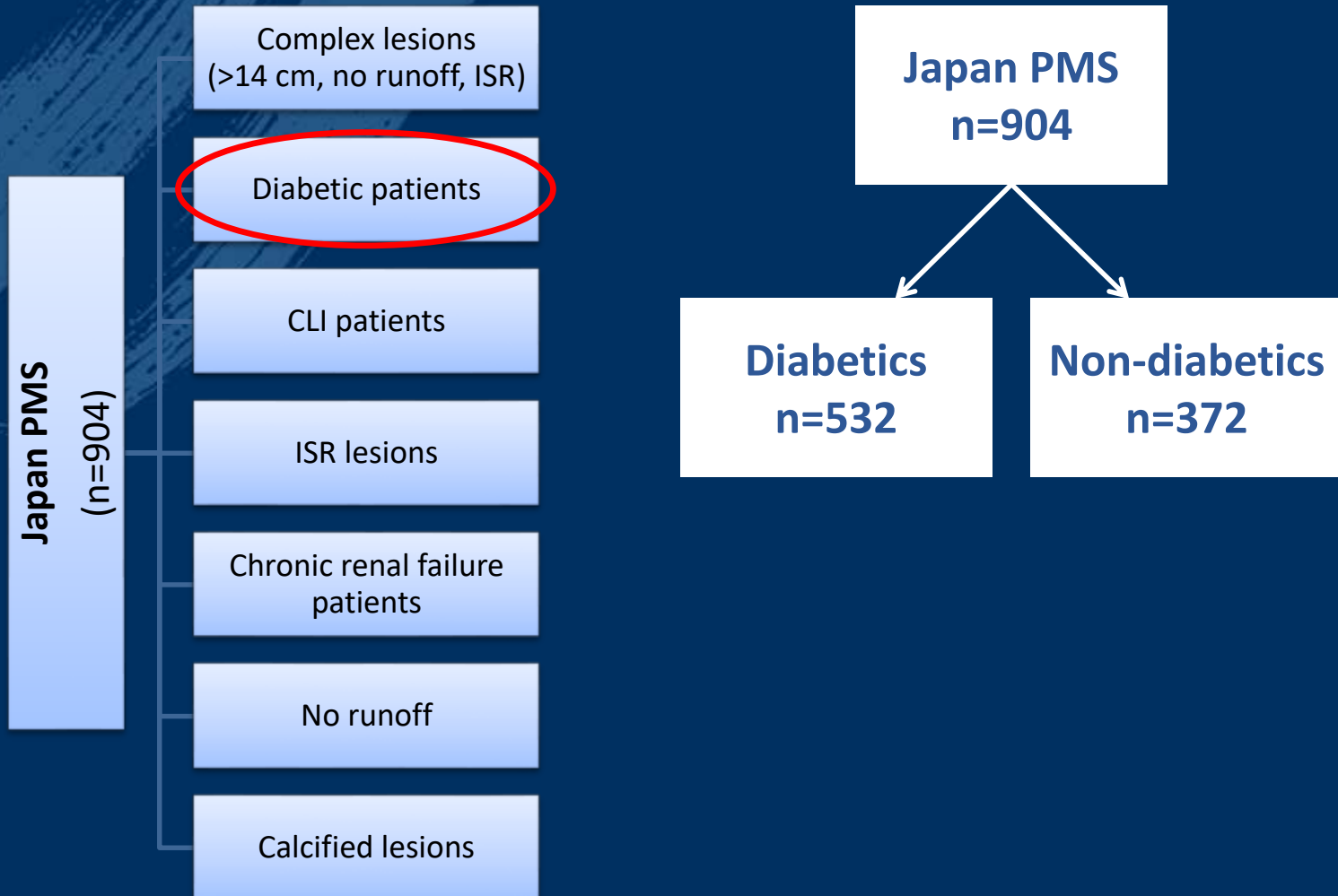


Consistently good results in challenging patient population including diabetics, renal failure, long lesions, ISR, no runoff, CLI

