Zilver PTX Drug Eluting Stent for Treating Femoro-Popliteal Lesions: Results from the Zilver PTX China Study

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Disclosure

Speaker name: Wei Guo Fu, MD

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I have the following potential conflicts of interest to report:

☐ Consulting

☐ Employment in industry

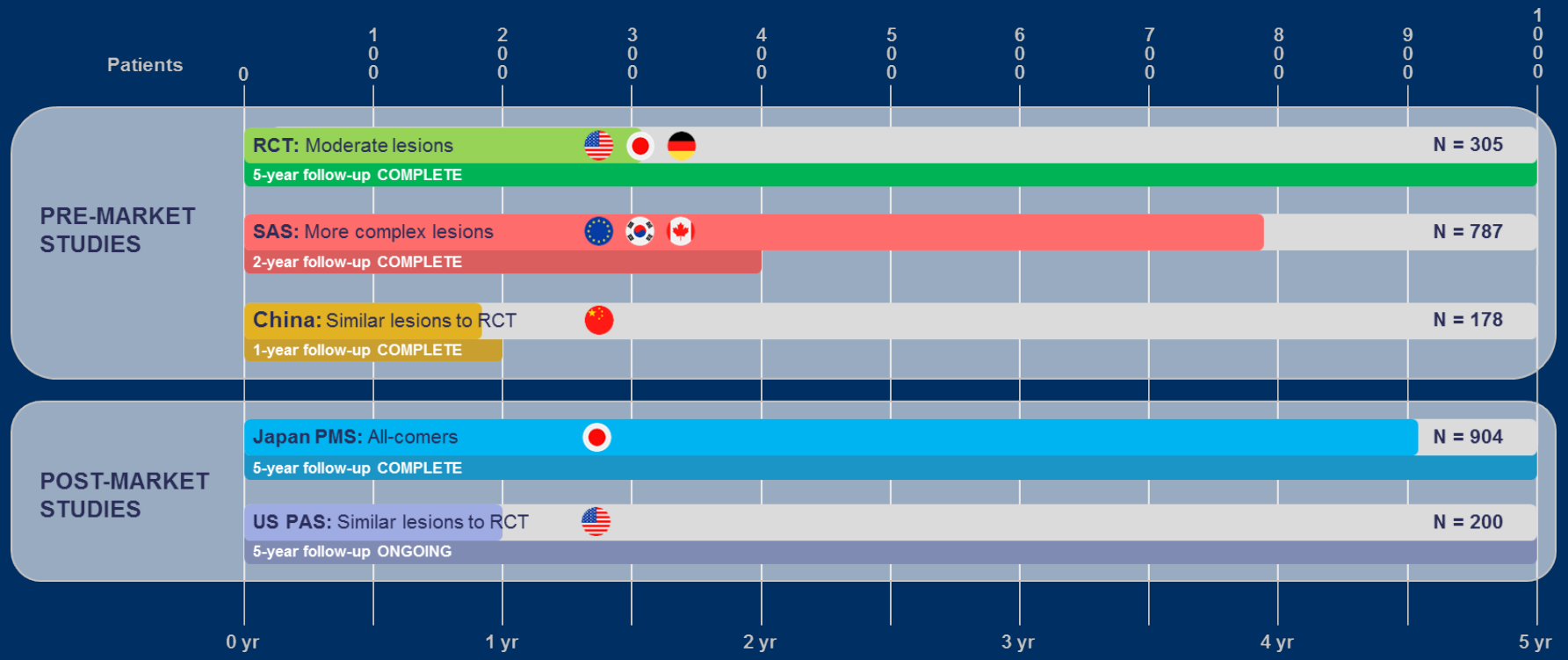
☐ Stockholder of a healthcare company

☐ 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

Zilver PTX China Trial

- Objective:
  - To evaluate the Zilver PTX Drug-Eluting Peripheral Stent for treatment of lesions of the above-the-knee femoropopliteal artery in Chinese patients
- Enrollment Criteria:
  - Rutherford classification 2 to 4
  - Single de novo or restenotic lesion ≤ 140 mm will be treated per patient

