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Overview of China PCI

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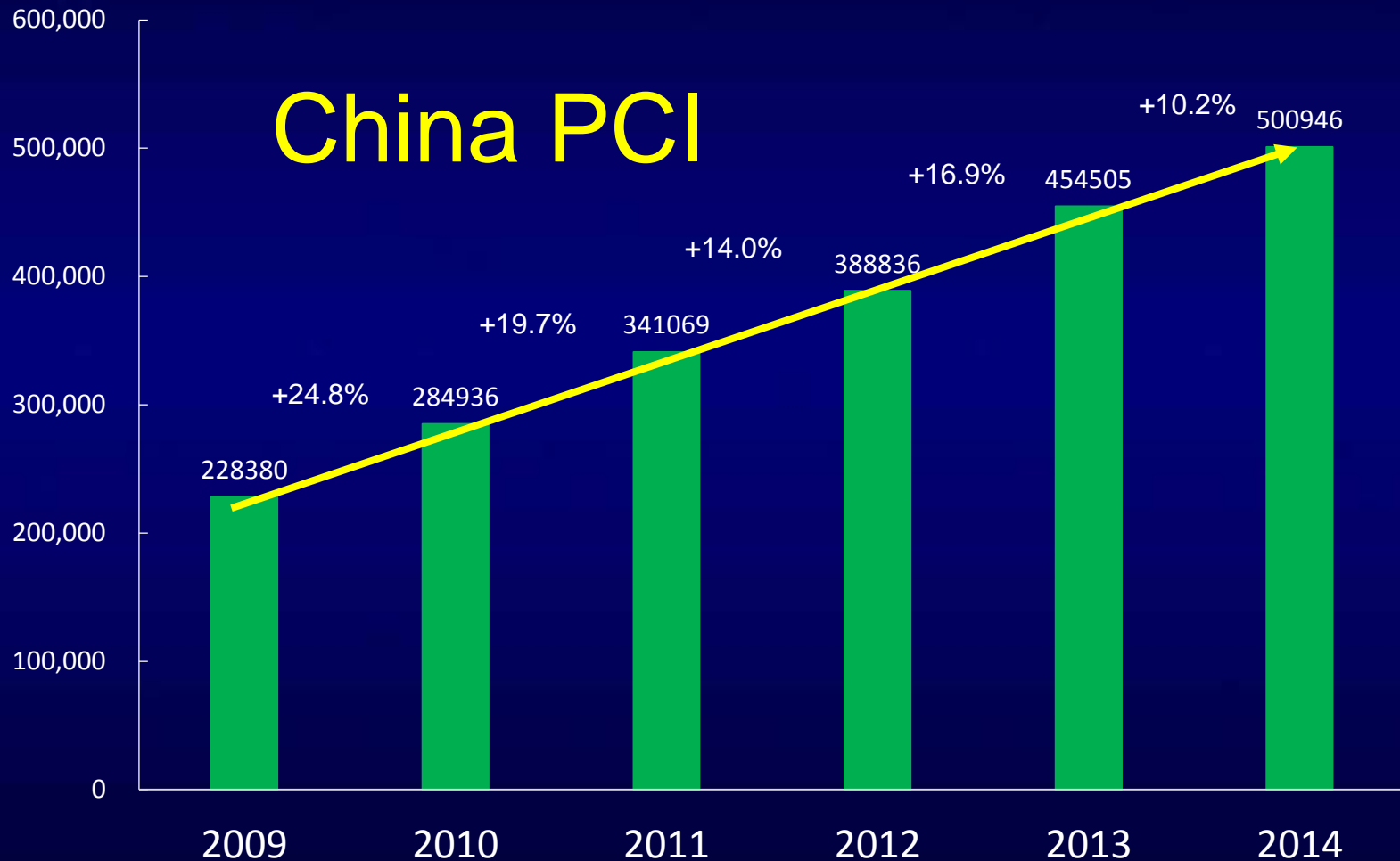
Professor of Medicine/Cardiology

Chairman, Shanghai Institute of Cardiovascular Diseases

Director, Dept. of Cardiology

Zhongshan Hospital, Fudan University

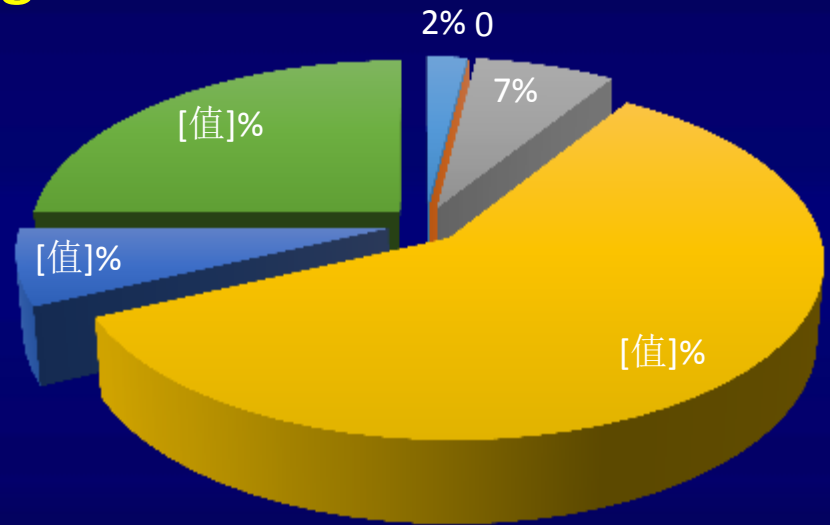
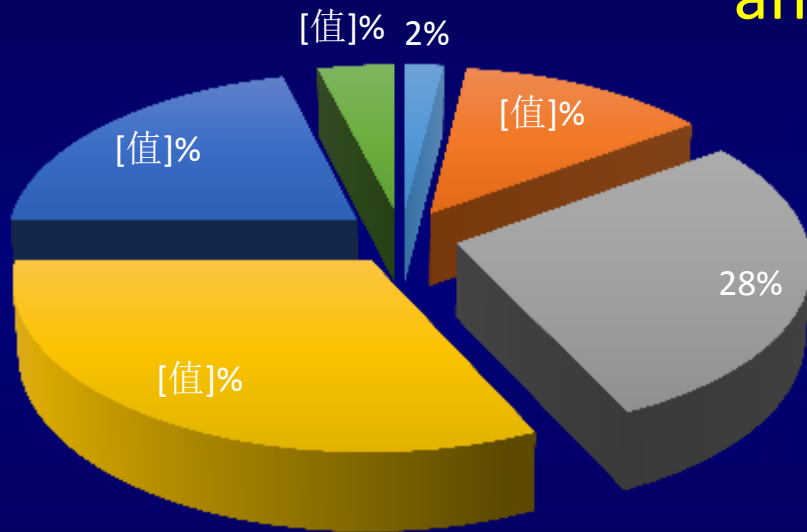
Overview of China PCI