Japan PMS Subgroups Analyzed



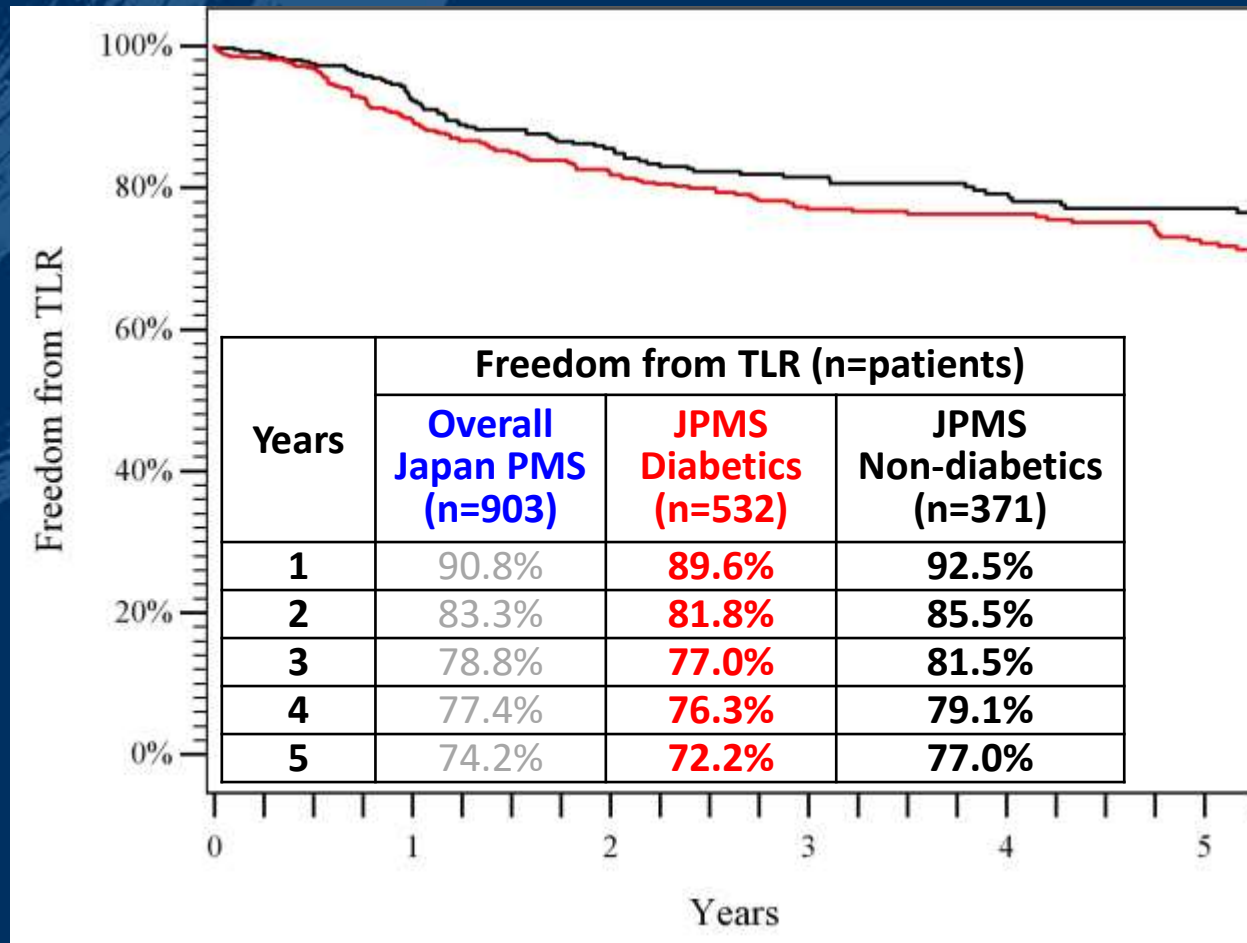
Diabetic Subgroup



Diabetic vs. Non-diabetic Patients

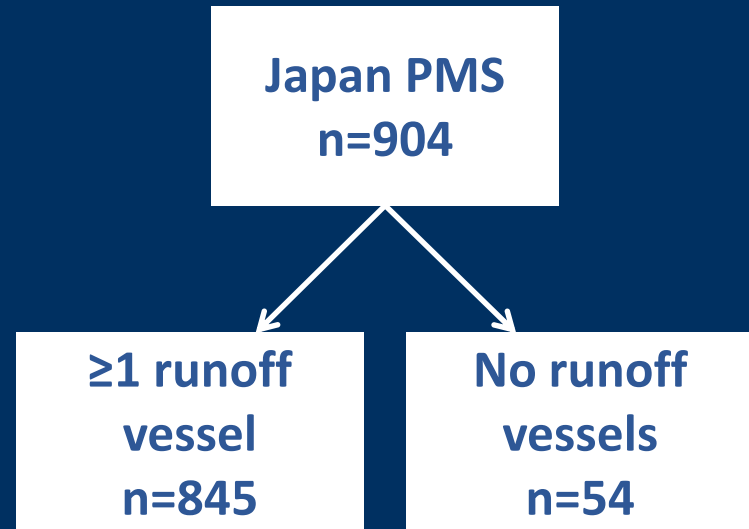
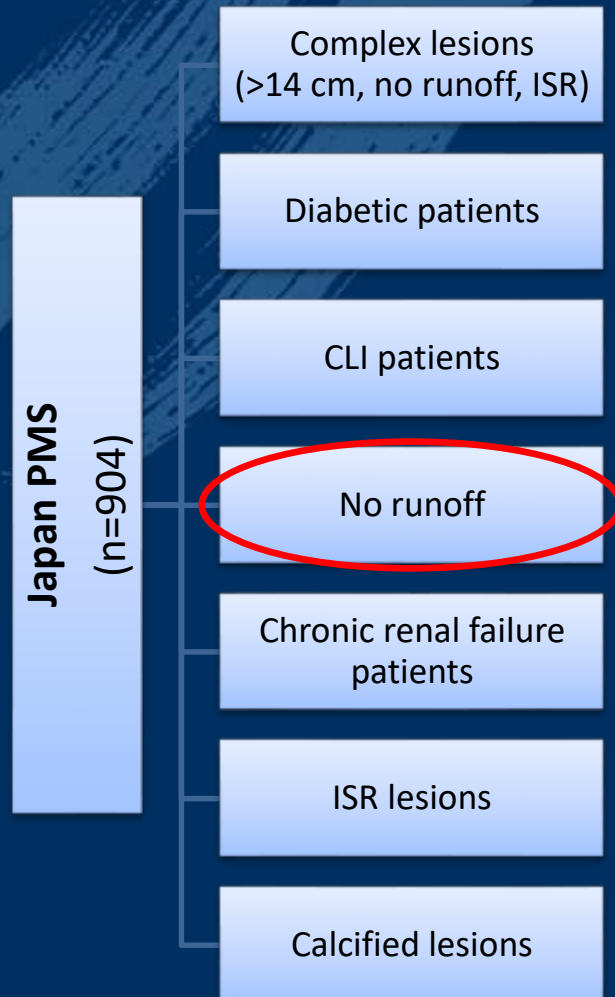
- Diabetic patients:
 - More hypercholesterolemia: 69% vs. 50%
 - More hypertension: 88% vs. 82%
 - More renal disease: 49% vs. 36%
 - More renal failure: 42% vs. 27%
 - More CLI: 26% vs. 14%
 - Fewer patent runoff vessels: 53% vs. 31%
 - Lower ABI: 0.61 vs. 0.65
 - Younger: 72 vs. 75
 - Fewer total occlusions: 39% vs. 46%