Enrollment

Site Name	Principal Investigator	Enrollment
Shanghai Ninth People's Hospital Affiliated Shanghai JiaoTong University School of Medicine	Xinwu Lu	31
Peking Union Medical College Hospital	Changwei Liu	34
Renji Hospital Shanghai Jiaotong Univiversity School of Medicine	Jiwei Zhang	27
Zhongshan Hospital Fudan University	Weiguo Fu	20
Beijing Anzhen Hospital	Zhong Chen	23
China-Japan Friendship Hospital	Peng Liu	15
Peking University People's Hospital	Xiaoming Zhang	9
Chinese PLA General Hospital	Wei Guo	10
Peking University First Hospital	Yinghua Zou	9
	Total	178

Patient Demographics

Patients		178
Age (years)		67 ± 9
Male		79%
Diabetes		56%
High cholesterol		19%
Hypertension		76%
Renal disease		6%
Pulmonary disease		2%
History of MI		5%
Rutherford Classification	**2**	22%
	3	70%
	4	8%

Lesion Characteristics

Lesions		178
Lesion length[1] (mm)		79 ± 49
Diameter stenosis[1] (%)		89 ± 15
Total occlusions[1]		50%
MLD (mm)		0.5 ± 0.7
Lesion calcification	**None**	24%
	Mild	35%
	Moderate	32%
	Severe	10%
Patent Runoff Vessels[1,2]	**0**	12%
	1	33%
	2+	42%
	N/A	14%

1 Angiographic core lab assessment

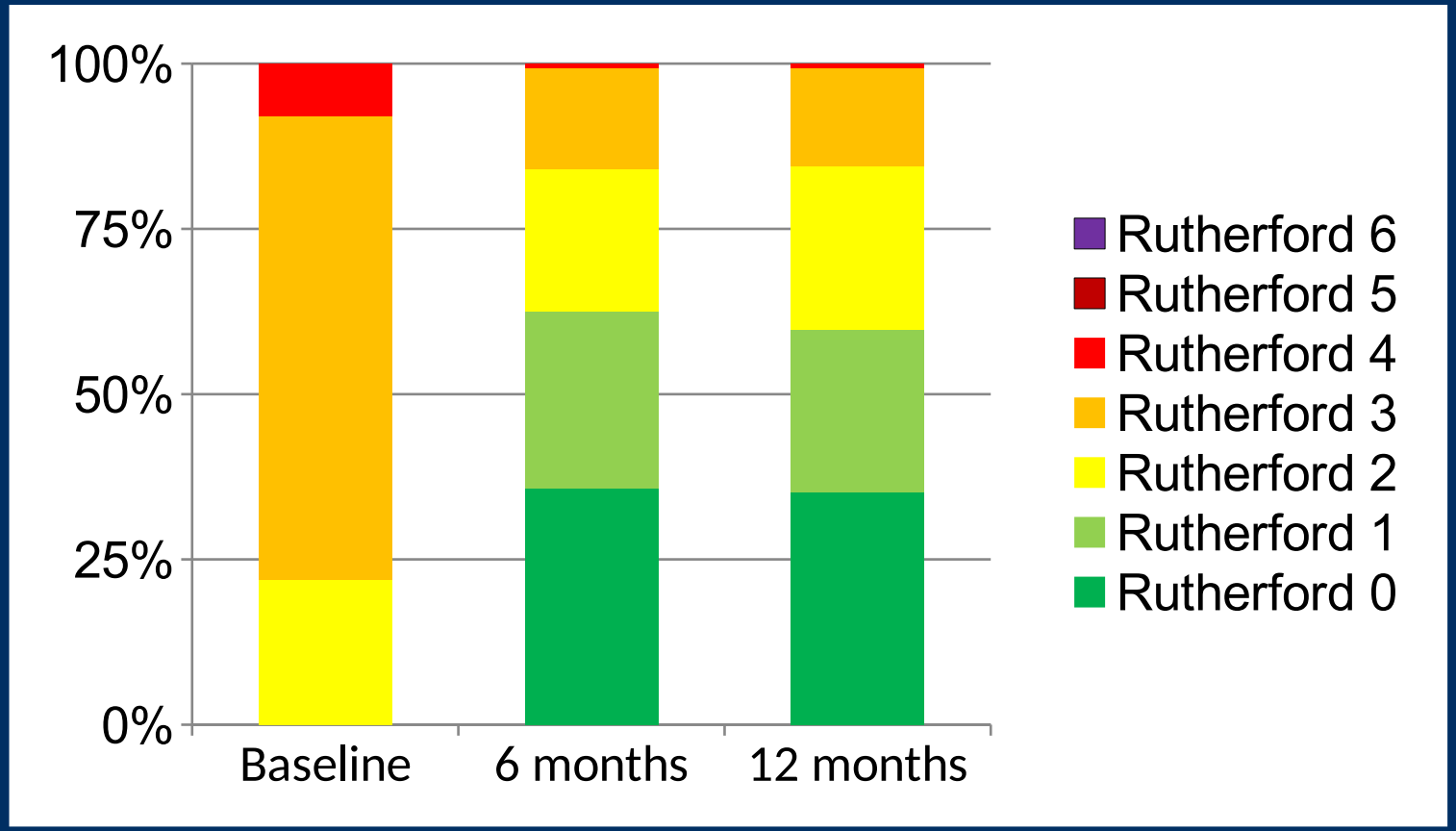
2 Site-reported “0 patent runoff vessels” was 0%

