Percutaneous Coronary Intervention: an Update for the Internist

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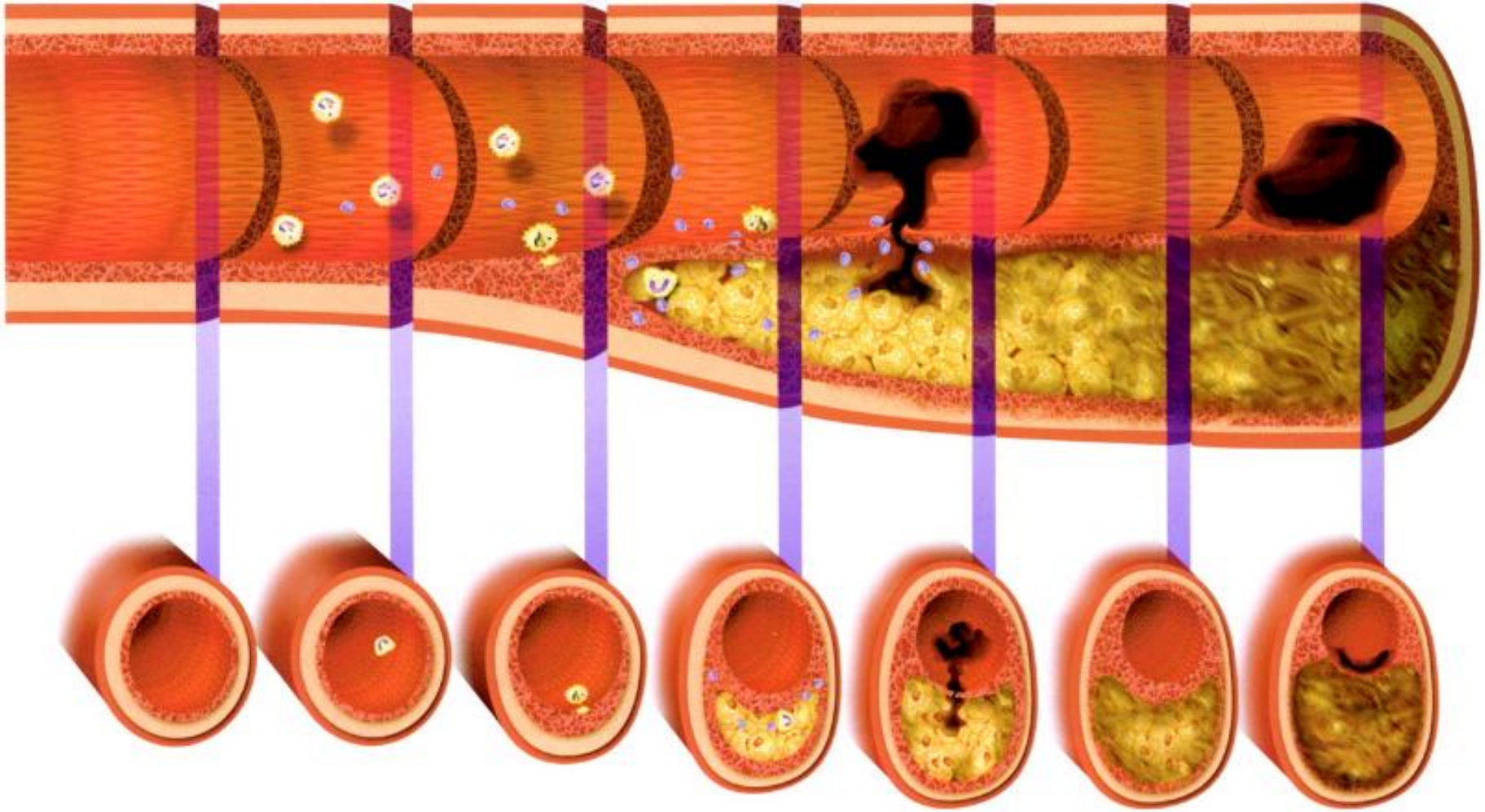
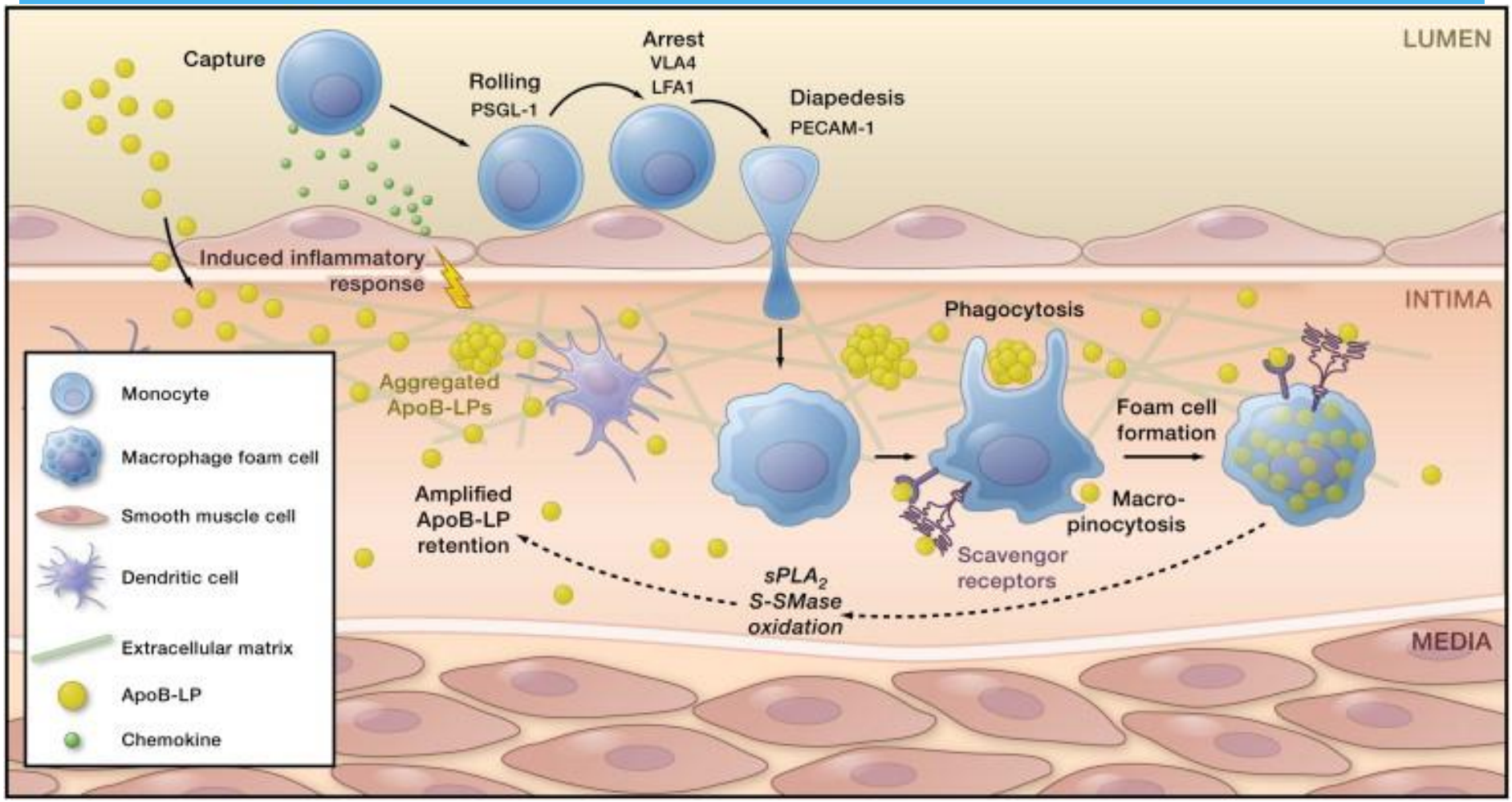
Objectives/Outline