Freedom from TLR



Diabetic patients have similar benefit with DES as non-diabetics

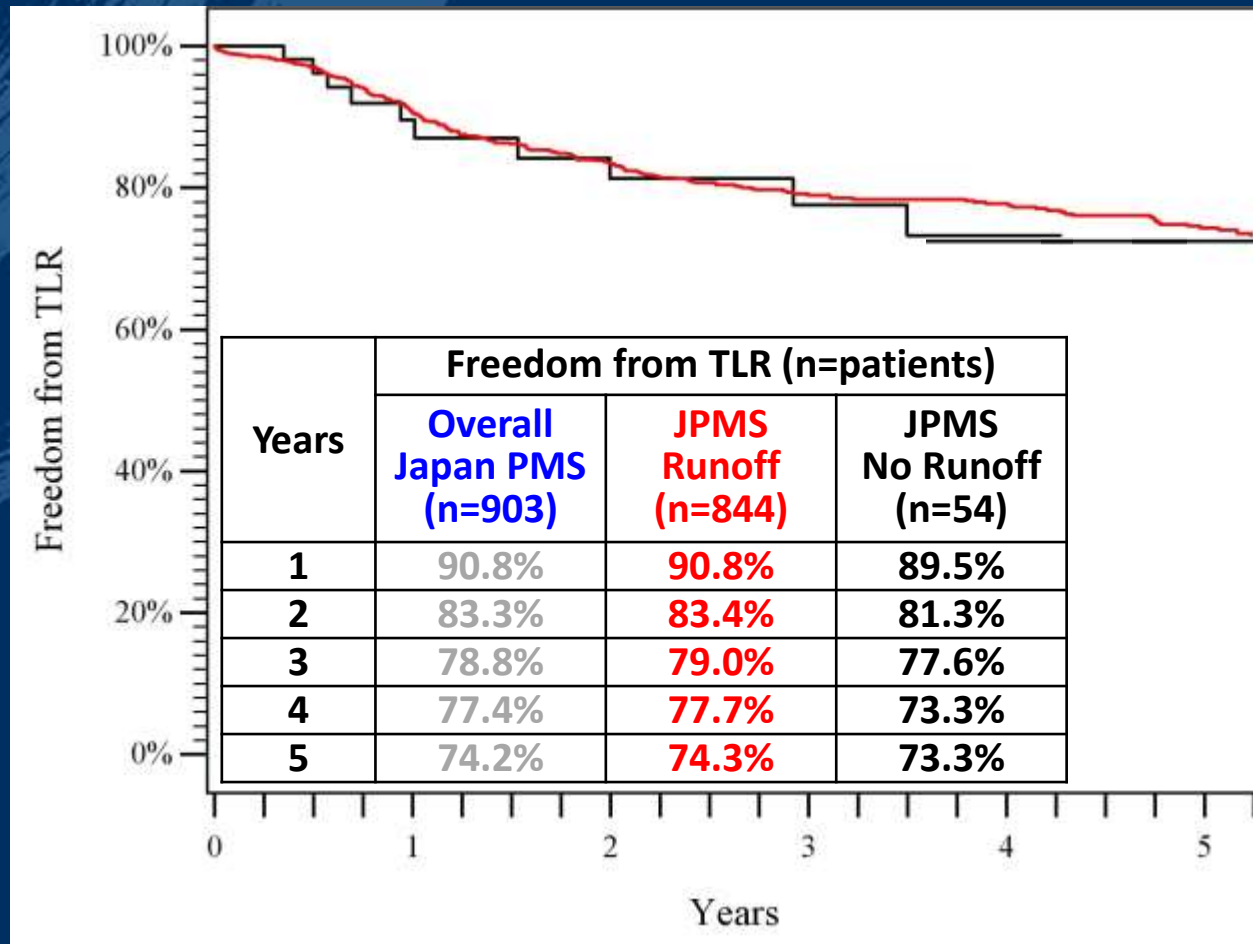
No Patent Runoff Vessel Subgroup



Runoff status was not reported for 5 patients.