Procedural Information

- Procedural success was defined as < 30% residual stenosis determined angiographically immediately after the procedure
  - 100% site-reported procedural success

- Stent usage
  - 5 mm and 6 mm diameter stents available in lengths ranging from 40 mm to 100 mm
  - 249 stents placed
    - 36% of patients had multiple stents

Clinical Outcomes



Rutherford significantly improved ($p<0.001$) through 12 months

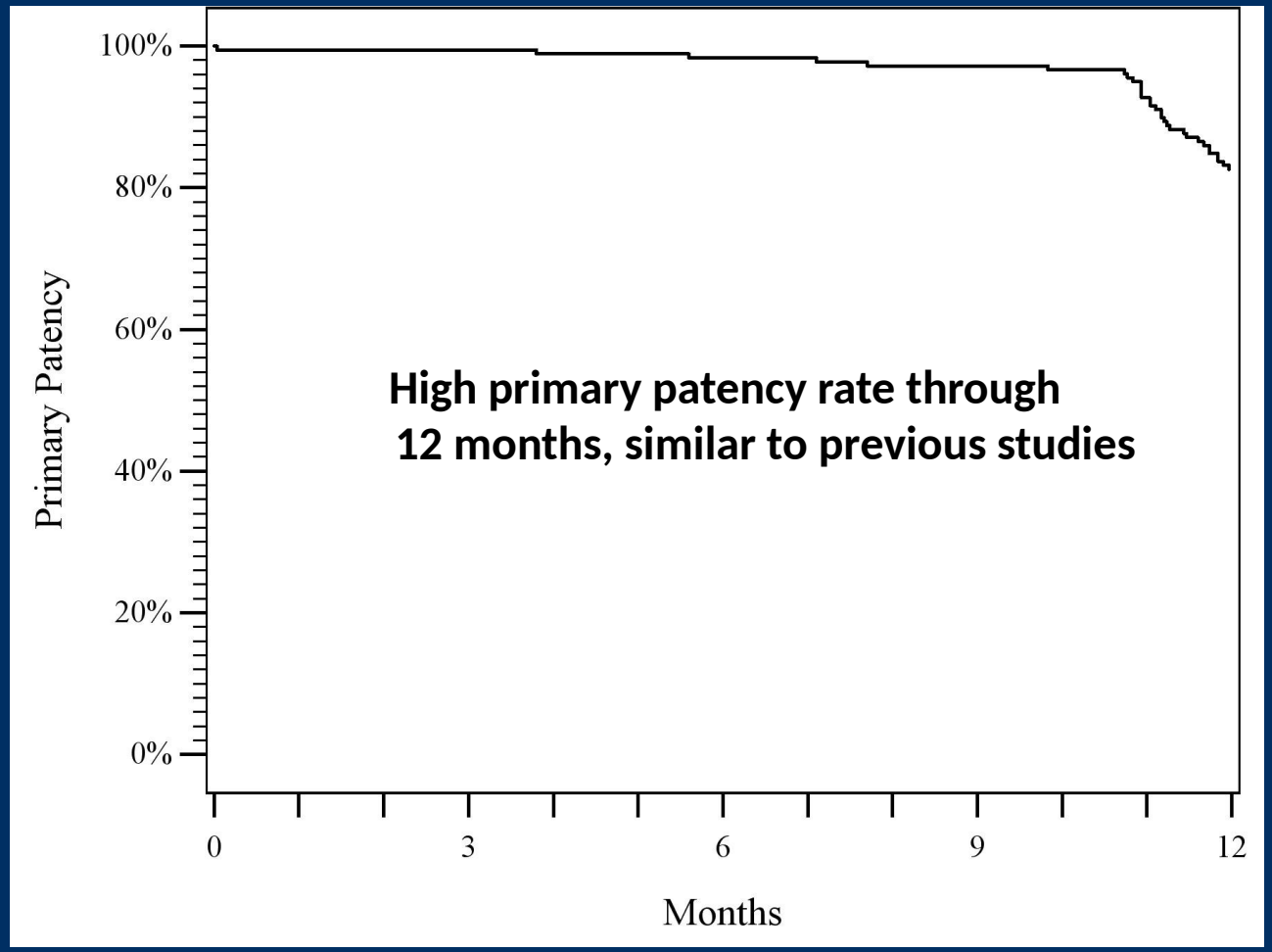
ABI and Walking Impairment

	Pre-procedure	6 months	12 months
ABI	0.6 ± 0.2	0.9 ± 0.2	0.8 ± 0.2
Walking distance (%)[1]	22.9 ± 20.5	74.3 ± 33.8	77.9 ± 32.3
Walking speed (%)[1]	27.8 ± 22.8	52.0 ± 32.3	52.5 ± 32.2
Stair climb (%)[1]	48.5 ± 33.8	75.0 ± 33.5	75.3 ± 35.3

[1] Walking scores were obtained from the Walking Impairment Questionnaire, which is a validated measure of patient-perceived walking performance. Patient responses are weighted and the weighted average is reported with a maximum possible score of 100% in each category.