Overview of China PCI



The distribution of age and diagnosis



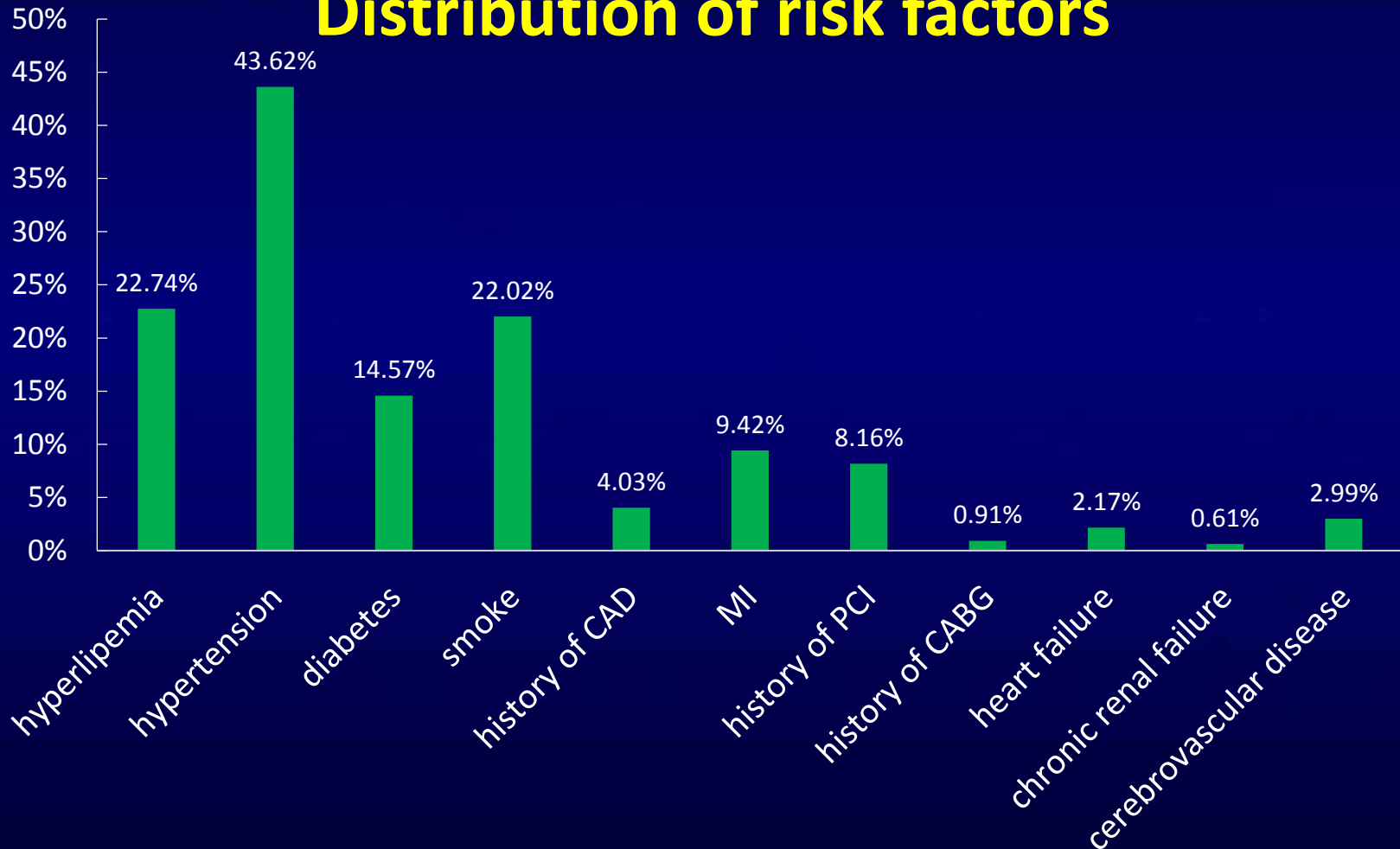
■ ≤40
 ■ 41~50
 ■ 51~60
 ■ 61~70
 ■ 71~80
 ■ > 81

■ suspected angina
 ■ silent ischemia
■ stable angina
 ■ unstable angina
■ NSTEMI
 ■ STEMI

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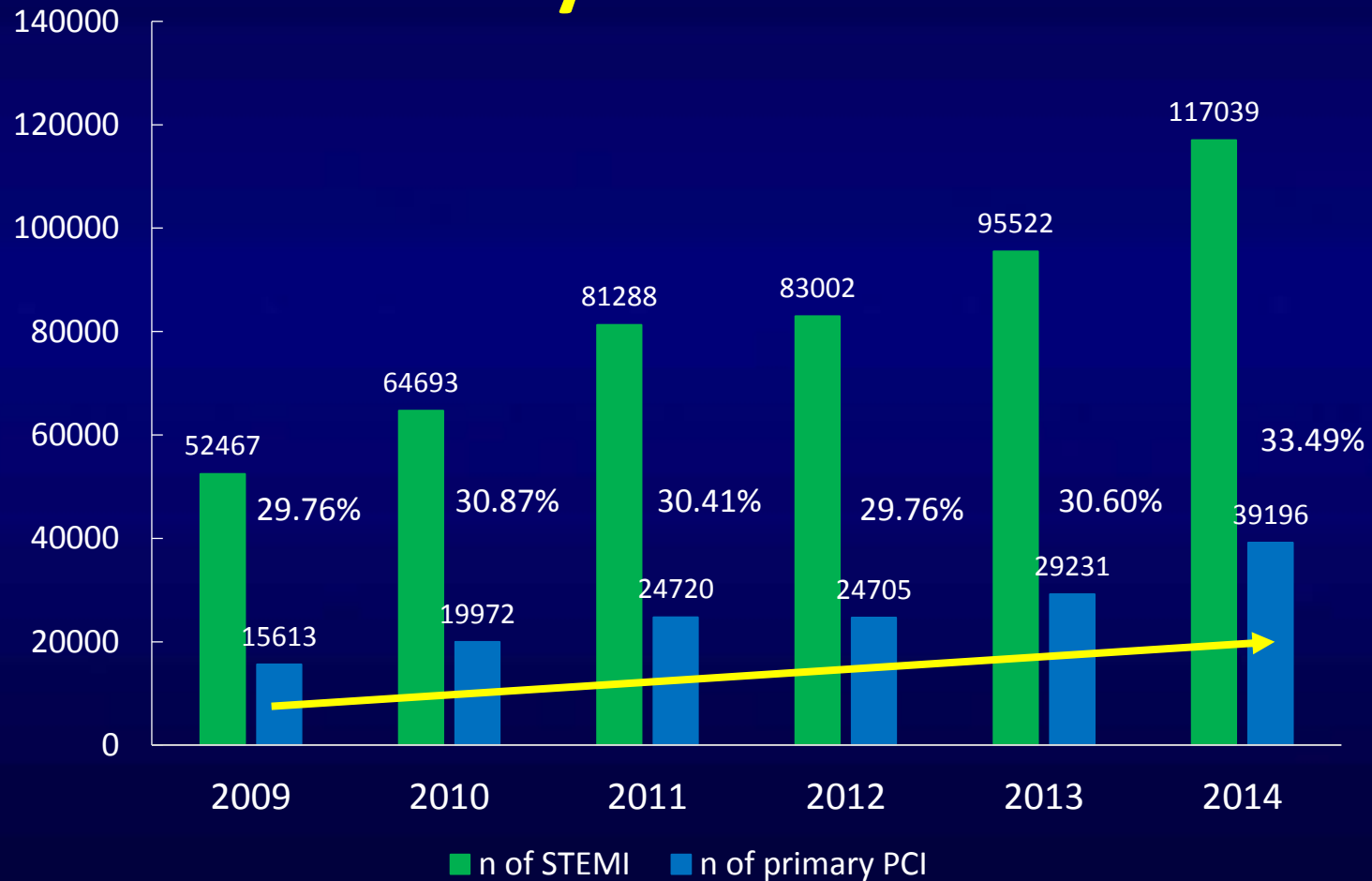
Distribution of risk factors



