Full-Metal Jacket in CTO-PCI from AMC Registry: Safe or Not? ; insights from the Asan Medical Center CTO Registry

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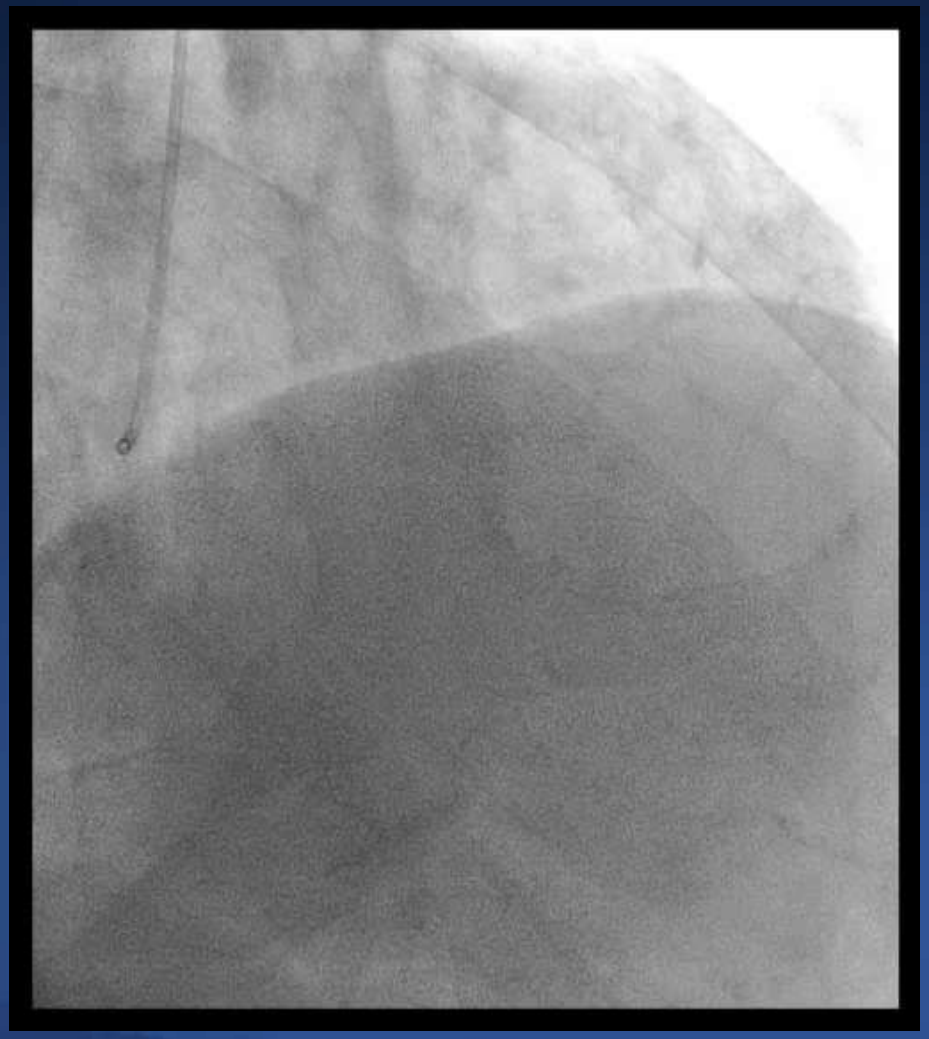
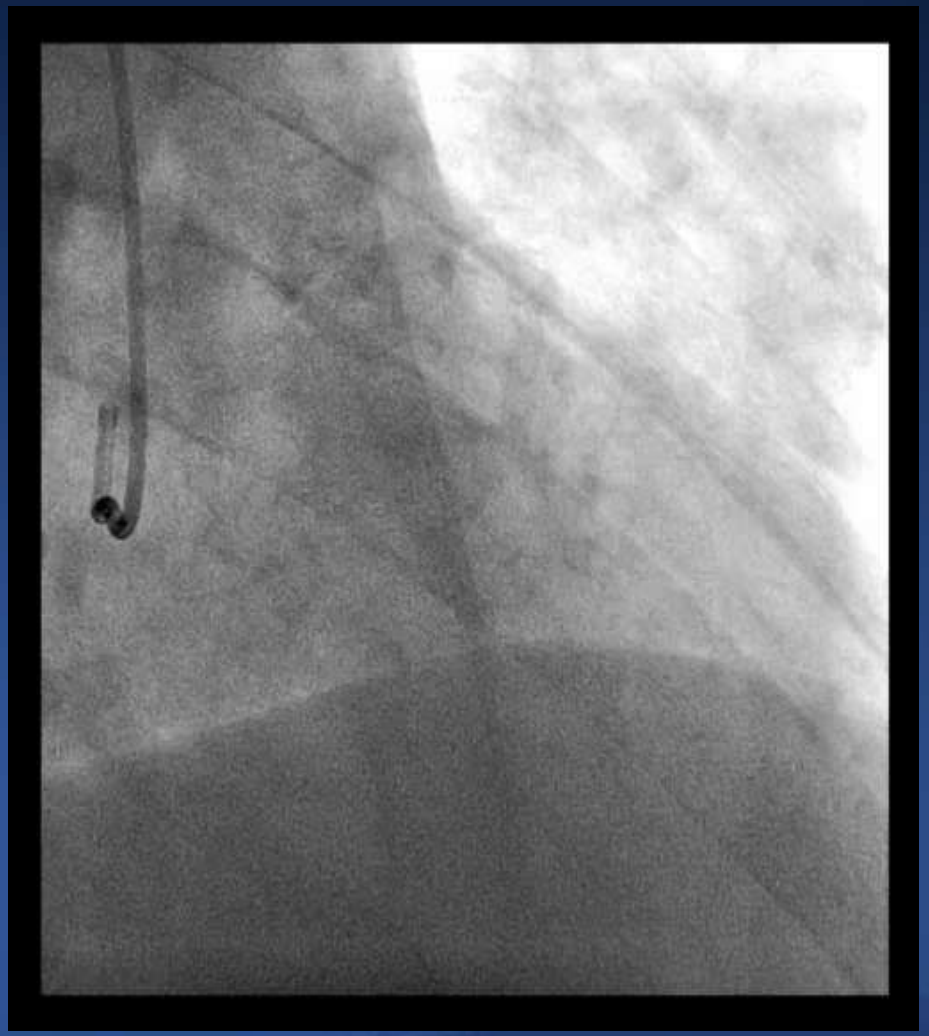
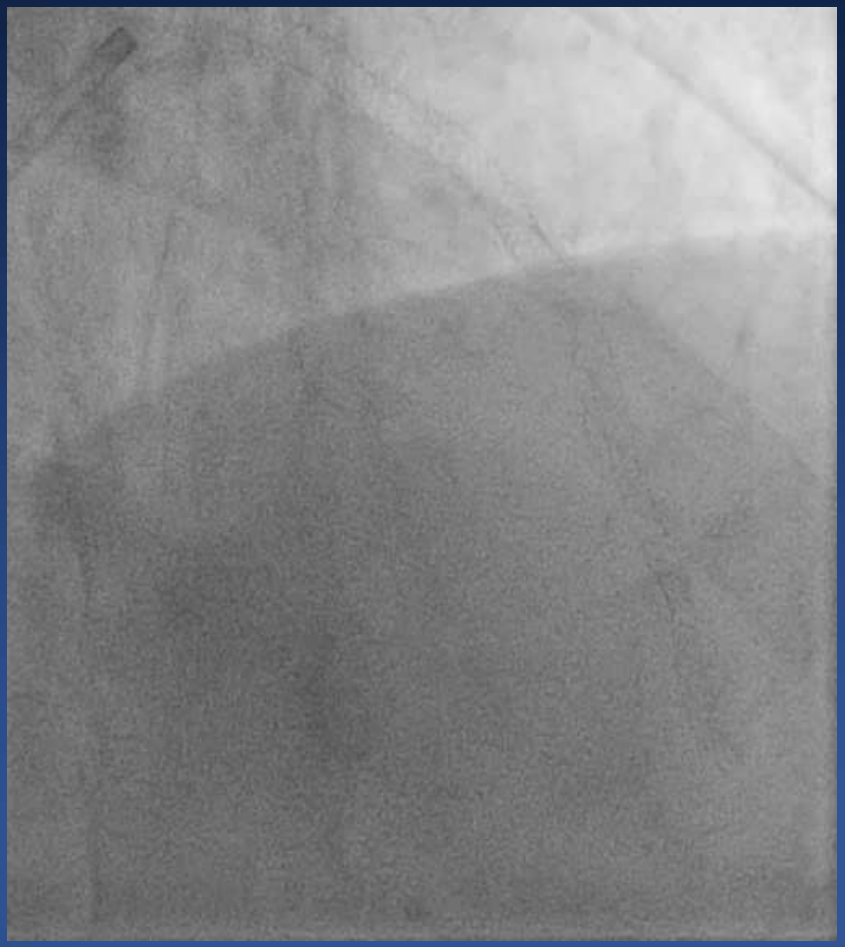
Long CTO