* Background/Introduction
* Patient selection
* Stent Selection
  * Bare Metal
  * DES
  * Bio-resorbable
* Post Stenting Therapy
* Future Directions

Coronary Atherosclerosis

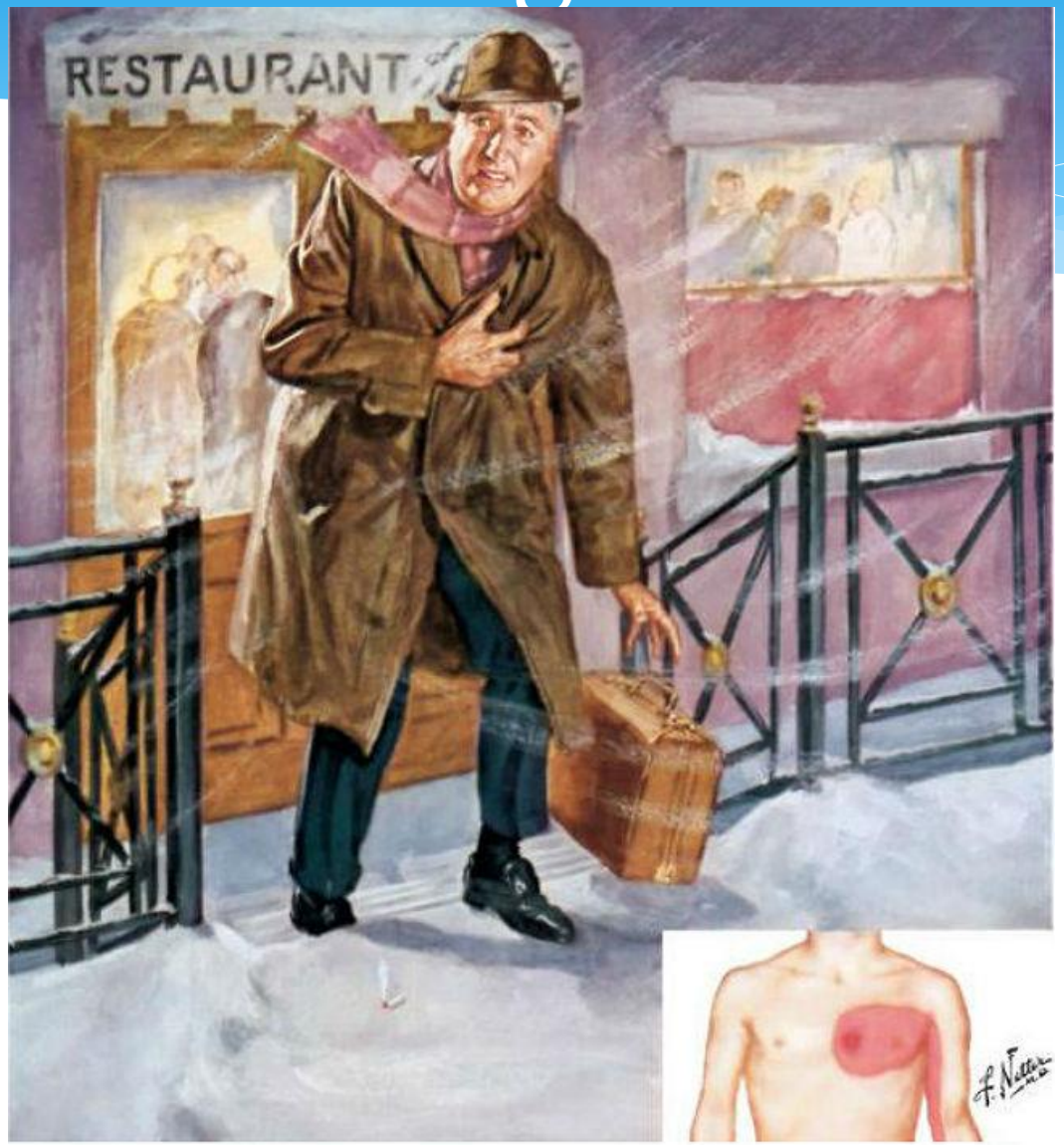


Coronary Atherosclerosis



Cell 2011 145, 341-355DOI: (10.1016/j.cell.2011.04.005)

Angina



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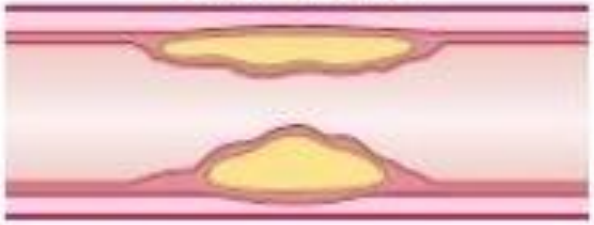
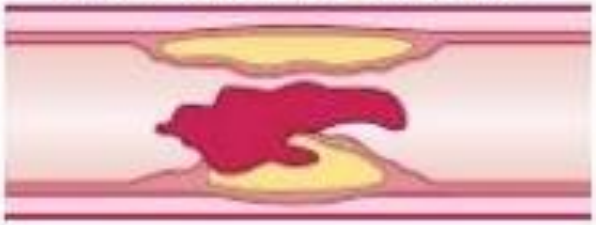
Angina

* Angina pectoris definition:
  * a syndrome characterized by paroxysmal, constricting pain below the sternum, most easily precipitated by exertion or excitement and caused by ischemia of the heart muscle, usually due to a coronary artery disease, as arteriosclerosis.