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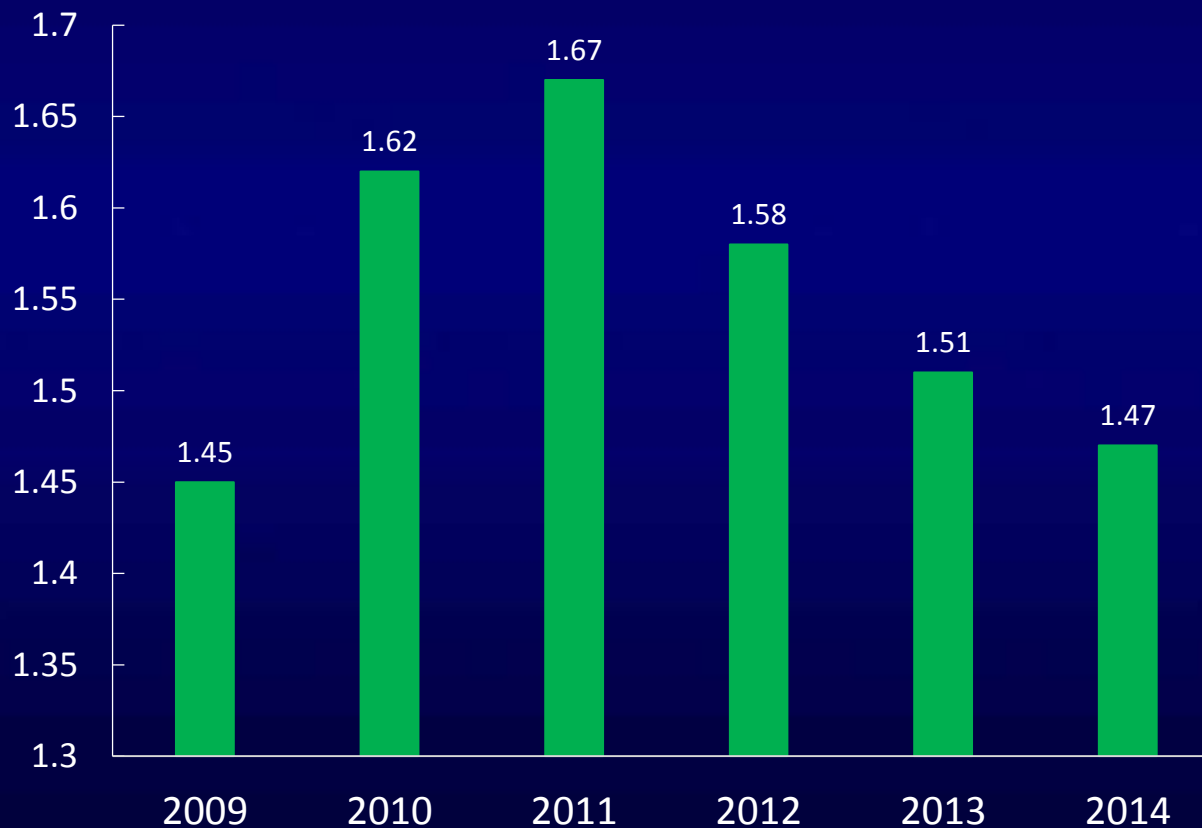
Primary PCI in STEMI



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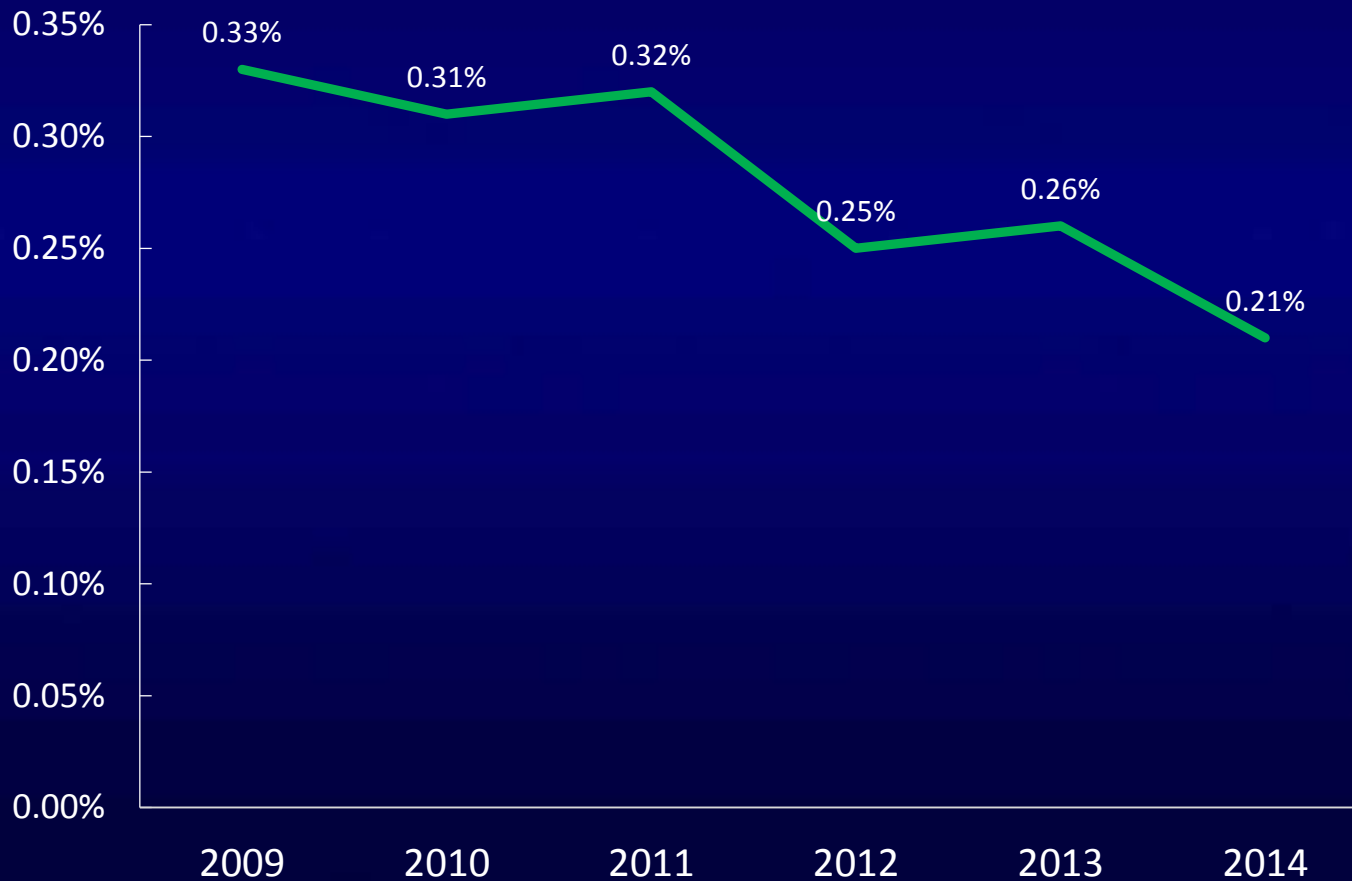
Stent(s) per patient in one procedure



Overview of China PCI



Mortality peri-PCI



Overview of China PCI



BRS in China

- Rapidly developed since 2006
- First domestic BRS (XINSORB) implantation in Sept. 2013
- Over 300 patients were treated with BRS
- 2 kinds of BRS (XINSORB & NeoVas scaffold) in clinical trail
- More BRS (including magnesium stent) will be introduced into clinical practice

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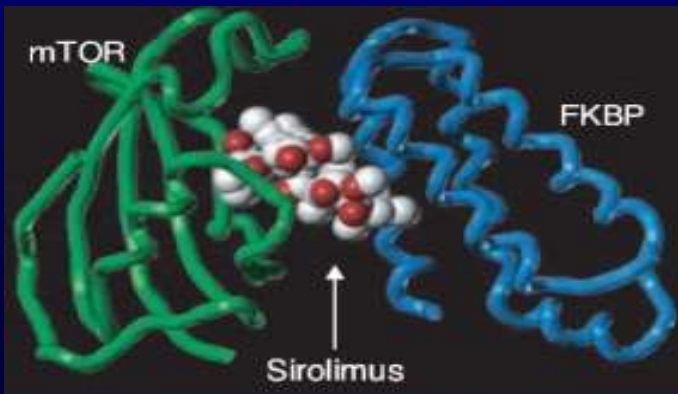


