Zilver PTX Global Data Analysis Highlights DES Benefits in Challenging Patient Populations

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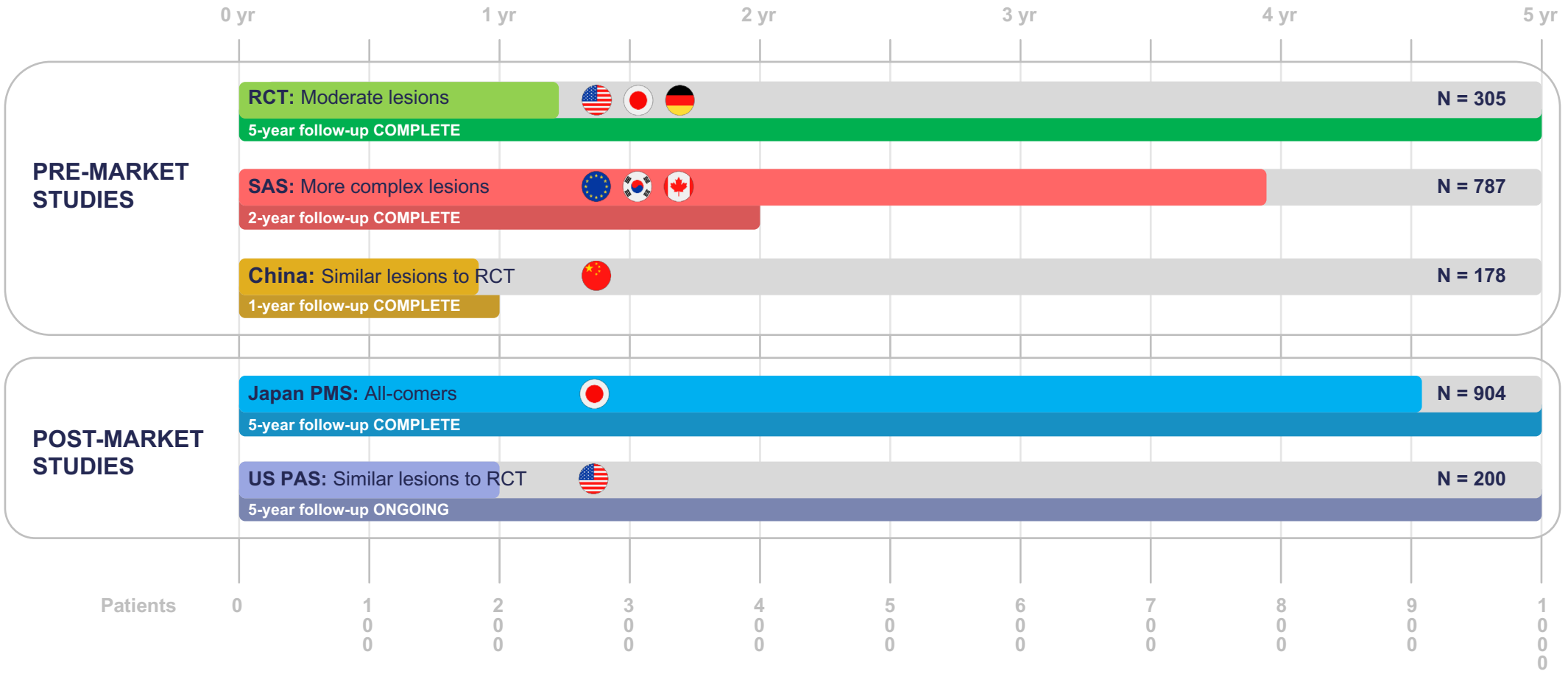
Zilver PTX Global Data Analysis