Stable vs Unstable Angina/ACS

	Stable angina	Acute coronary syndrome
		
Pathophysiology	• Fixed stenosis • Stable fibrous plaque	• Dynamic stenosis • Ruptured or inflamed plaque
Clinical features	• Demand-led ischaemia • Related to effort • Predictable • Symptoms over long term	• Supply-led ischaemia • Symptoms at rest • Unpredictable • Symptoms over short term • Frequent or nocturnal symptoms
Risk assessment	• Symptoms on minimal exertion • Exercise testing Duration of exercise Degree of ECG changes Abnormal BP response • CT coronary angiogram	• ECG changes at rest • ECG changes with symptoms • Elevation of troponin

Evaluation of Stable Ischemic Heart Disease (SIHD)

* Symptoms consistent with stable coronary artery disease.
* Proceed with stress testing

Evaluation of Stable Ischemic Heart Disease (SIHD)

Indication	Asymptomatic		Ischemic Symptoms					
	Not on AA Therapy or With AA Therapy		Not on AA Therapy		On 1 AA Drug (BB Preferred)		On ≥2 AA Drugs	
	PCI	CABG	PCI	CABG	PCI	CABG	PCI	CABG
Proximal LAD or Proximal Left Dominant LCX Involvement Present								
4. ▪ Low-risk findings on noninvasive testing	M (4)	R (3)	M (4)	M (4)	M (5)	M (5)	A (7)	A (7)
5. ▪ Intermediate- or high-risk findings on noninvasive testing	M (5)	M (5)	M (6)	M (6)	A (7)	A (7)	A (8)	A (8)
6. ▪ No stress test performed or, if performed, results are indeterminate ▪ FFR ≤0.80	M (5)	M (5)	M (6)	M (6)	M (6)	M (6)	A (8)	A (7)

Evaluation of NSTEACS

Recommendations	COR	LOE
Perform rapid determination of likelihood of ACS, including a 12-lead ECG within 10 min of arrival at an emergency facility, in patients whose symptoms suggest ACS	I	C
Perform serial ECGs at 15- to 30-min intervals during the first hour in symptomatic patients with initial nondiagnostic ECG	I	C
Measure cardiac troponin (cTnI or cTnT) in all patients with symptoms consistent with ACS*	I	A
Measure serial cardiac troponin I or T at presentation and 3-6 h after symptom onset* in all patients with symptoms consistent with ACS	I	A
Use risk scores to assess prognosis in patients with NSTE-ACS	I	A
Risk-stratification models can be useful in management	IIa	B
Obtain supplemental electrocardiographic leads V_7 to V_9 in patients with initial nondiagnostic ECG at intermediate/high risk for ACS	IIa	B
Continuous monitoring with 12-lead ECG may be a reasonable alternative with initial nondiagnostic ECG in patients at intermediate/high risk for ACS	IIb	B
BNP or NT-pro-BNP may be considered to assess risk in patients with suspected ACS	IIb	B

Evaluation of NSTEACS

Recommendations	COR	LOE
Diagnosis		
Measure cardiac-specific troponin (troponin I or T) at presentation and 3–6 h after symptom onset in all patients with suspected ACS to identify pattern of values	I	A
Obtain additional troponin levels beyond 6 h in patients with initial normal serial troponins with electrocardiographic changes and/or intermediate/high risk clinical features	I	A
Consider time of presentation the time of onset with ambiguous symptom onset for assessing troponin values	I	A
With contemporary troponin assays, CK-MB and myoglobin are not useful for diagnosis of ACS	III: No Benefit	A
Prognosis		
Troponin elevations are useful for short- and long-term prognosis	I	B
Remeasurement of troponin value once on d 3 or 4 in patients with MI may be reasonable as an index of infarct size and dynamics of necrosis	IIb	B
BNP may be reasonable for additional prognostic information	IIb	B