XINSORB Scaffold

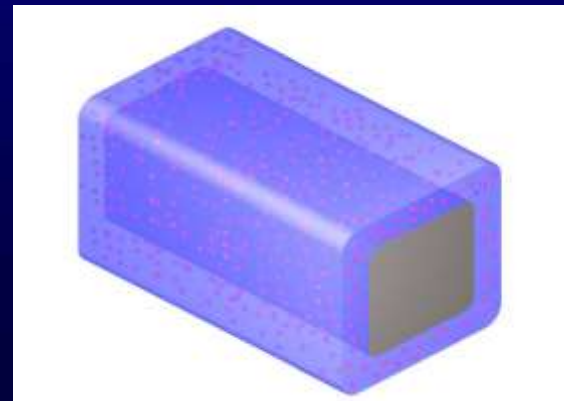


Rx. & balloon
expandable

1. PLLA bioresorbable compositions
2. 150 μm thickness
3. Radial strength similar to BMS
4. Sirolimus-eluting
5. Available size: 2.75mm, 3.0mm and 3.5mm in diameter; 12mm, 15mm, 18mm, 23mm and 28mm in length



Sirolimus



P-DL-LA polymer
carrying sirolimus

Overview of China PCI

First in Man (FIM) (Apr.2013)



Clinical FU (N=30)

Post-procedure 30days 90days 180days 270days 365days

Angiographic FU (N=30)

Study objective:	Prospective, bi-centers, first-in-man clinical trial
PI:	Prof. Junbo GE
End point:	Primary point: MACE at 30 days FU and LLL at 180 days FU Secondary point: instantly device / procedure success, in-stent / in-segment restenosis, and TLR
Treatment:	Single <i>de novo</i> lesion with %DS \geq 50% and <100%, TIMI grade >1. Diameter of lesion 2.75mm ~ 3.25mm (based on QCA). Length of lesion must \leq 24mm.
Device sizes:	Scaffold diameter: 3.0mm Scaffold lengths: 12, 15, 18, 23, 28mm

Overview of China PCI Study Profile



30 patients in the intention-to-treat population

3 patients excluded
1 bailout stenting used
2 personally refused angiographic FU

27 patients analyzed with
QCA at 6 months

19 patients analyzed by
IVUS and OCT

30 patients clinically assessed at
1, 3, 6, 9 and 12 month

Overview of China PCI



Baseline Characteristic

		intention-to-treat population (n=30)	Per-treatment-evaluable population (n=27)
Age (years)		53.5 ± 9.9	53.0 ± 10.3
Men		21 (70%)	19 (70.4%)
Diabetes		4 (13.3%)	4 (14.8%)
Hypertension		16 (53.3%)	15 (55.6%)
Previous MI		2 (6.7%)	1 (3.7%)
Stable angina		5 (16.7%)	5 (18.5%)
Unstable angina		23 (76.6%)	21 (77.8%)
Target vessel	LAD	16 (53.3%)	15 (55.6%)
	LCX	8 (26.7%)	6 (22.2%)
	RCA	6 (20%)	6 (22.2%)

Overview of China PCI



Acute Data (n=30)

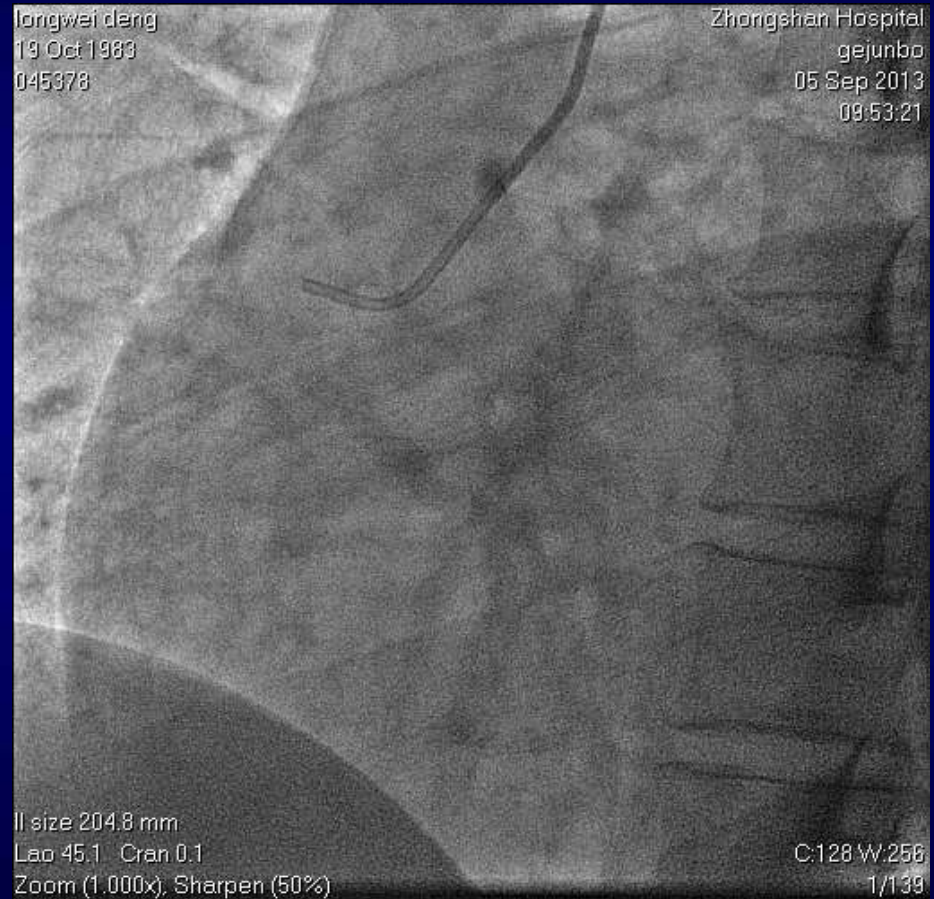
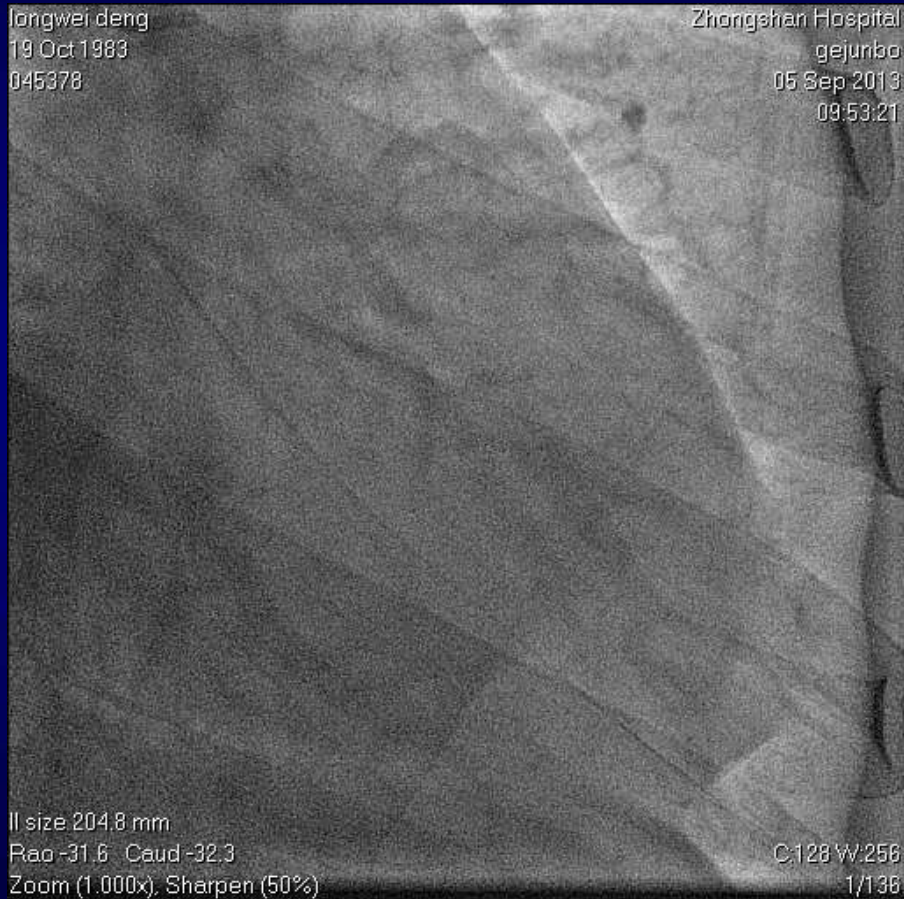
	Before procedure	After procedure	
		In-scaffold	Peri-scaffold
Diameter of Reference vessel (mm)	2.90 ± 0.30	2.92 ± 0.29	
Minimal Luminal Diameter (mm)	1.20 ± 0.40	2.61 ± 0.25	2.71 ± 0.25
Lesion length (mm)	12.75 ± 3.84	—	—
Acute gain (mm)	—	1.42 ± 0.43	1.28 ± 0.41
Percentage of diameter stenosis (%)	58.9 ± 12.4	10.4 ± 4.5	10.6 ± 4.8