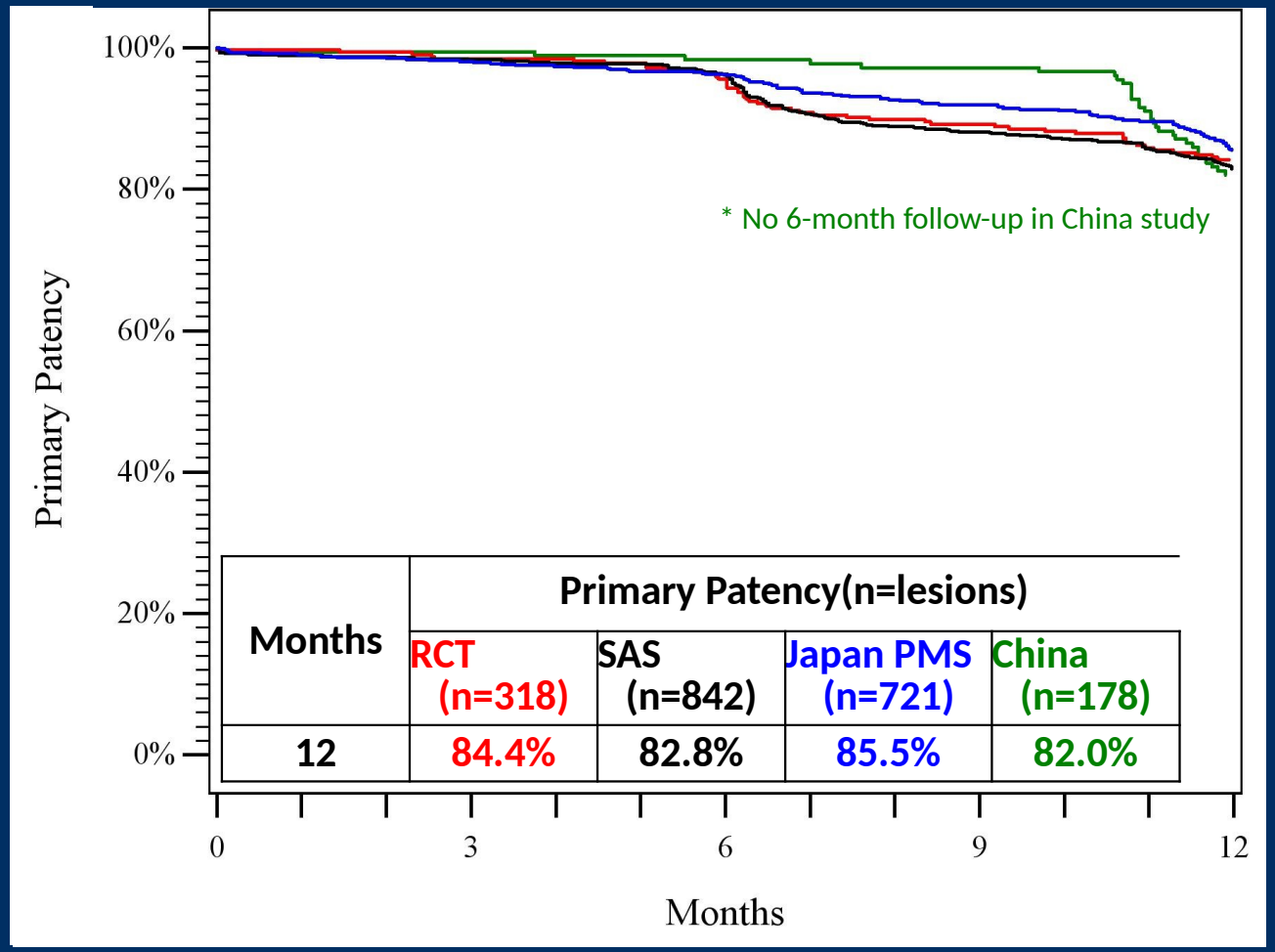
ABI and walking impairment significantly improved ($p<0.001$) through 12 months