NSTEACS AUC

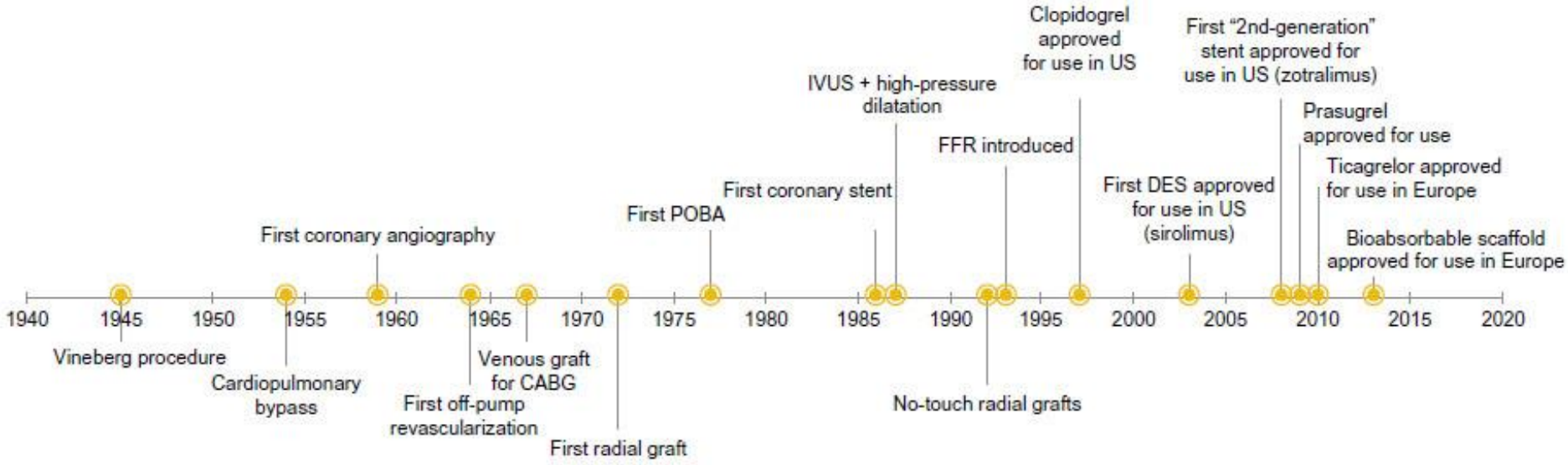
NSTEMI/Unstable Angina

	Indication	Appropriate Use Score (1–9)
Revascularization by PCI or CABG		
15.	▪ Evidence of cardiogenic shock ▪ Immediate revascularization of 1 or more coronary arteries	**A (9)**
16.	▪ Patient stabilized ▪ Intermediate- OR high-risk features for clinical events (e.g., TIMI score 3–4) ▪ Revascularization of 1 or more coronary arteries	**A (7)**
17.	▪ Patient stabilized after presentation ▪ Low-risk features for clinical events (e.g., TIMI score ≤2) ▪ Revascularization of 1 or more coronary arteries	**M (5)**

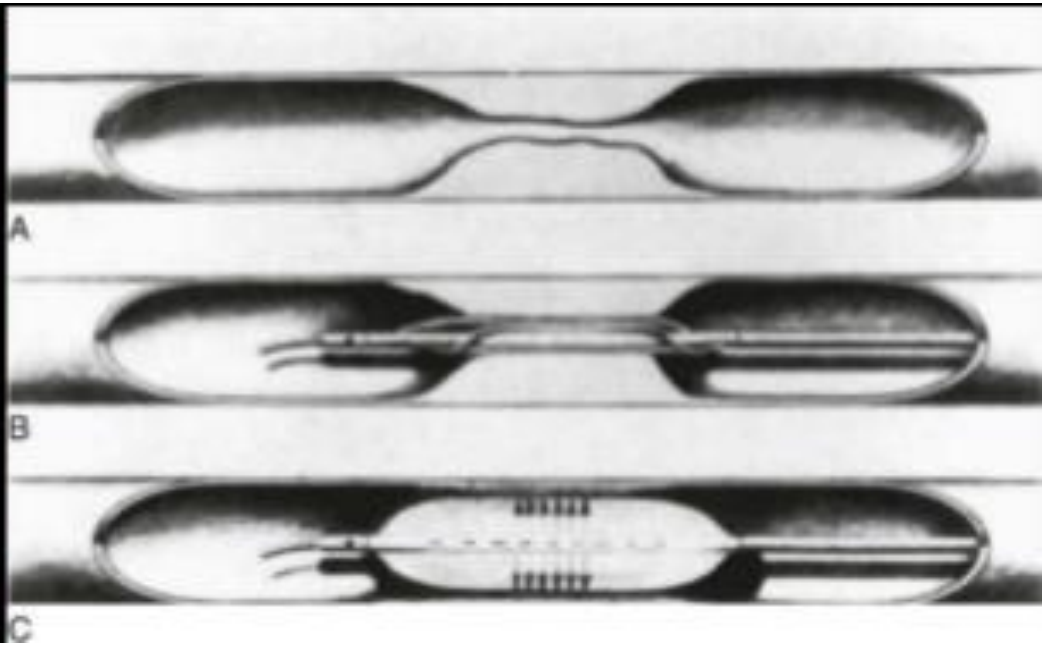
Anti-anginal Medications

* Beta Blocker
  * Metoprolol
    * Goal Dose 100mg BID
  * Coreg
    * Goal Dose 25mg BID
* CCB
  * Amlodipine
    * Goal Dose 10 mg daily
* Long acting nitrates
  * Imdur
    * Goal Dose 60 mg or more daily
* Ranolazine
  * Goal Dose 1000 mg BID

PCI Historic Timeline



Plain Old Balloon Angioplasty - PTCA



POBA/PTCA

* Initial percutaneous therapy
* High rate of restenosis (recoil)
* High rate of re-intervention (in the range of 30-50%)
* High rate of coronary artery dissection.
* Very widely available early on, however, with the advent of stents, this therapy was essentially relegated to pre-dilation of lesions, dilation of in stent lesions or as a last resort for difficult lesions.