Baseline

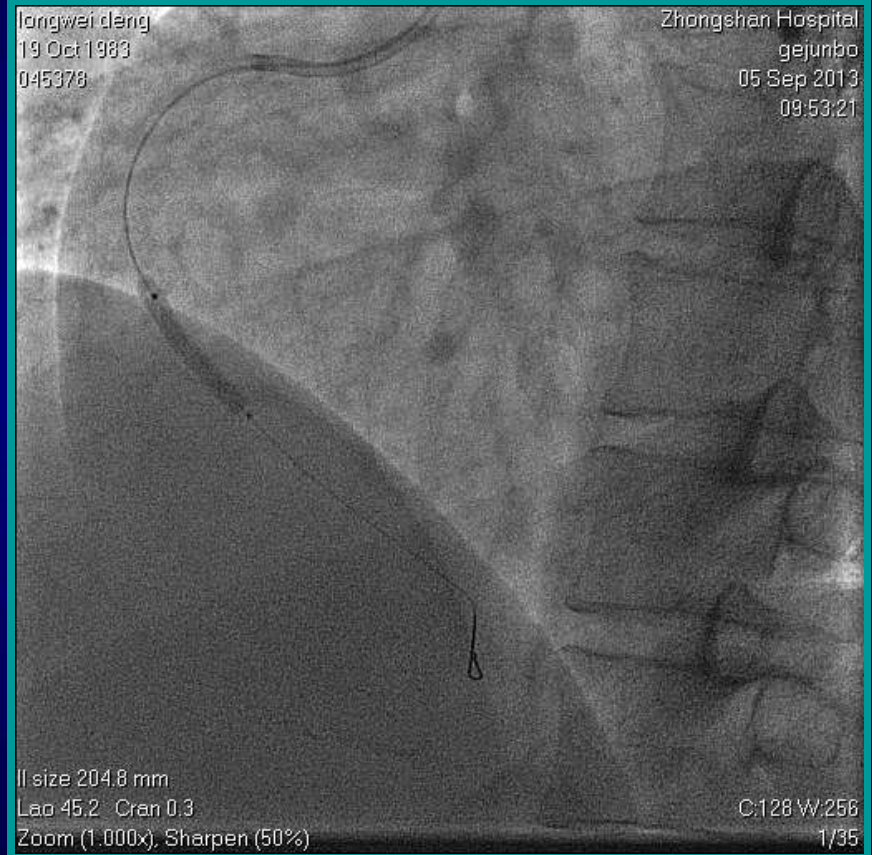


- 30-year-old Male
- inferior myocardial infarction 12 days before procedure
- No hypertension or type 2 diabetes
- Smoke for 15 years
- ECG showed Q-wave in II / III / aVF with T inversion
- ECHO showed regional wall (inferior) constriction attenuation

Coronary Angiography



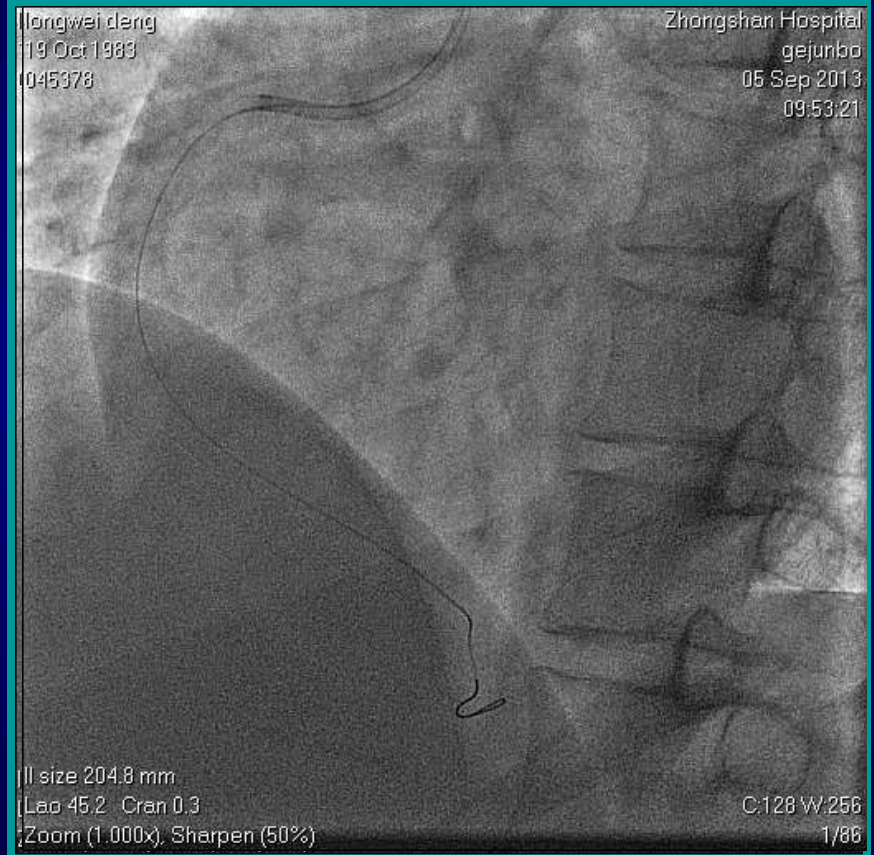
Stent deployment



Pre-dilation(Sapphire 3.0*15mm 12atm*10s)