Long CTO



Xience 3.5/38 mm,
Xience 2.75/38 mm,
Xience 2.5/18 mm

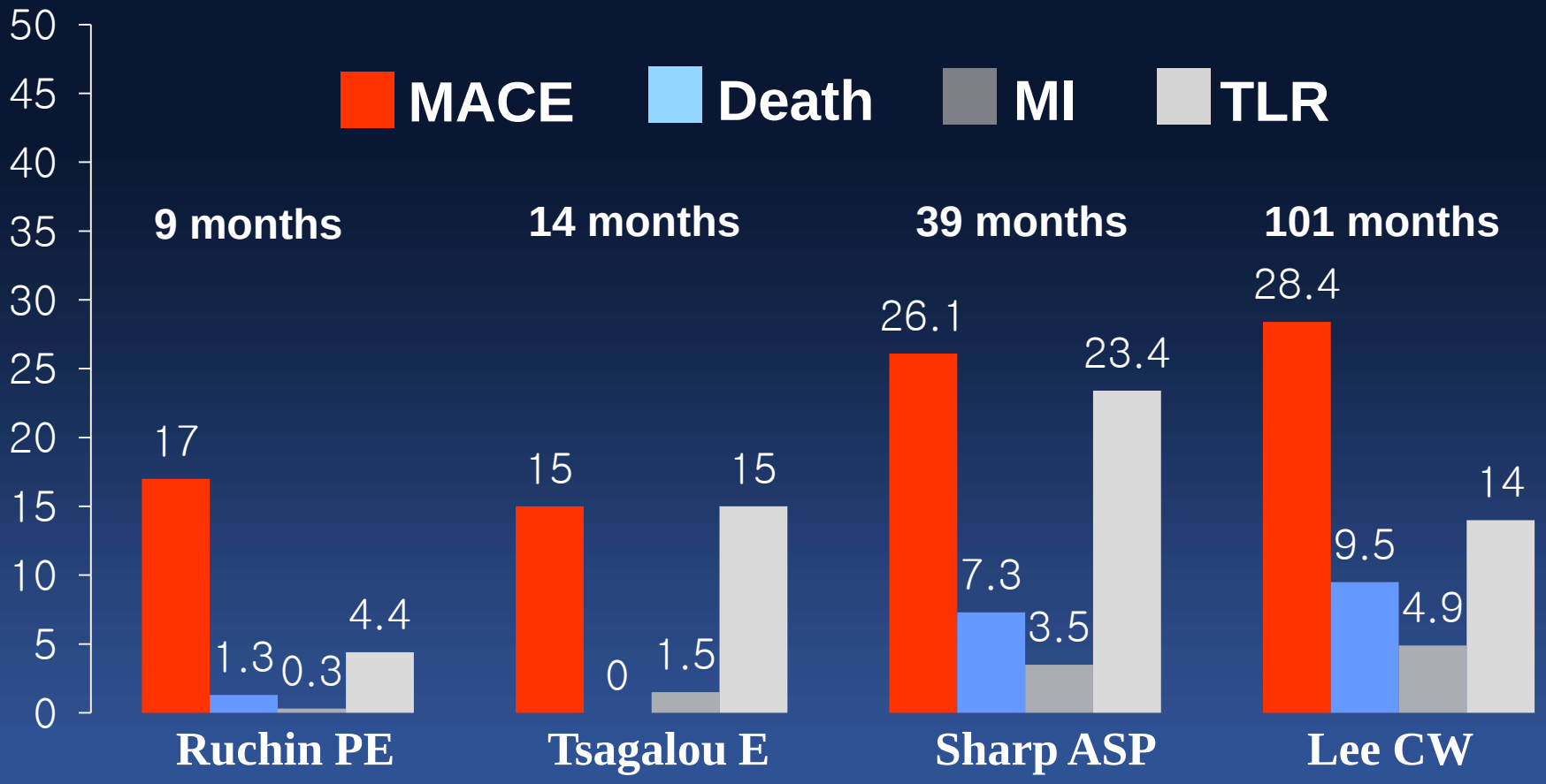
Procedure time: 180 min
Fluro time: 114 min
Contrast : 680 cc