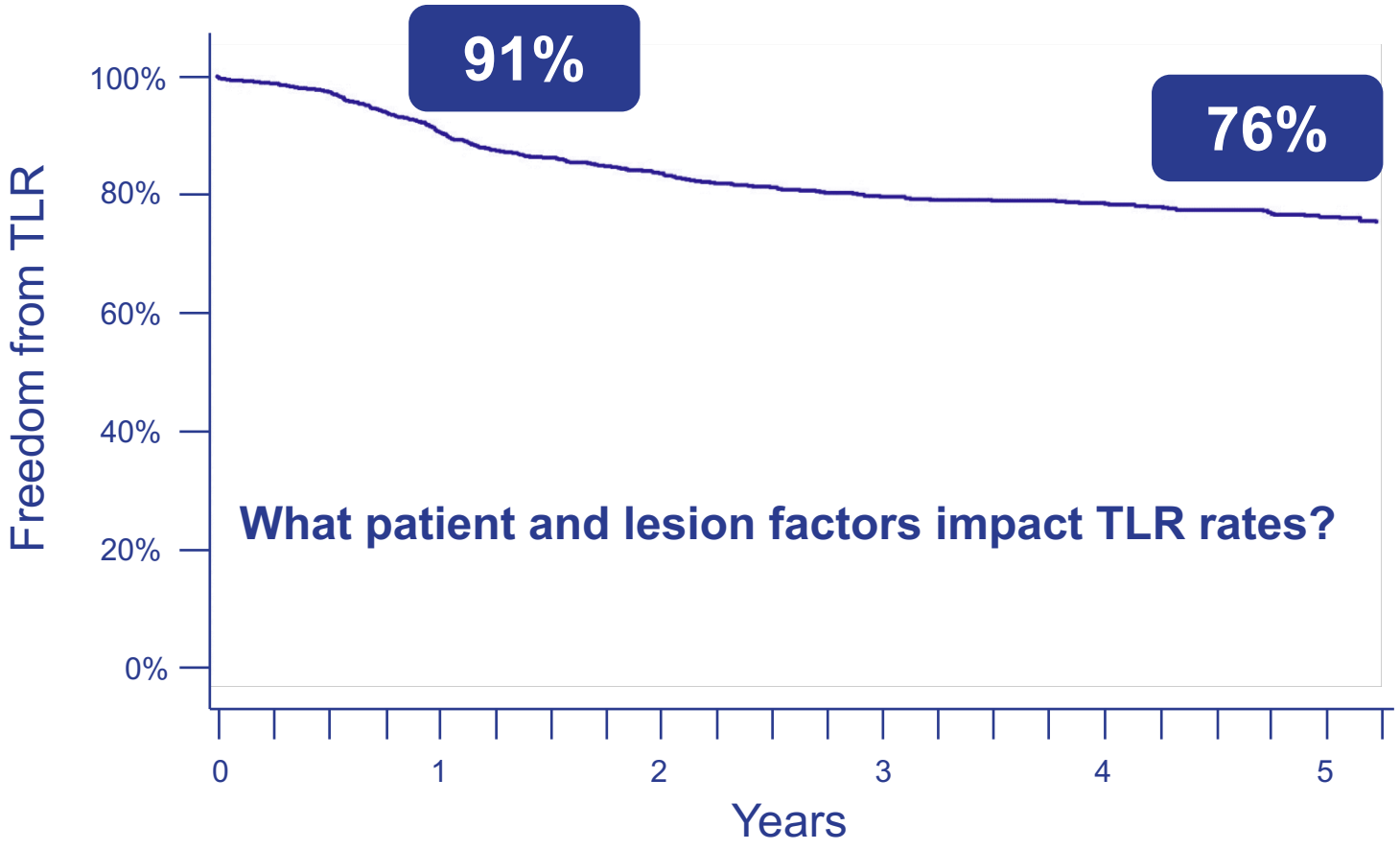


Speaker Name

Patient and Lesion Characteristics

Characteristic	Value
Patients / Lesions	2374 / 2686
Age (years)	69.5 ± 9.6
Male	71%
Diabetes	49%
Lesion length	11.1 ± 8.7 cm
Total occlusions	36%
In-stent restenosis	13%
Rutherford 4-6 (CLI)	14.7%
No patent runoff vessels	2.1%

Freedom from TLR from Global Data Analysis



- High rate of freedom from TLR
- Nearly 2400 patients
- 5 year results

Speaker Name

What Patient and Lesion Factors Impact TLR Rates?