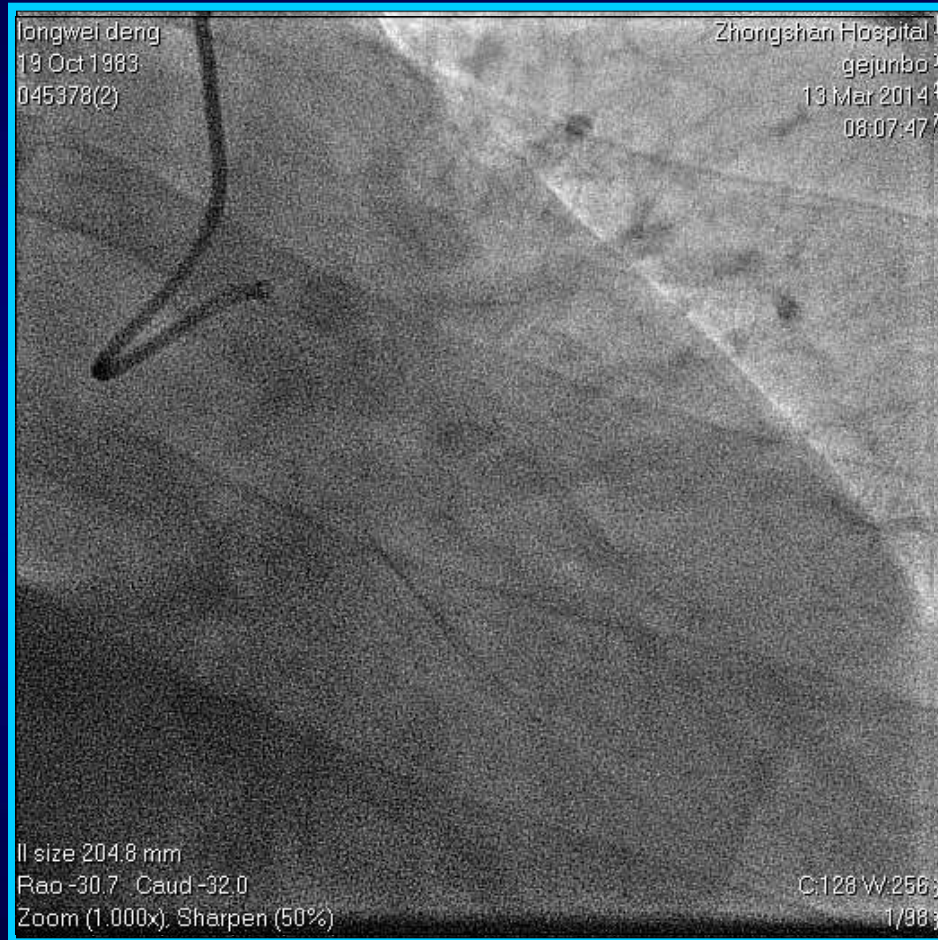
Stent deployment(xinsorb 3.0*18mm 14atm*30s)

Post-dilation and Final Result



Post-dilation(Quantum 3.25*12mm 20-22atm*10s)