Palmaz Shatz Stent

* **CONCLUSIONS:**
  * The implantation of a Palmaz-Schatz stent almost completely eliminates the decrease in vessel dimensions caused by elastic recoil and therefore diminishes the impact of hyperplasia and reduces the rate of restenosis.

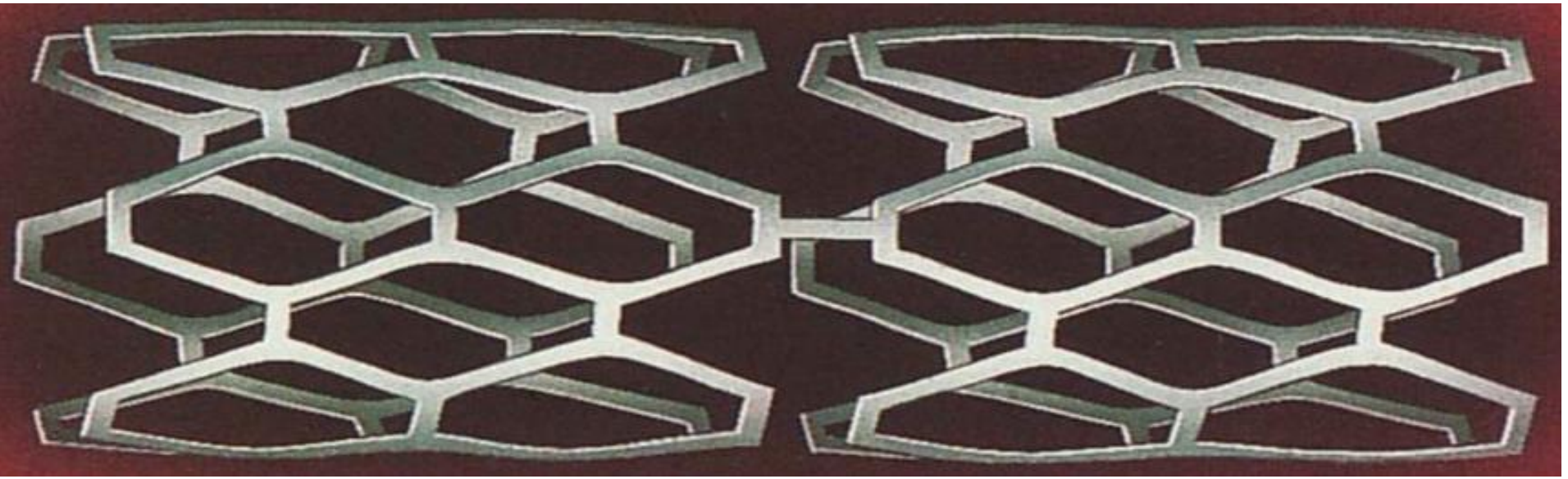
A comparison of balloon-expandable-stent implantation with balloon angioplasty in patients with coronary artery disease

Serruys PW, de Jaegere P, Kiemeneij F, Macaya C, Rutsch W, Heyndrickx G, Emanuelsson H, Marco J, Legrand V, Materne P, Belardi J, Sigwart U, Colombo A, Goy JJ, van den Heuvel P, Delcan J, Morel MA. for the BENESTENT study group. Benestent Study Group. *N Engl J Med* 1994; 331: 489–95.

Acute angiographic and procedural success rates were similar between the two groups. At seven-month follow-up, the primary clinical end point was achieved in 30% of patients in the balloon angioplasty group versus 20% of patients in the stent group ($p = 0.02$). The difference in primary end point was largely driven by the significant reduction in TLR in the stent group (10% vs. 21%; $p = 0.001$). Furthermore, the incidence of re-stenosis was 22% in the stent group versus 32% in the POBA group ($p = 0.002$). Bleeding and vascular complications were significantly higher in the stent group who received warfarin in addition to dual antiplatelet therapy (13.5% vs. 3.1%; $p < 0.001$). In addition, the mean hospital stay was significantly longer in the stent group compared with the POBA group (8.5 vs. 3.1 days; $p < 0.001$).