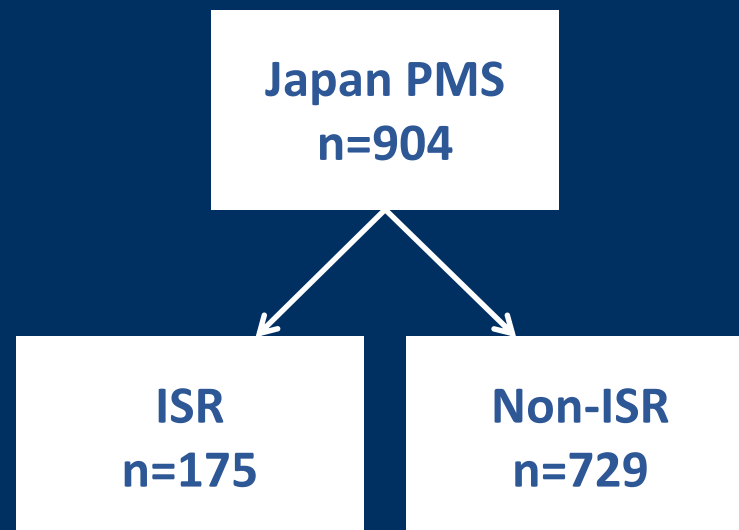
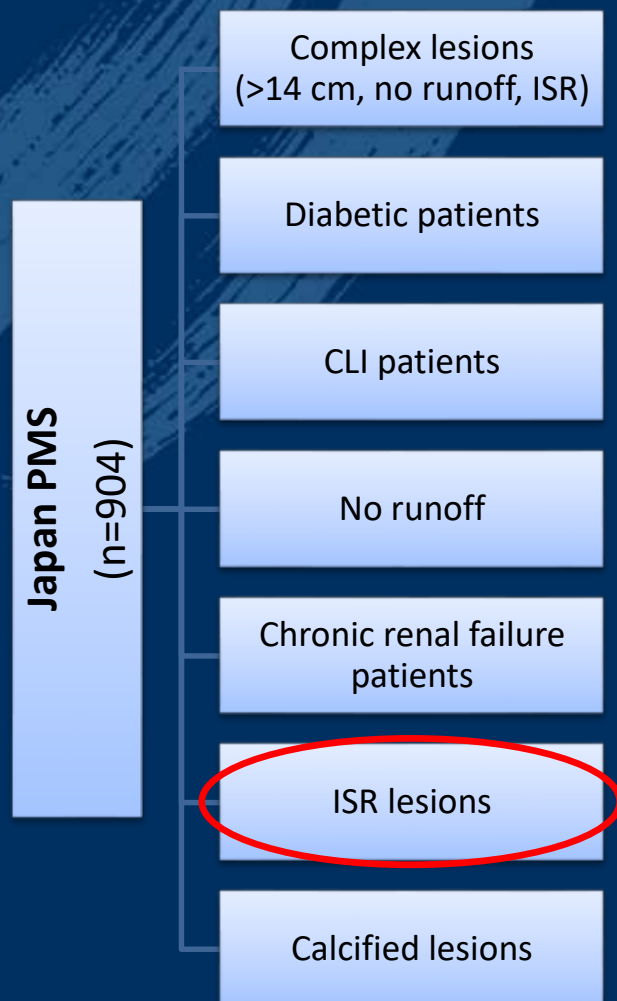
- In the no runoff group:
 - Higher incidence of CLI : 45% vs. 20%