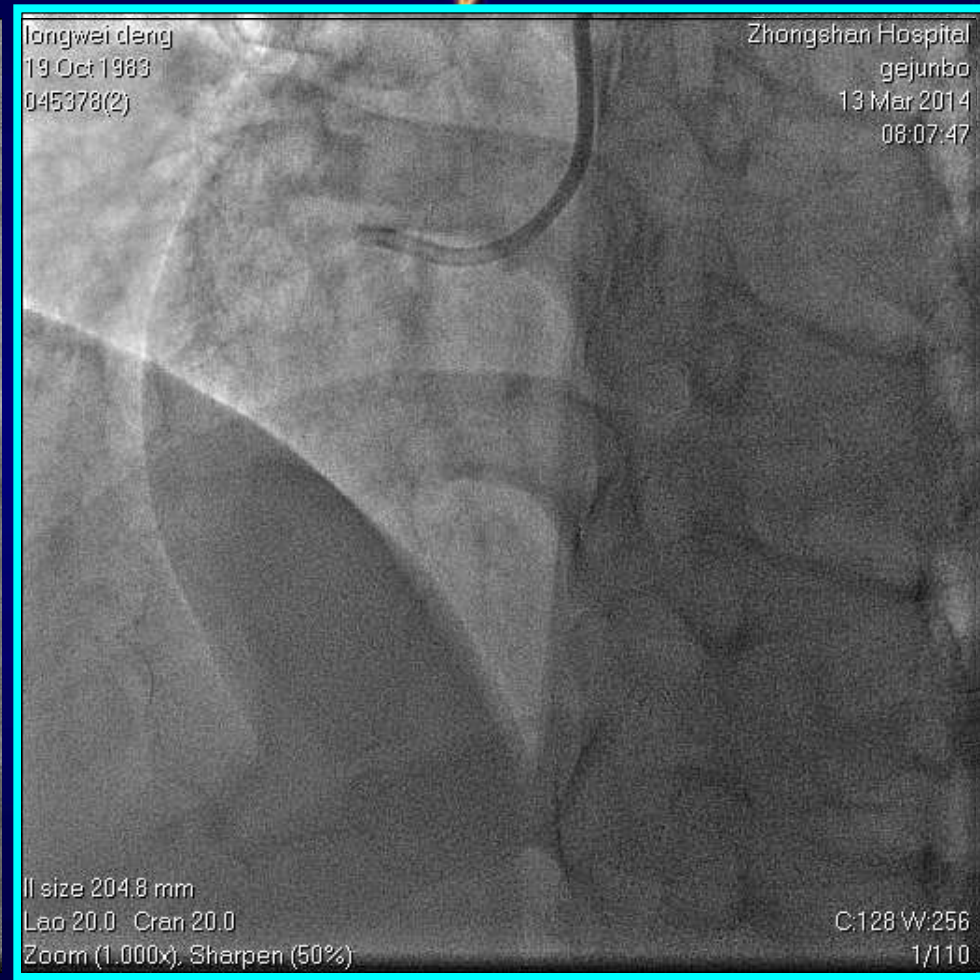
6m angiographic FU

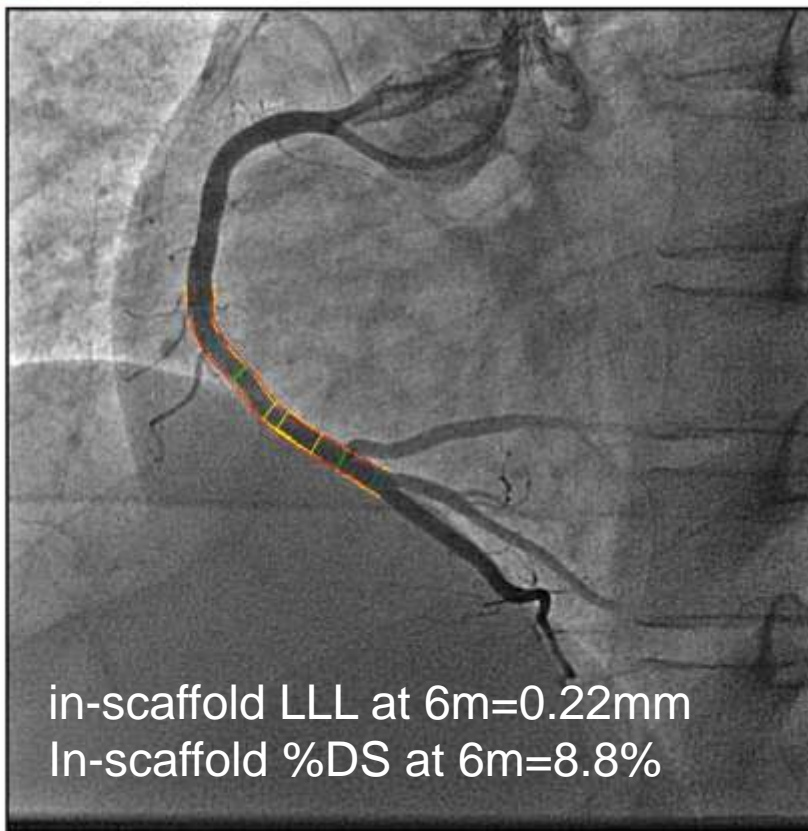


LAD and LCX

Shanghai Institute of Cardiovascular Diseases

6m angiographic FU

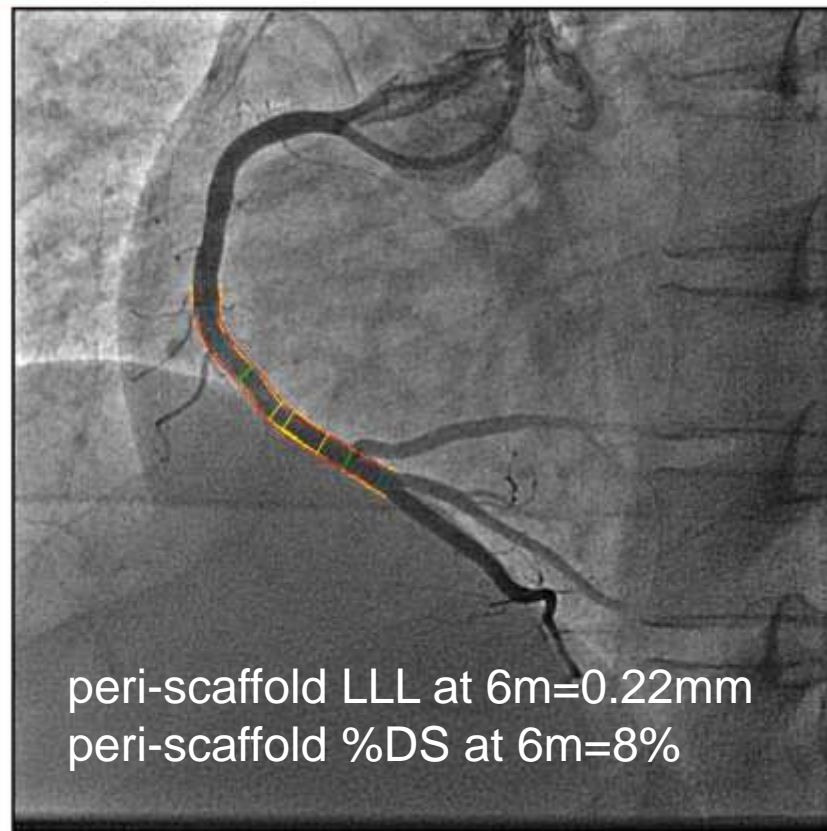




in-scaffold LLL at 6m=0.22mm
In-scaffold %DS at 6m=8.8%

病人姓名 [0]	deng longwei [045378(2)]	检查日期	检查类型	直径 (mm)	长度 (mm)	支架长度 (mm)
病人姓名	deng longwei [045378(2)]	检查日期	检查类型	直径 (mm)	长度 (mm)	支架长度 (mm)
医生姓名	张明	检查日期	检查类型	直径 (mm)	长度 (mm)	支架长度 (mm)
患者姓名	张明	检查日期	检查类型	直径 (mm)	长度 (mm)	支架长度 (mm)
患者ID	张明	检查日期	检查类型	直径 (mm)	长度 (mm)	支架长度 (mm)
患者性别	张明	检查日期	检查类型	直径 (mm)	长度 (mm)	支架长度 (mm)
患者年龄	张明	检查日期	检查类型	直径 (mm)	长度 (mm)	支架长度 (mm)
患者职业	张明	检查日期	检查类型	直径 (mm)	长度 (mm)	支架长度 (mm)
患者住址	张明	检查日期	检查类型	直径 (mm)	长度 (mm)	支架长度 (mm)
患者电话	张明	检查日期	检查类型	直径 (mm)	长度 (mm)	支架长度 (mm)
患者邮编	张明	检查日期	检查类型	直径 (mm)	长度 (mm)	支架长度 (mm)
患者邮箱	张明	检查日期	检查类型	直径 (mm)	长度 (mm)	支架长度 (mm)
患者身份证号	张明	检查日期	检查类型	直径 (mm)	长度 (mm)	支架长度 (mm)
患者医保号	张明	检查日期	检查类型	直径 (mm)	长度 (mm)	支架长度 (mm)
患者过敏史	张明	检查日期	检查类型	直径 (mm)	长度 (mm)	支架长度 (mm)
患者手术史	张明	检查日期	检查类型	直径 (mm)	长度 (mm)	支架长度 (mm)
患者家族史	张明	检查日期	检查类型	直径 (mm)	长度 (mm)	支架长度 (mm)
患者其他信息	张明	检查日期	检查类型	直径 (mm)	长度 (mm)	支架长度 (mm)

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peri-scaffold LLL at 6m=0.22mm
peri-scaffold %DS at 6m=8%

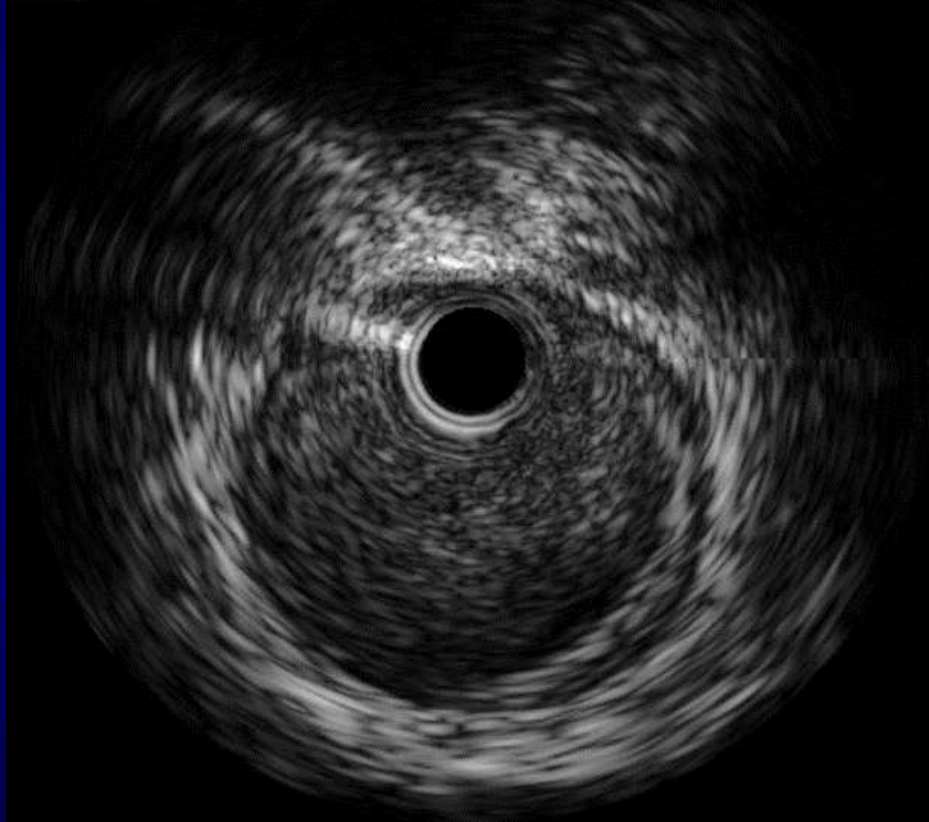
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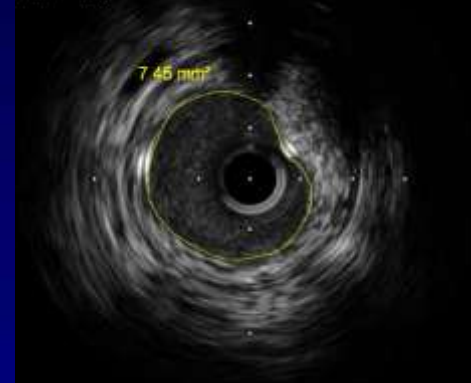
IVUS at 6m FU