Background

- Stent length has been identified the key factor related to higher rates of restenosis and stent thrombosis after percutaneous coronary intervention (PCI).

- Despite this limitation, previous observational studies have shown acceptable outcomes from the ‘full metal jacket (FMJ, stent length ≥ 60mm without gaps)” procedure using first generation drug-eluting stent (DES).

Full metal jacket DES



Int J Cardiol 2009;134:231-237.

Circ Cardiovasc Intervent 2009;2:416-422.

J Am Coll Cardiol 2005;45:1570–1573

Catheter Cardiovasc Interv. 2014;84:361-5

Background

- PCI of chronic total occlusion (CTO) commonly require FMJ stent implantation to cover full coronary artery lesions.
- However, long-term clinical outcomes after FMJ procedure in CTO lesion remains largely unknown.

Objective

- To evaluate long-term clinical outcomes after FMJ procedure with DES implantation for CTO

Study Population (1)

- **The Asan Medical Center CTO registry** is a pro spective, single center registry to assess the cont emporary practice and outcomes of PCI for CTO.
- Between February 2003 and August 2014, a total of 1084 patients (for 1113 CTO vessels) successf ully received DES implantation.

Study Population (2)

Inclusion Criteria

- Revascularization was clinically indicated (symptomatic angina and/or a positive functional ischemia study)
- All consecutive patients who underwent PCI for at least 1 CTO (TIMI flow grade 0 and occlusion estimated to be of at least 3-month duration)

Exclusion Criteria

- Cardiogenic shock
- Life expectancy <12 months
- PCI with a mixture of different types of DES
- A contraindication to the placement of DESs
- Patients that necessitated interruption of antiplatelet drugs within 6 months

Study Endpoints

Primary Endpoint

- MACE: Composite of death, nonfatal MI, or target-vessel revascularization

Secondary End Point

- Individual components of primary endpoints
- Cardiac and non-cardiac deaths
- Composite of death or MI
- Repeat revascularization: TVR, TLR
- Stent thrombosis: ARC definite or probable

Procedure

- Heparin was administered to maintain an ACT > 250s.
- Aspirin and clopidogrel for at least 12 months
- Limited use of GP IIb/IIIa inhibitor
- Selection of the stent type, IVUS use was at the discretion of the treating physician.
- PCI of the CTO was performed with contemporary techniques: bilateral injection, specialized wires, microcatheters, retrograde approach

Follow-up

- Clinical, angiographic, procedural, and outcome data were prospectively recorded in the dedicated PCI database by in dependent research personnel.
- Patients were clinically followed up at 1, 6, and 12 months, and annually thereafter by office visits or telephone contact.
- Angiographic follow-up was not recommended.
- All outcomes of interest were carefully verified and adjudica ted by independent clinicians.

Statistics

- Student t-test for continuous variables.
- Chi-square and Fisher-exact for categorical variables.
- *Multivariate Cox regression analyses* were used to identify the influenc e of the FMJ procedure.
- *A propensity-score analysis was performed* to control for selection biases and to determine the effect of FMJ procedure on outcome.
- All reported P-values are two-sided, and P-values of less than 0.05 we re considered statistically significance.

Baseline Clinical Characteristics

N=1084	Stent Length < 60mm (N=700)	Stent Length ≥ 60mm (N=384)	P value
Age, years	59.7±10.9	59.1±10.0	0.377
Sex, male	558 (79.7%)	336 (87.5%)	0.001
Body mass index, kg/m^2	25.4±3.1	25.6±3.2	0.374
Hypertension	417 (59.6%)	234 (60.9%)	0.697
Diabetes mellitus	194 (27.7%)	135 (35.2%)	0.013
Hyperlipidemia	440 (62.9%)	263 (68.5%)	0.072
Current smoker	179 (25.6%)	106 (27.6%)	0.472
Previous PCI	143 (20.4%)	131 (34.1%)	<0.001
Previous CABG	17 (2.4%)	15 (3.9%)	0.190
Previous myocardial infarction	60 (8.6%)	45 (11.7%)	0.107
Previous congestive heart failure	65 (9.3%)	43 (11.2%)	0.340

Baseline Clinical Characteristics

N=1084	Stent Length < 60mm (N=700)	Stent Length ≥ 60mm (N=384)	P value
Previous stroke	39 (5.6%)	28 (7.3%)	0.292
Peripheral vascular disease	11 (1.6%)	9 (2.3%)	0.357
Chronic lung disease	21 (3.0%)	8 (2.1%)	0.435
Chronic renal failure (Cr ≥ 2.0 mg/dL)	15 (2.1%)	6 (1.6%)	0.647
LV Ejection fraction, %	57.7±8.3	57.5±9.0	0.793
LV Ejection fraction <40%	25 (3.6%)	18 (4.7%)	0.416
Atrial fibrillation	12 (1.7%)	7 (1.8%)	1.000
Clinical diagnosis at presentation			0.001
Stable angina	487 (69.6%)	302 (78.6%)	
Acute coronary syndrome	213 (30.4%)	82 (21.4%)	
Multiple (≥2) CTO	48 (6.9%)	35 (9.1%)	0.190