Palmaz Schatz Stent

* Thick struts
* Very early design
* No very deliverable



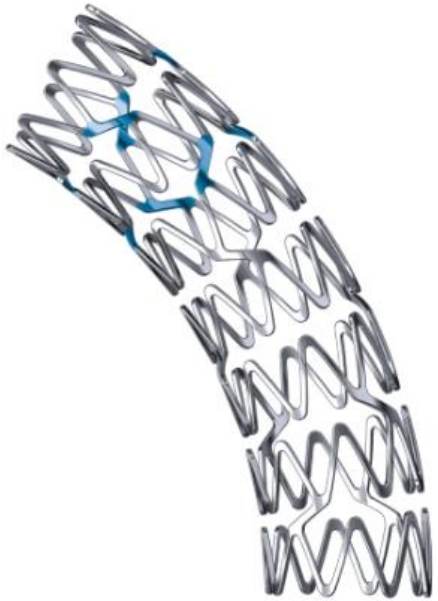
2nd generation Bare Metal Stent

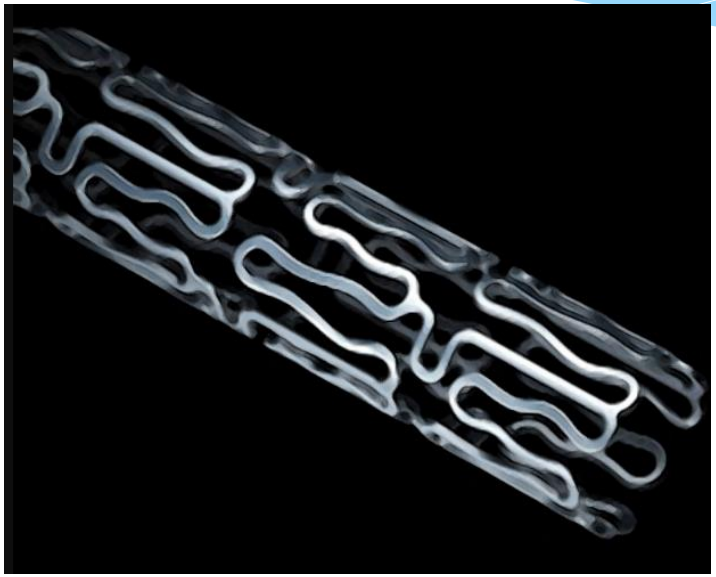
* Multi-link Vision stent – Abott Vascular
* Rebel Stent – Boston Scientific
* Intergrity - Medtronic

2nd generation Bare Metal Stent

* Multi-link Vision stent – Abott Vascular
  * CoCr alloy
  * Open cell design
  * Thin struts
* Rebel Stent – Boston Scientific
  * PlCr alloy – allows for better visibility
  * Open cell design
  * Thin struts
* Driver – Medtronic
  * CoCr alloy
  * Open cell design
  * Thin struts

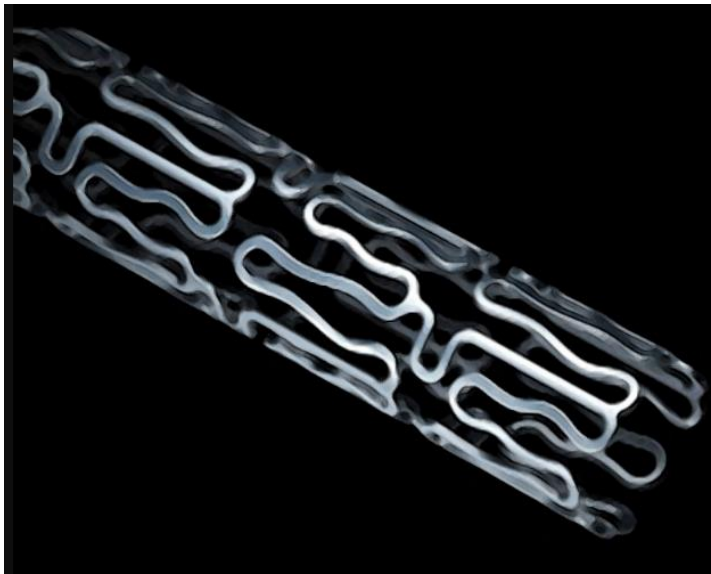
2nd generation Bare Metal Stent





Multi-Link Vision

* Approved through Vision registry data in 2003.
* 268 patient enrolled
* 11% TLR at 270 days
* No stent thrombosis

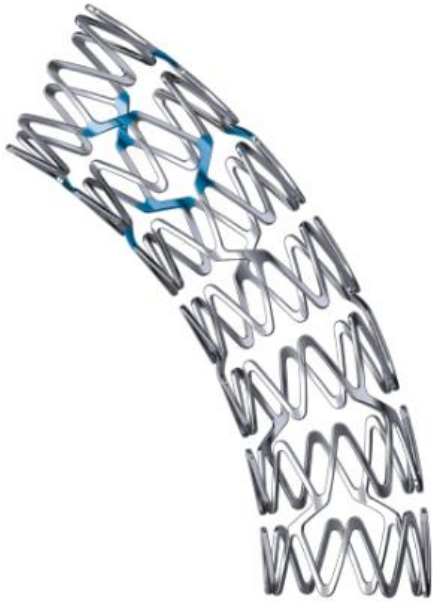


Driver

* Approved through the Driver Regist[illegible]
* 298 patient enrolled
* 7% TLR at 270 days
* No stent thrombosis