Freedom from TLR



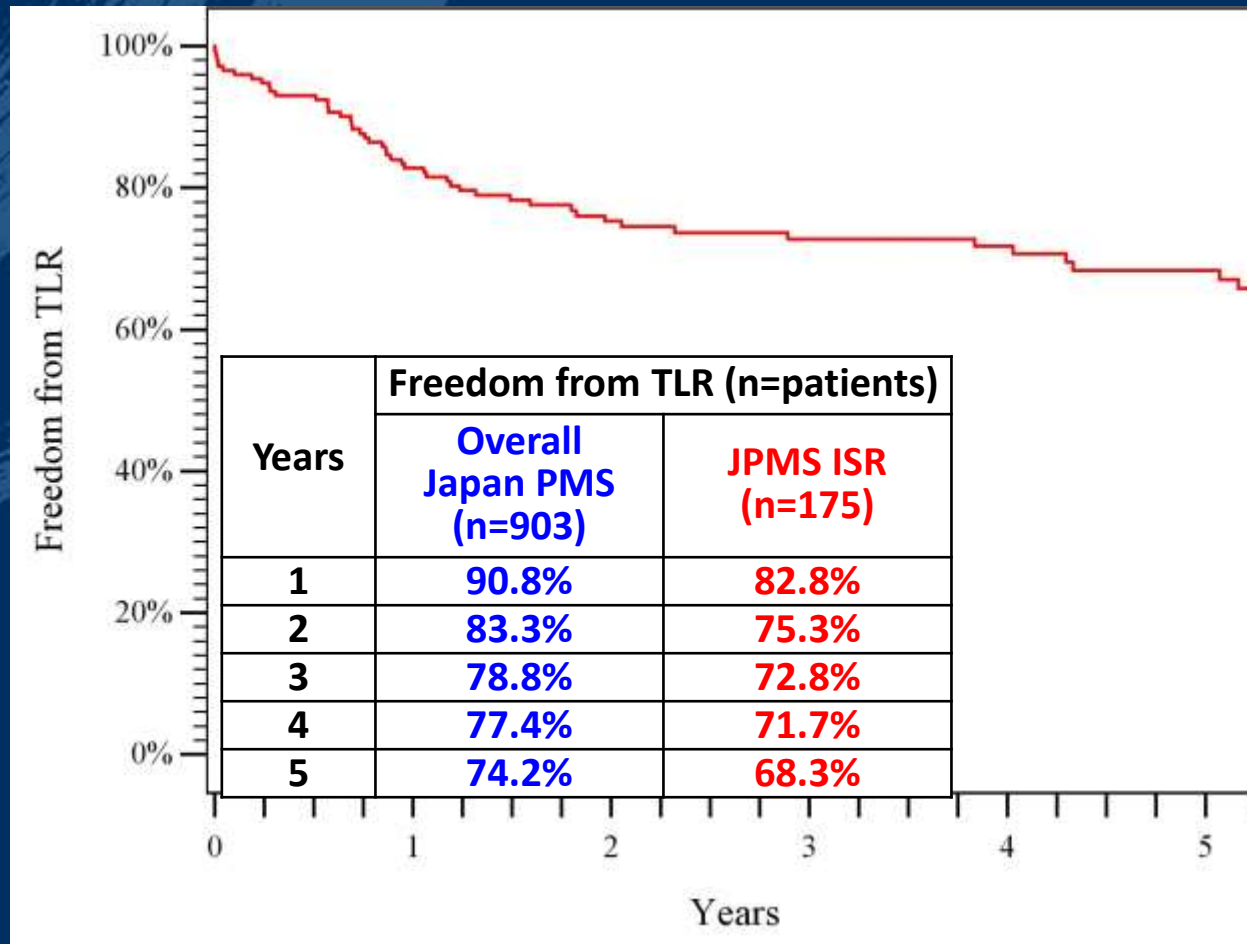
Similar outcomes for patients with and without patent runoff vessels

In-Stent Restenosis Subgroup



- In the ISR group:
 - Higher incidence of hypercholesterolemia: 70% vs. 59%
 - Lower ABI : 0.59 vs. 0.64
 - Longer lesion length: 17.8 cm vs. 14.0 cm

Freedom from TLR



Positive outcomes for ISR patients

Conclusions

- The Japan PMS included challenging patient subgroups often excluded from clinical studies
- Results from the Japan PMS are consistently good through 5 years
 - Diabetic patients have similar benefit as non-diabetics
 - Similar outcomes for patients with and without patent runoff vessels
 - Positive results for patients with in-stent restenosis

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