Angiographic Characteristics

*N=1113 CTO lesions (725 versus 388)	Stent Length < 60mm (N=700)	Stent Length ≥ 60mm (N=384)	P value
CTO located in*			<0.001
Left anterior descending artery	342 (47.2%)	154 (39.7%)	
Left circumflex artery	148 (20.4%)	11 (2.8%)	
Right coronary artery	230 (31.7%)	223 (57.5%)	
Left main coronary artery	3 (0.4%)	0	
Saphenous vein graft	2 (0.3%)	0	
Restenotic CTO*	48 (6.6%)	22 (5.7%)	0.605
Multivessel disease	359 (51.3%)	232 (60.4%)	0.004
Triple-vessel disease	122 (17.4%)	78 (20.3%)	0.252
Left main disease	23 (3.3%)	21 (5.5%)	0.106
Collateral flow, Rentrop scale*			<0.001
0/1	186 (25.7%)	59 (15.2%)	
2	256 (35.3%)	157 (40.5%)	
3	283 (39.0%)	172 (44.3%)	

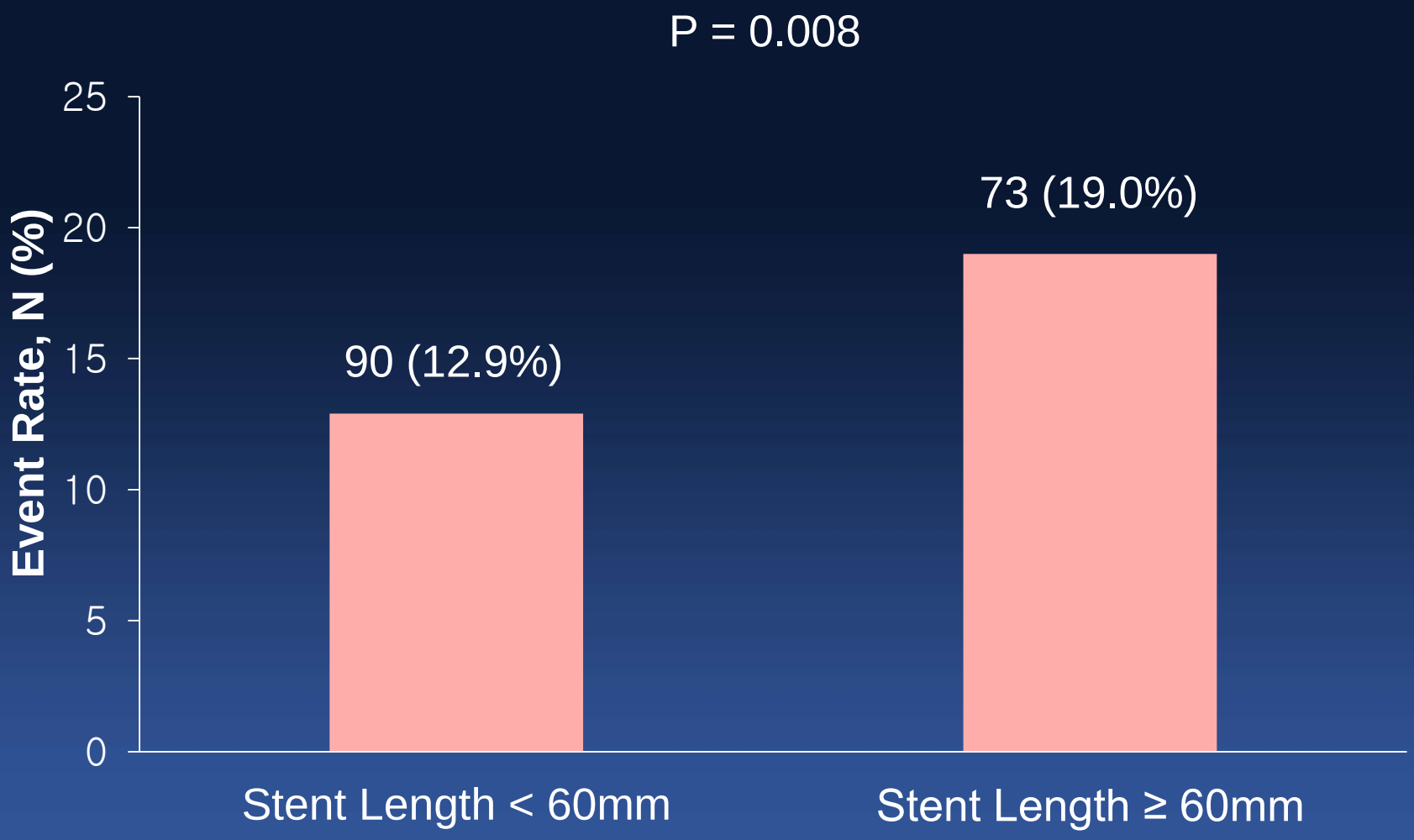
Procedural Characteristics

*N=1113 CTO lesions (725 versus 388)	Stent Length < 60mm (N=700)	Stent Length ≥ 60mm (N=384)	P value
Multivessel stenting	239 (34.1%)	125 (32.6%)	0.638
Stent, implanted*			0.004
1st generation DES	355 (49.0%)	154 (39.7%)	
2nd generation DES	370 (51.0%)	234 (60.3%)	
No. of stent per lesion*	1.35±0.49	2.54±0.61	<0.001
Length of stent per lesion (mm)*	36.1±12.2	76.6±14.5	<0.001
Average stent diameter, mm*	3.14±0.34	3.16±0.30	0.181
Double coronary injection*	180 (24.8%)	186 (47.9%)	<0.001
Success by retrograde approach*	36 (5.0%)	59 (15.2%)	<0.001
Intravascular ultrasound use*	628 (86.6%)	351 (90.5%)	0.066
Fluoroscope time, min	32±28	60±67	<0.001
Contrast amount, ml	388±28	503±218	<0.001

Medications at follow-up

Medications	Stent Length < 60mm	Stent Length ≥ 60mm	p value
Aspirin			
1 month after procedure	693 (99.4)	379 (99.2)	0.70
6 months after procedure	659 (98.2)	352 (96.2)	0.06
12 months after procedure	604 (94.8)	310 (90.6)	0.02
Clopidogrel			
1 month after procedure	692 (99.3)	378 (99.0)	0.73
6 months after procedure	643 (95.8)	347 (94.8)	0.44
12 months after procedure	512 (80.4)	277 (81.0)	0.87
Cilostazol			
1 month after procedure	146 (20.9)	130 (34.0)	<0.001
6 months after procedure	80 (11.9)	69 (18.9)	0.003
12 months after procedure	56 (8.8)	27 (7.9)	0.72