Series: MainSeries:Post:RCA:RUN1(1-4340)
Frames: 1...4340 by 1
Frame Time: 0.00s
Frame: 1

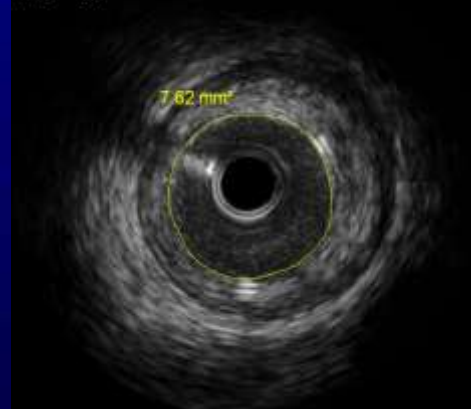


Series: MainSeries:Post:RCA:RUN2(1-2092)
Frames: 1...2092 by 1
Frame Time: 34.56s
Frame: 1026



post-procedure
luminal area =
 7.45mm^2

Series: MainSeries:Post:RCA:RUN1(1-4340)
Frames: 1...4340 by 1
Frame Time: 20.74s
Frame: 614



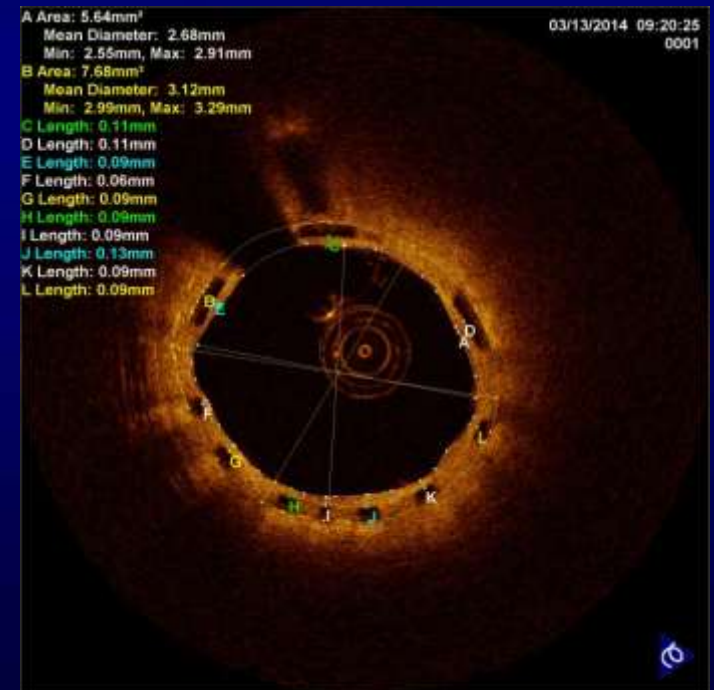
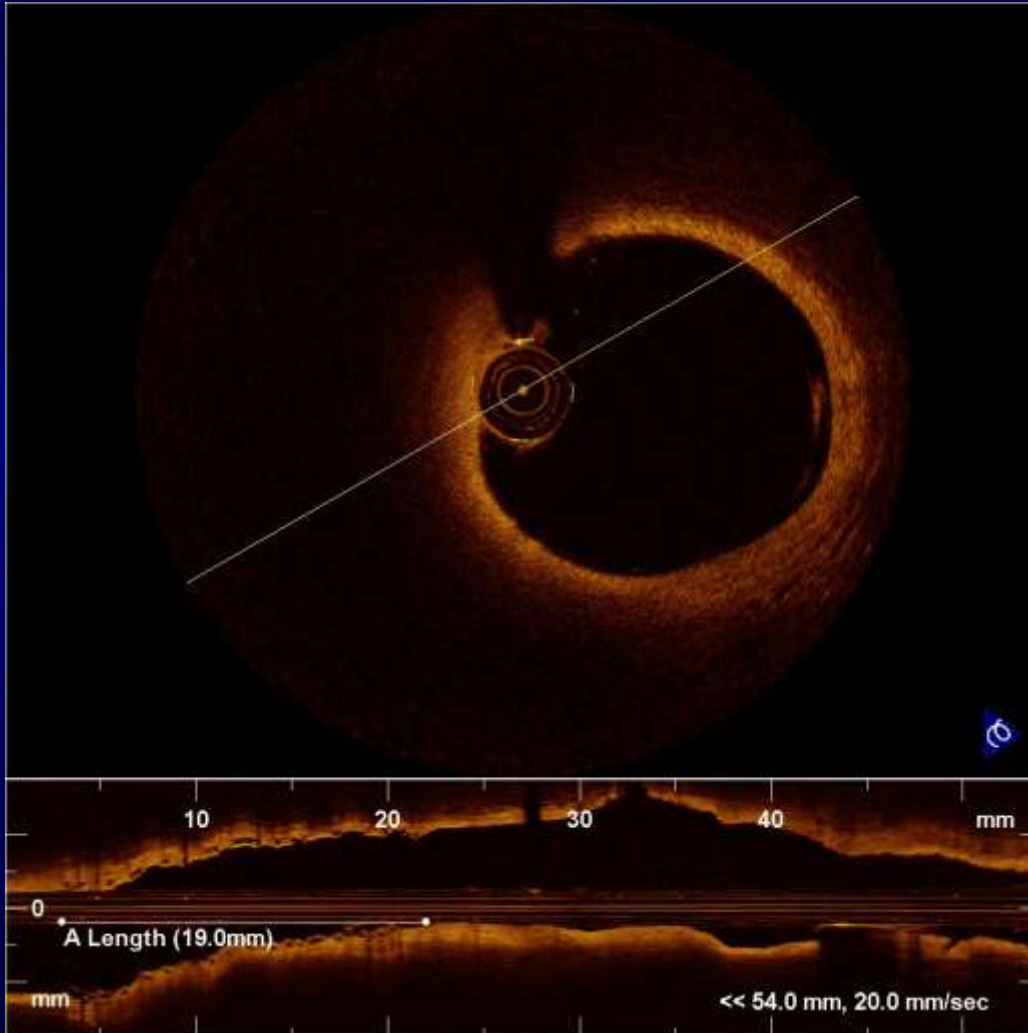
luminal area at
6m = 7.62mm^2

IVUS at 6m FU

OCT at 6m FU



1. Almost all struts were covered by neointima.
2. No stent malapposition.
3. Neointima thickness on the struts was 100 μm



6-month Angiographic FU (n=27)

	proximal	In-scaffold	distal
Diameter of reference vessel (mm)			
After p	<p>In-scaffold LLL = 0.17 ± 0.12 mm</p> <p>Peri-scaffold LLL = 0.13 ± 0.24 mm</p>		
6-mont			
P value			
Minimal l			
After p			
6-mont			
P value	0.11	0.02	0.36
Acute gain (mm)	—	1.43 ± 0.43	—
Late luminal loss (mm)	0.17 ± 0.30	0.18 ± 0.21	0.10 ± 0.32
Diameter stenosis (%)			
After procedure	6.8 ± 5.6	10.0 ± 4.2	7.2 ± 7.1
6-month follow-up	6.4 ± 5.7	10.6 ± 6.6	7.4 ± 7.5
P value	0.78	0.70	0.89

Clinical FU

MACE = 0 @ 6-month FU

No ARC confirmed/probable ST

Overview of China PCI



Prospect of China PCI

- Increase the early reperfusion rate of STEMI, decrease the D2B time
- FFR and IVUS guided PCI, identify the lesions which really matters the ischemia
- Balance the development of coronary intervention between the east and west of China
- New devices and stents are being made or introduced by several industries
- Primary prevention of CAD should be emphasized

Overview of China PCI



Thank You!