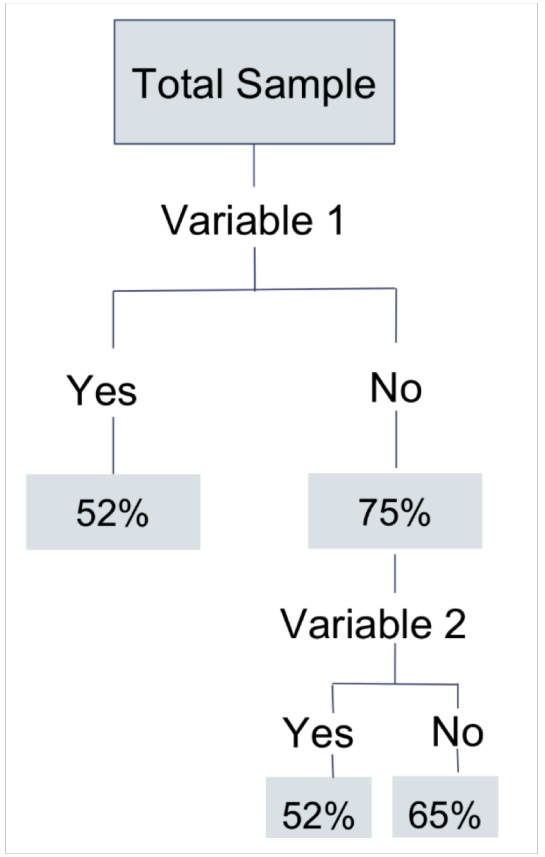
Patient Factors	Lesion Factors
Male vs. Female	Lesion length (≤15cm vs. >15cm)
Diabetes	Total occlusion
Smoking Status	In-stent restenosis
Rutherford (0-4 vs. 5-6)	Calcification (none-moderate vs. severe)
Patent runoff vessels (0-1 vs. 2+)	Reference vessel diameter (<5mm vs. ≥5mm)
	Stent diameter
	Stent oversizing (≤30% vs. >30%)

What Patient and Lesion Factors Have the Most Impact on TLR Rates Over Time?

- Step 1:
  Classification Tree analysis to rank factors for impact on TLR
  - Most impact
  - Moderate impact
  - Minimal impact
- Step 2:
  Cox model to confirm impact of the patient and lesion factors and evaluate interactions

Step 1: Classification Tree Analysis

- Ranks variables based on impact on TLR
  - Most impactful variable selected at each bifurcation
  - Identifies overall most and least impactful variables
- Provides input to other predictive models



Step 1: Classification Tree Analysis

Impact on 1-year TLR rate

Most impact on TLR	Moderate impact on TLR	Minimal impact on TLR
In-stent restenosis	Stent diameter	Rutherford
Lesion length	Smoking status	Male vs. Female
Reference vessel diameter	Patent runoff vessels	Calcification
Total occlusion	Stent oversizing	Diabetes

Step 2:
Cox Proportional Hazards Model

- Factors from Classification Tree were included in Cox Proportional Hazards model
  - All 2-, 3-, and 4-way interactions were tested
- Cox model confirmed the impact of the various patient and lesion factors
  - Identified significant interactions between some factors

Factors with Most Impact on TLR

Factors with most impact on TLR from Classification Tree	*p*-value[1]	Interpretation
In-stent restenosis	< 0.001	• **ISR is significant** • **Lesion length is significant in non-ISR lesions** • **Shorter lesions (≤15 cm) more likely to be free from TLR**
Lesion length	0.34	
ISR and lesion length	**0.013**	
Total occlusion	< 0.001	• **Occlusion is significant** • **RVD is significant in non-CTO** • **Larger vessels (≥5 mm) more likely to be free from TLR**
Reference vessel diameter	0.33	
Occlusion and RVD	**0.037**	

[1] **joint *p*-value; not univariate**

Factors with Moderate Impact on TLR

Factors with moderate impact on TLR from Classification Tree	*p*-value[1]	Interpretation
Stent oversizing	0.043	• **Oversizing (>30%) may impact TLR**
Smoking status	0.64	• **No significant impact on TLR**
Patent runoff vessels	0.91	
Stent diameter	0.12	

[1] **joint *p*-value; not univariate**

Factors with Minimal Impact on TLR

Factors with minimal impact on TLR from Classification Tree	*p*-value[1]	Interpretation
Rutherford	0.065	• **No significant impact on TLR**
Male vs. Female	0.68	
Calcification	0.98	
Diabetes	0.22	

[1] **joint *p*-value; not univariate**

Conclusions from Zilver PTX Global Data Analysis

- Nearly 2400 patients from 5 studies across 16 countries
  - Including ISR, long lesions, no runoff
- High freedom from TLR sustained through 5 years
- Consistency between Classification Tree and Cox model results
- ISR and total occlusions identified as significant factors for TLR
  - Lesion length is significant in non-ISR lesions
  - RVD is significant in non-CTO
- For Zilver PTX patients, sex, calcification, and diabetes did NOT have significant impact on TLR