Primary Patency



82.0%

Primary Patency for Global Clinical Studies



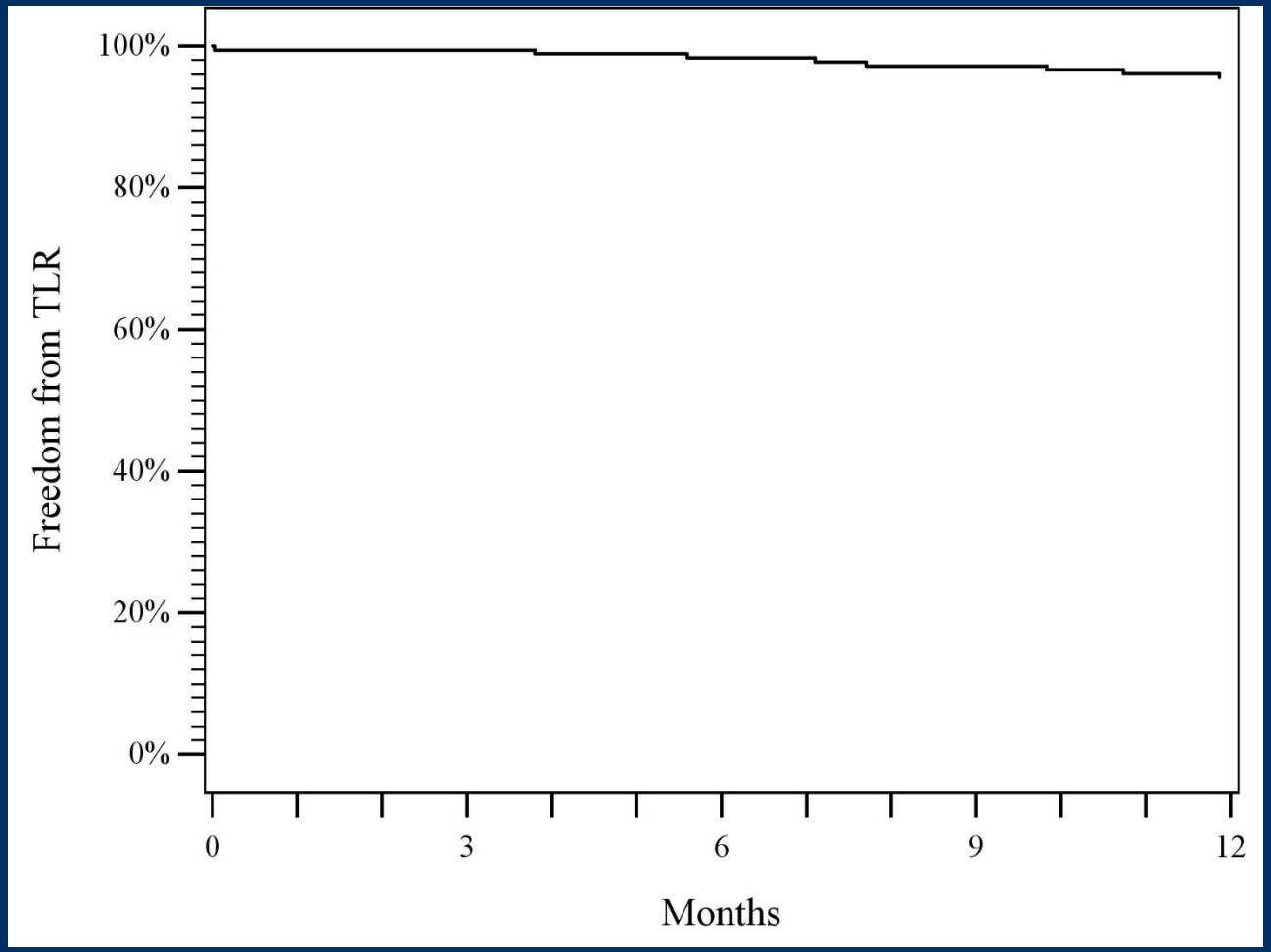
Months	Primary Patency(n=lesions)			
	RCT (n=318)	SAS (n=842)	Japan PMS (n=721)	China (n=178)
12	84.4%	82.8%	85.5%	82.0%

Event Free Survival

Event	Total (0-410 days)
	Rate (n)
Related death	0% (0)
Related amputation	0% (0)
Clinically-driven TLR	**5.6% (10)**
Ischemia requiring surgical intervention	0% (0)
Surgical repair of the target vessel	0.6% (1)
Worsening of Rutherford Classification (by two classes or to class 5 or 6)	0% (0)
Total Events	**6.2% (11)**

