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Insights from Global Zilver PTX Experience: What are the Predictors for Clinical Failure and TLR

Michael D. Dake, MD

University of Arizona Health Sciences

Tucson, AZ

Disclosure

Speaker name: **Michael Dake**

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)
- I do not have any potential conflict of interest

Global Clinical Program for Zilver PTX

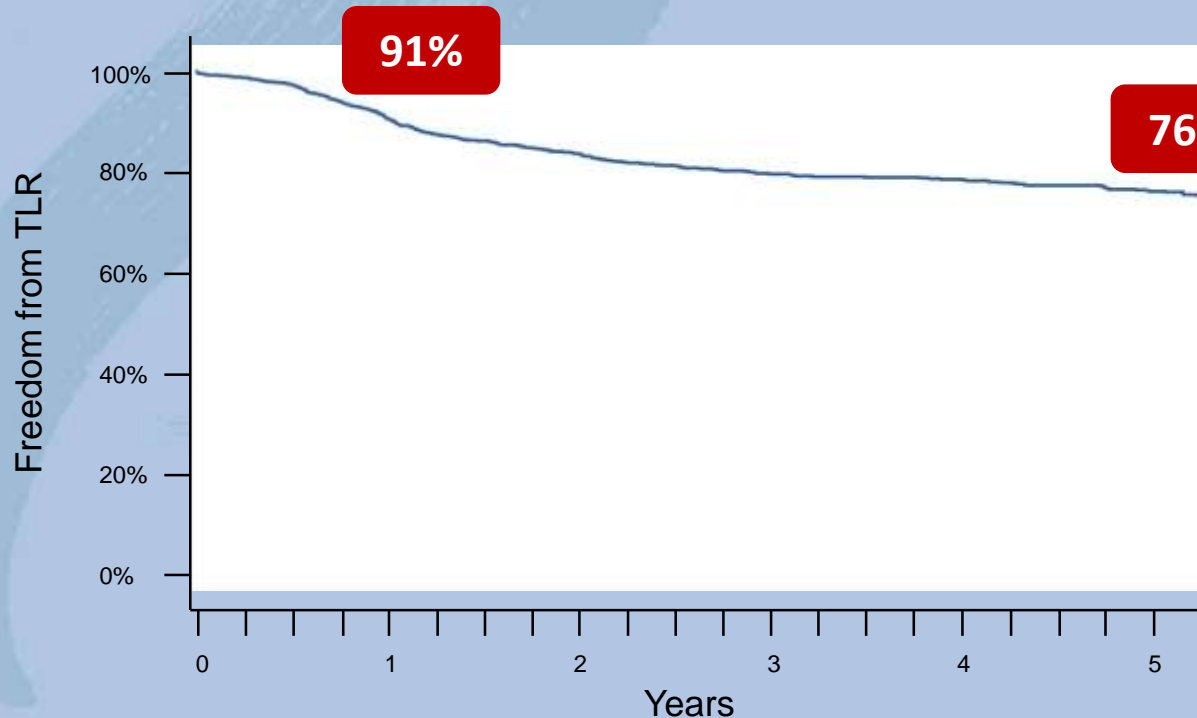


More than 2400 patients included in current Zilver PTX clinical program

Patient and Lesion Characteristics

Characteristic	Value
Patients / Lesions	2374 / 2686
Age (years)	69.5 ± 9.6
Male	71%
Diabetes	49%
Lesion length (cm)	11.1 ± 8.7
Total occlusions	36%
In-stent restenosis	13%
Severe calcification	17%
Rutherford 4-6 (CLI)	15%
No patent runoff vessels	2%

Freedom from TLR Based on Global Data Analysis



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

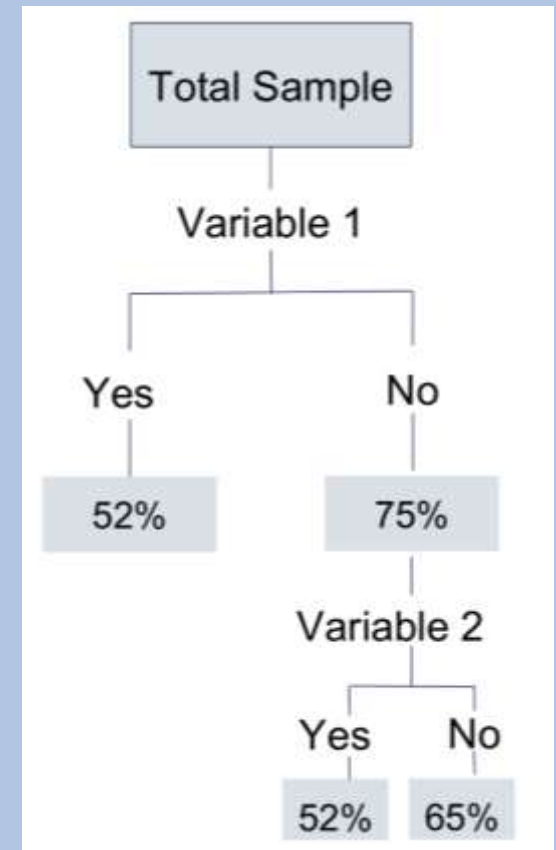
What patient and lesion factors impact TLR rates?

What Patient and Lesion Factors Impact TLR Rates?

Patient Factors	Lesion Factors
Male vs. Female	Lesion length ($\leq 15\text{cm}$ vs. $>15\text{cm}$)
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 ($<5\text{mm}$ vs. $\geq 5\text{mm}$)
	Stent diameter
	Stent oversizing ($\leq 30\%$ vs. $>30\%$)

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

- Ranked factors based on impact on TLR and identified most and least impactful factors



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

- Classification Tree ranked factors for impact on TLR
 - Most impact
 - Moderate impact
 - Minimal impact
- All factors from Classification Tree were included in Cox Proportional Hazards model
 - 2-, 3-, and 4-way interactions were tested for factors with the most impact
- Cox model confirmed the impact of the various patient and lesion factors on TLR
 - 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	<ul style="list-style-type: none"> • ISR is significant • Lesion length is significant in non-ISR lesions
Lesion length	0.34	
ISR and lesion length	0.013	
Total occlusion	< 0.001	<ul style="list-style-type: none"> • Occlusion is significant • RVD is significant in non-CTO <ul style="list-style-type: none"> • 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

For Zilver PTX patients, Rutherford, sex, calcification, and diabetes did NOT have significant impact on TLR

Conclusions from Zilver PTX Global Data Analysis

- Nearly 2400 patients from 5 studies across 16 countries
 - Including ISR, long lesions, no patent runoff vessels
- 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 lesions
- For Zilver PTX patients, sex, calcification, and diabetes did NOT have significant impact on TLR

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