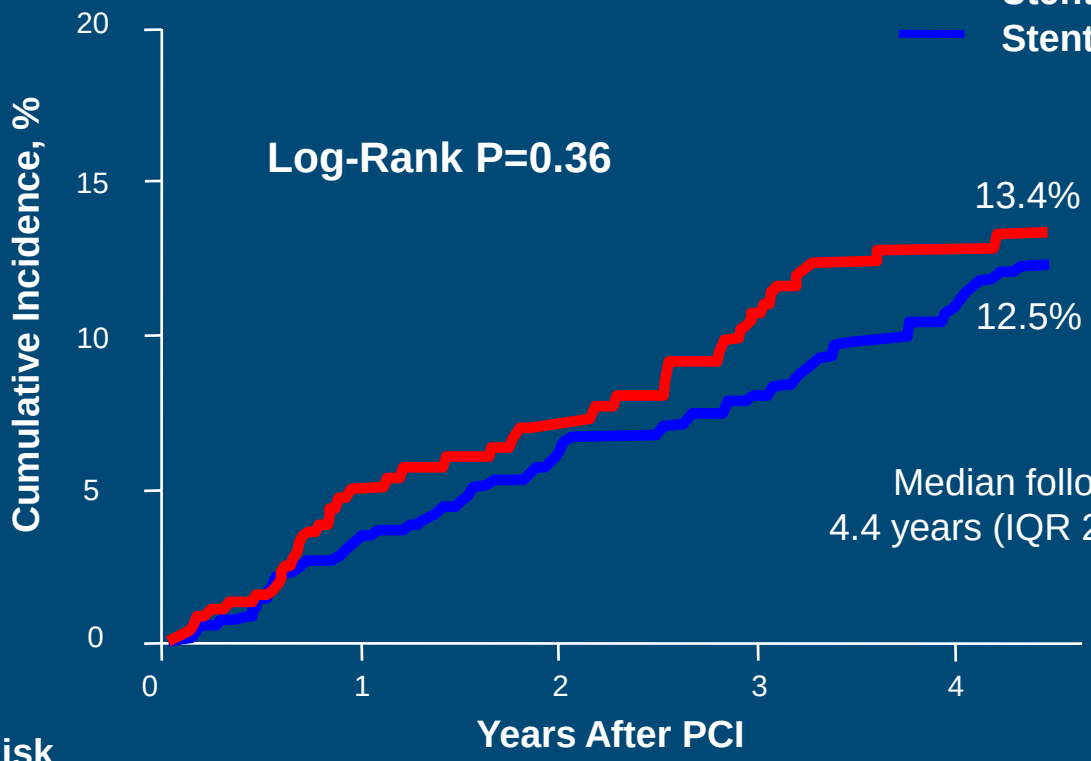
Periprocedural MI



Unadjusted Kaplan-Meier Curve

Primary End Point

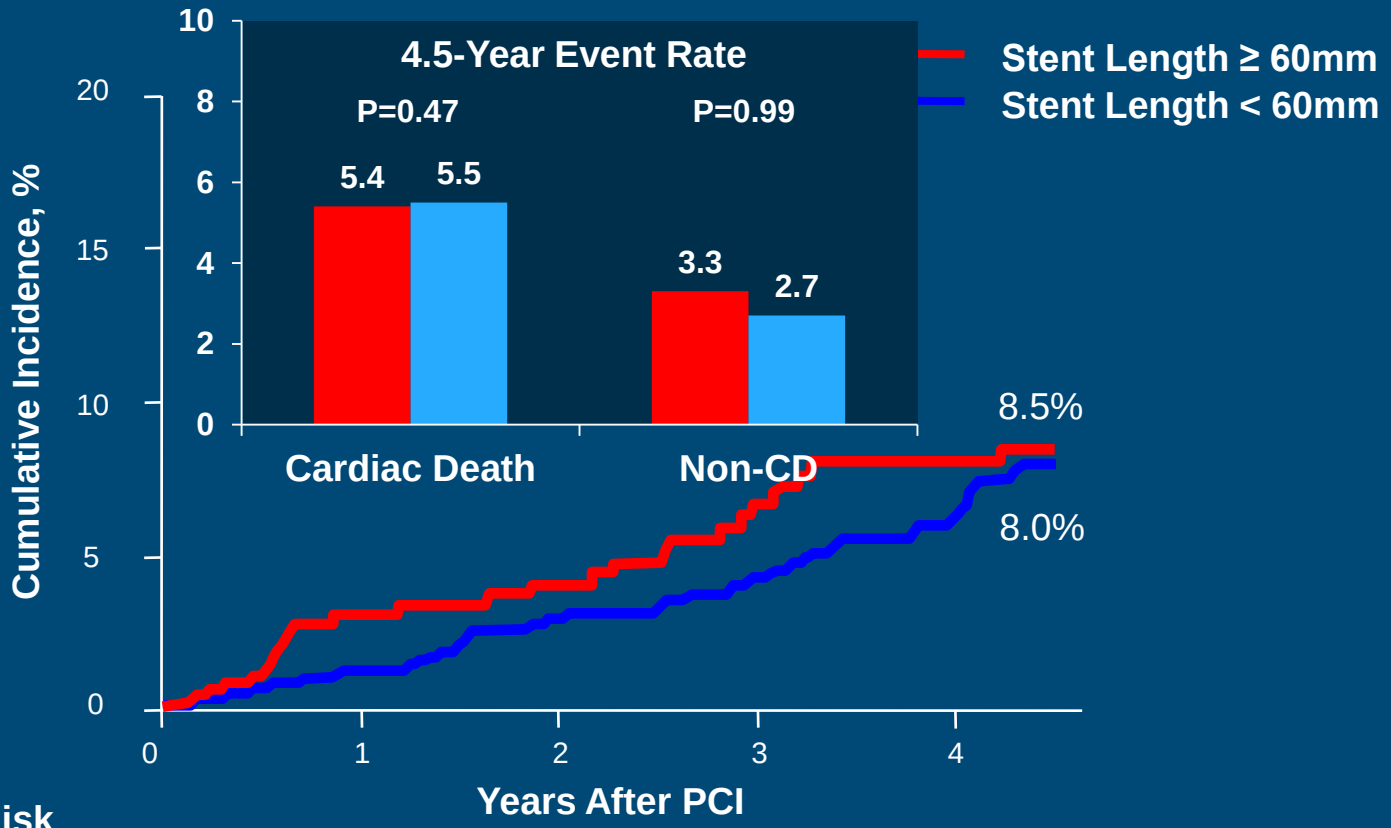
(Death, Q-MI, or Target Vessel Revascularization)