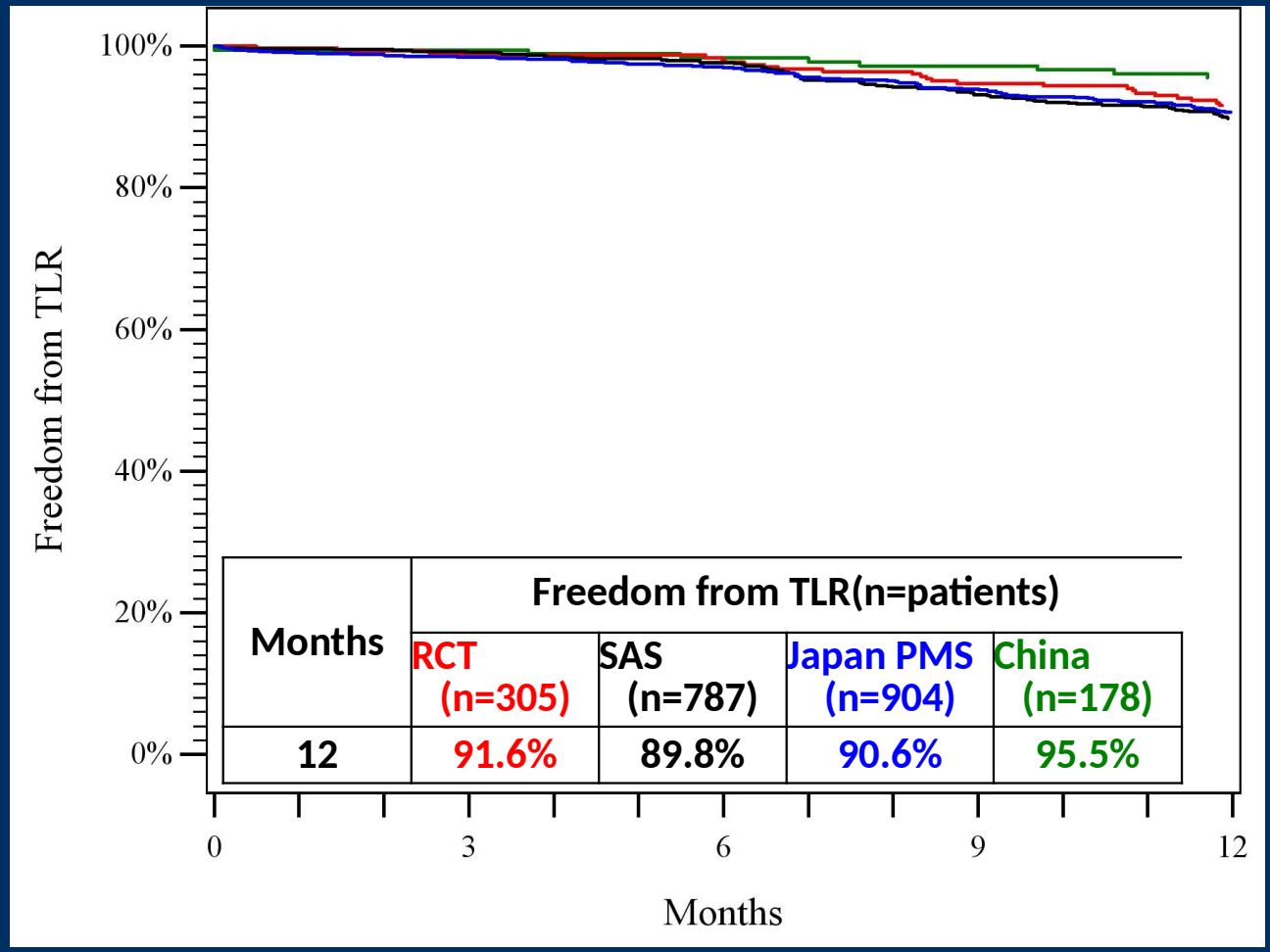
Major adverse events were primarily TLR; no related death or amputation

Freedom from TLR



95.5%

Freedom from TLR for Global Clinical Studies



Months	Freedom from TLR(n=patients)			
	RCT (n=305)	SAS (n=787)	Japan PMS (n=904)	China (n=178)
12	91.6%	89.8%	90.6%	95.5%

High freedom from TLR rate through 12 months

Conclusions

- Moderate patients enrolled
  - Lesion length 79 mm; 50% total occlusions
- Positive results indicate Zilver PTX is safe and effective in Chinese patients
  - Clinical improvement demonstrated by Rutherford, ABI, and walking distantce
  - Similar patency to previous studies
  - No death, amputation, or worsening Rutherford classification
  - High rates of freedom from TLR and primary patency; both are similar to previous studies