No. at Risk					
FMJ	384	312	268	219	184
Non-FMJ	700	617	527	443	380

Unadjusted Kaplan-Meier Curve

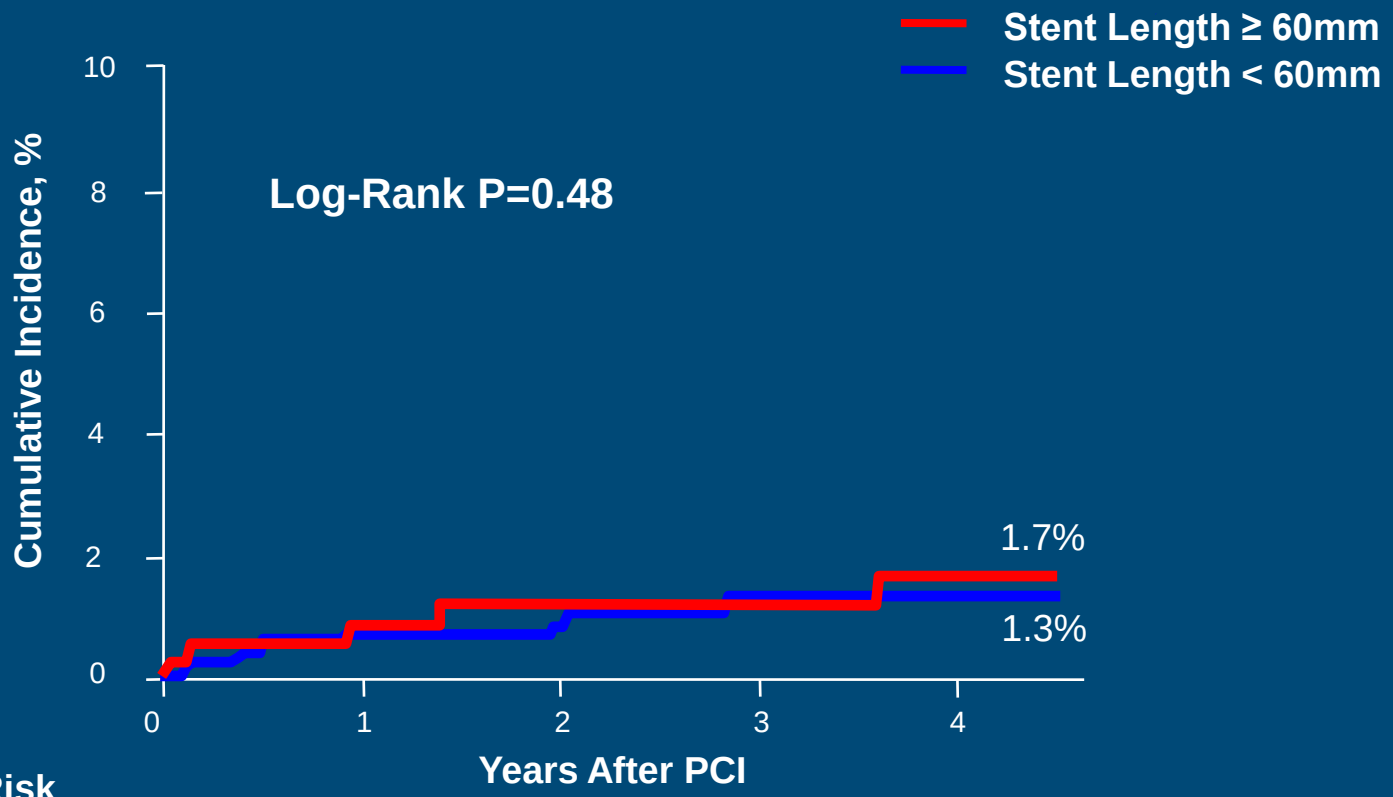
Death



No. at Risk					
FMJ	384	319	277	227	192
Non-FMJ	700	631	548	462	399

Unadjusted Kaplan-Meier Curve

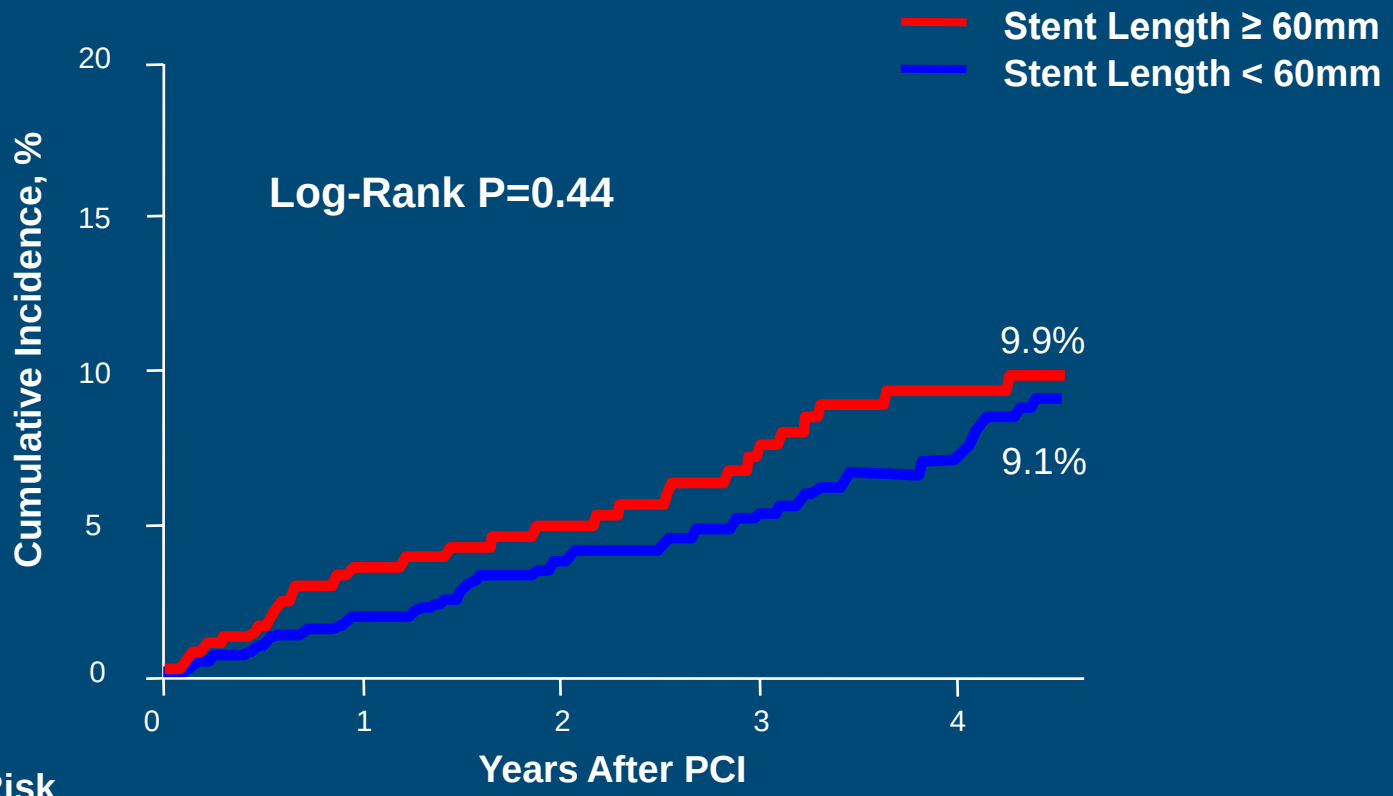
Q-wave myocardial infarction



No. at Risk					
FMJ	384	317	274	224	188
Non-FMJ	700	626	542	456	396

Unadjusted Kaplan-Meier Curve

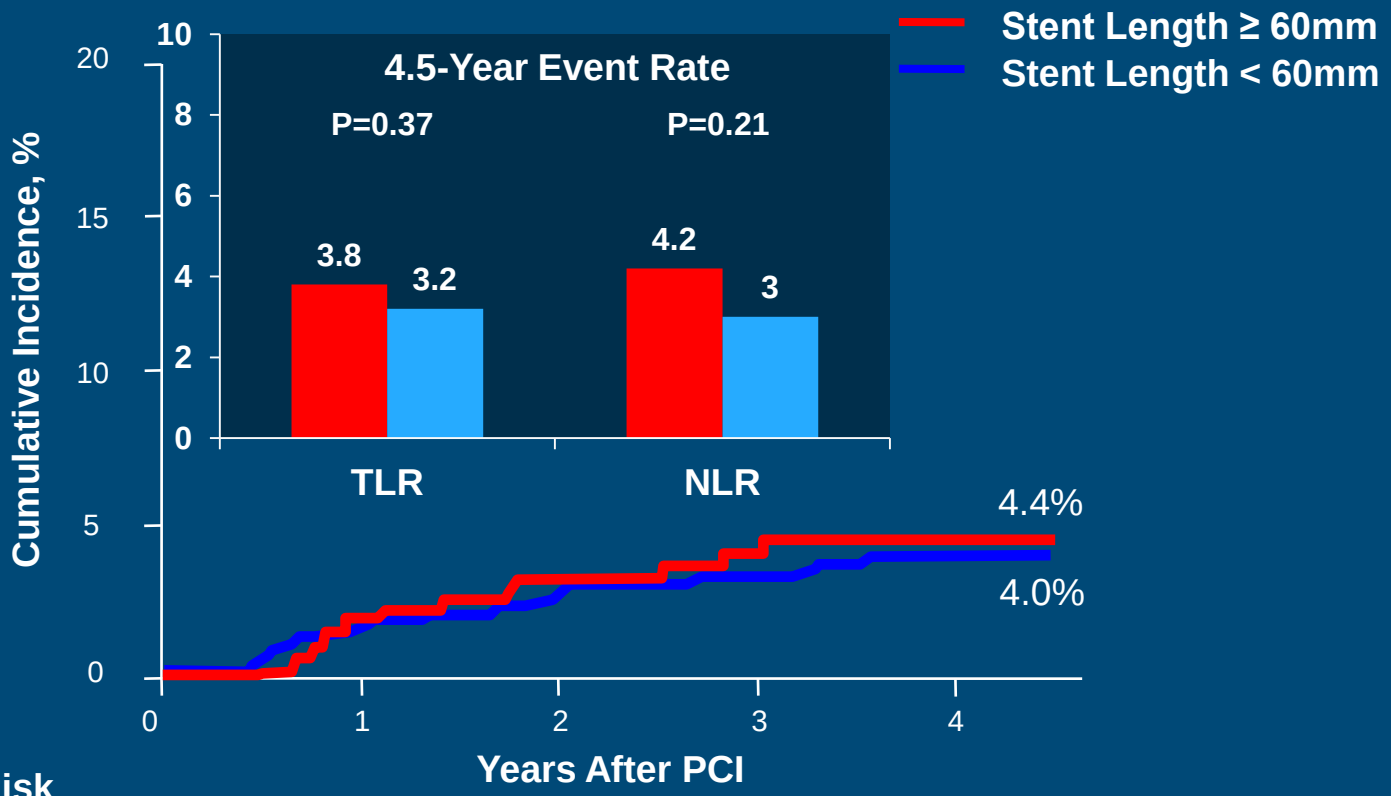
Death or Q-wave MI



No. at Risk					
FMJ	384	317	274	224	188
Non-FMJ	700	626	542	456	396

Unadjusted Kaplan-Meier Curve

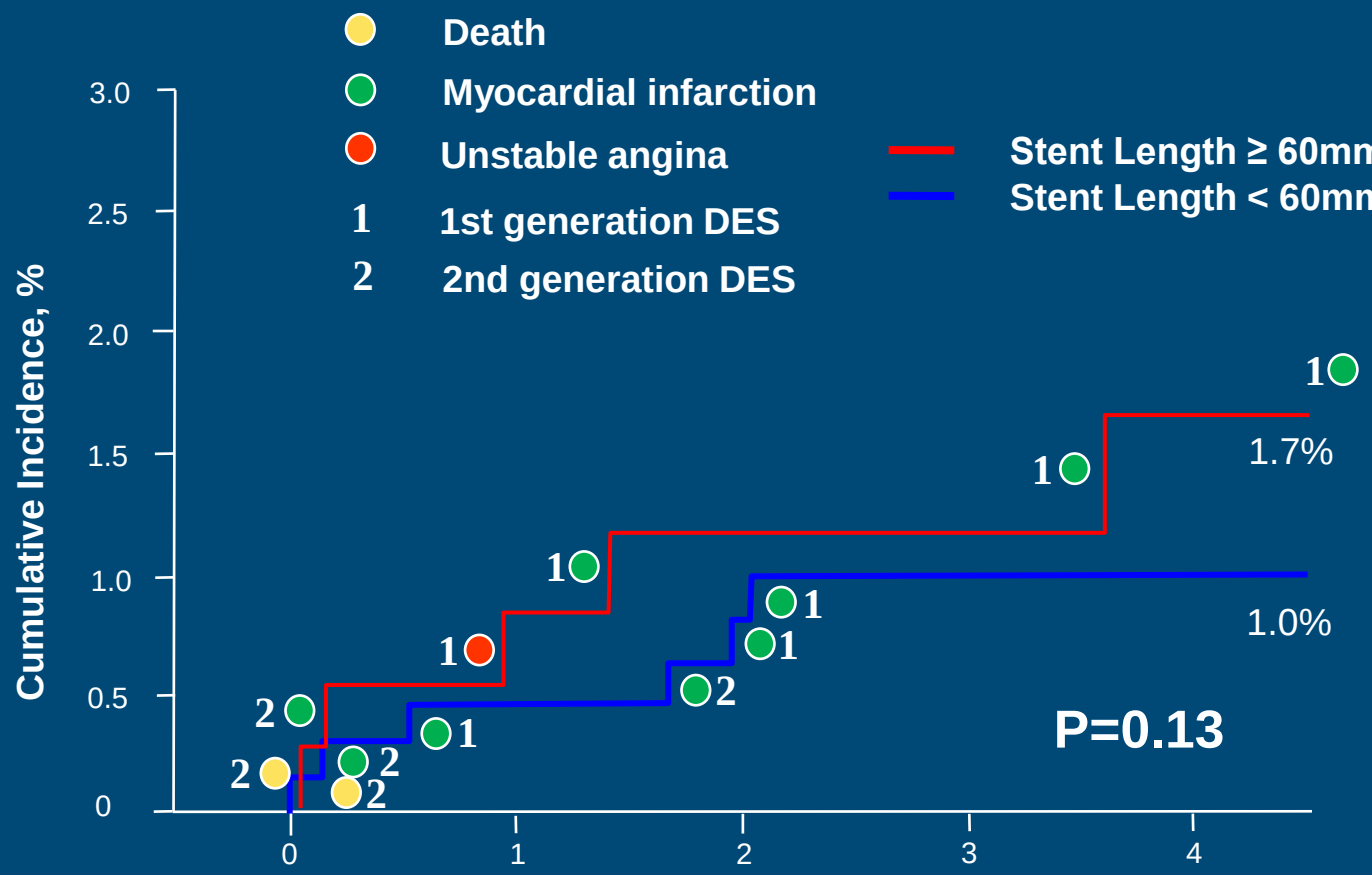
TVR



No. at Risk

FMJ	384	313	269	220	186
Non-FMJ	700	621	531	446	381

Cumulative Event Rate of Stent Thrombosis*



No. at Risk					
FMJ	384	316	274	224	188
Non-FMJ	700	629	543	458	395

* ARC defined definite and probable stent thrombosis

Crude Hazard Ratios of Clinical Outcomes

	Event rates at 4.5 years*		Hazard ratio (95% CI)	P value
	Stent Length ≥ 60mm	Stent Length < 60mm		
Death, Q-wave MI, or TVR	40 (13.4%)	69 (12.5%)	1.17 (0.83-1.64)	0.36
Secondary outcome				
Death	25 (8.5%)	42 (8.0%)	1.14 (0.74-1.75)	0.55
Cardiac death	16 (5.4%)	27 (5.5%)	1.21 (0.72-2.02)	0.47
Q-wave MI	5 (1.7%)	8 (1.3%)	1.46 (0.51-4.20)	0.49
TVR	12 (4.2%)	21 (3.6%)	1.29 (0.71-2.33)	0.40
Death or Q-wave MI	29 (9.9%)	49 (9.1%)	1.17 (0.79-1.75)	0.44

***Event rates are shown as Kaplan-Meier estimates (No and percent of events)**

Adjusted Hazard Ratios of Clinical Outcomes

	Multivariable adjusted*	P value	Adjusted for propensity	P value
Death, Q-wave MI, or TVR	1.14 (0.67-1.94)	0.63	1.18 (0.82-1.70)	0.85
Secondary outcome				
Death	1.43 (0.74-2.76)	0.29	1.17 (0.74-1.85)	0.84
Cardiac death	1.17 (0.68-2.03)	0.57	1.17 (0.67-2.03)	0.58
Q-wave MI	0.90 (0.29-2.79)	0.86	1.38 (0.45-4.25)	0.57
TVR	1.34 (0.74-2.44)	0.33	1.28 (0.68-2.41)	0.45
Death or Q-wave MI	1.20 (0.66-2.18)	0.55	1.22 (0.79-1.86)	0.37

***Event rates are shown as Kaplan-Meier estimates (No. and percent of events)**

Conclusion

- 35% pts of our CTO registry received FMJ procedure
- Patients with CTO lesions who successfully underwent “FMJ” procedure with DES implantation showed acceptable 4.5-year clinical outcomes compared with patients who received shorter stent implantation.
- IVUS-guided FMJ implantation might attenuate impact of stent length
- Therefore, FMJ is acceptable option in CTO-PCI if it is performed using standard implantation technique