Rebel

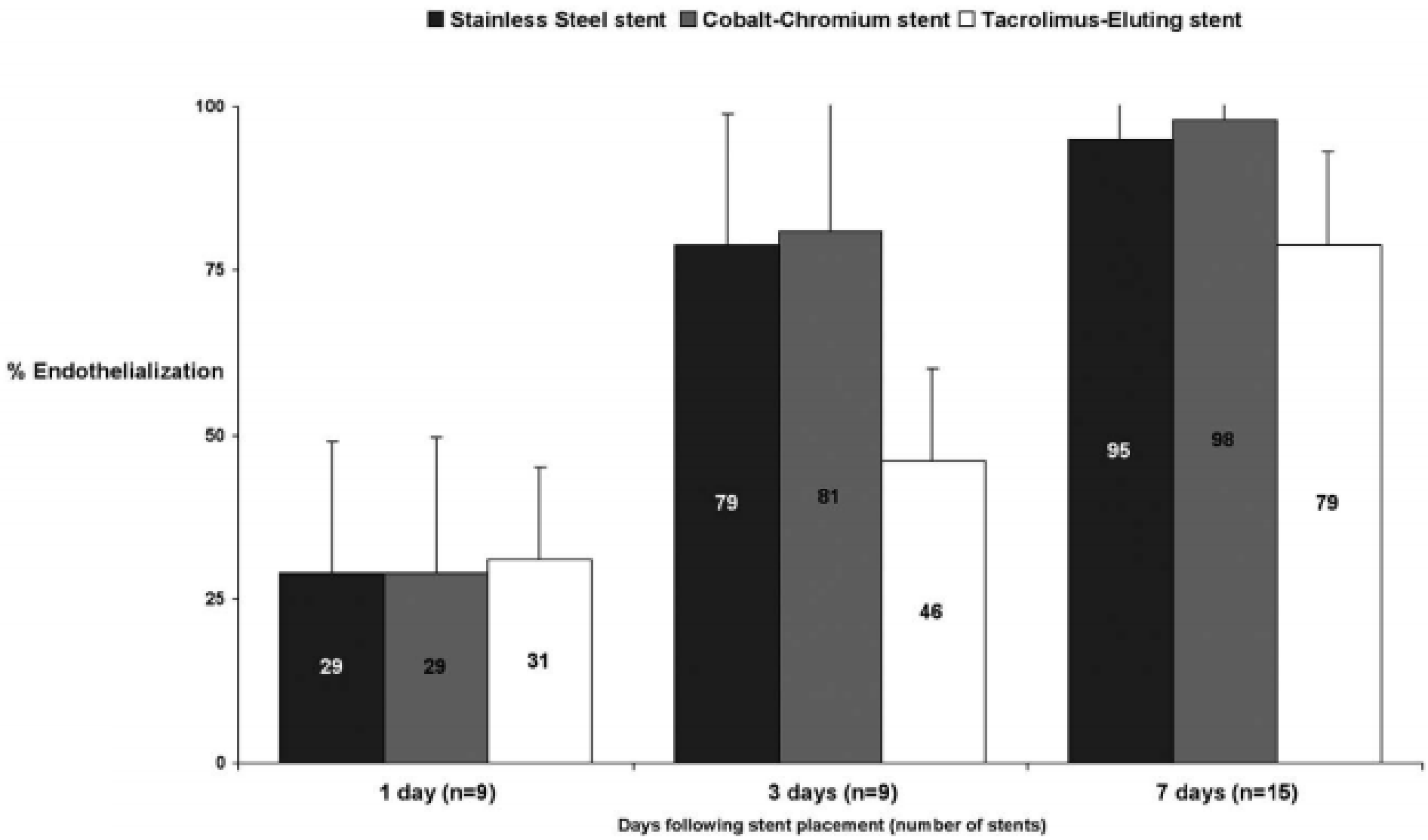
* Approved through OMEGA trial 2014
* 328 patient enrolled
* 7% TLR at 270 days
* 0.6% stent thrombosis



Bare Metal Stents

* Endothelialize fairly rapidly
* This leads to
  * a lower rate of ST than say a DES
  * Increased rate of restenosis and TLR
* Mostly indicated for patients felt to be poor candidates for long term DAPT
  * Adherence issues
  * Upcoming surgeries

Bare Metal Stents



Drug Eluting Stents

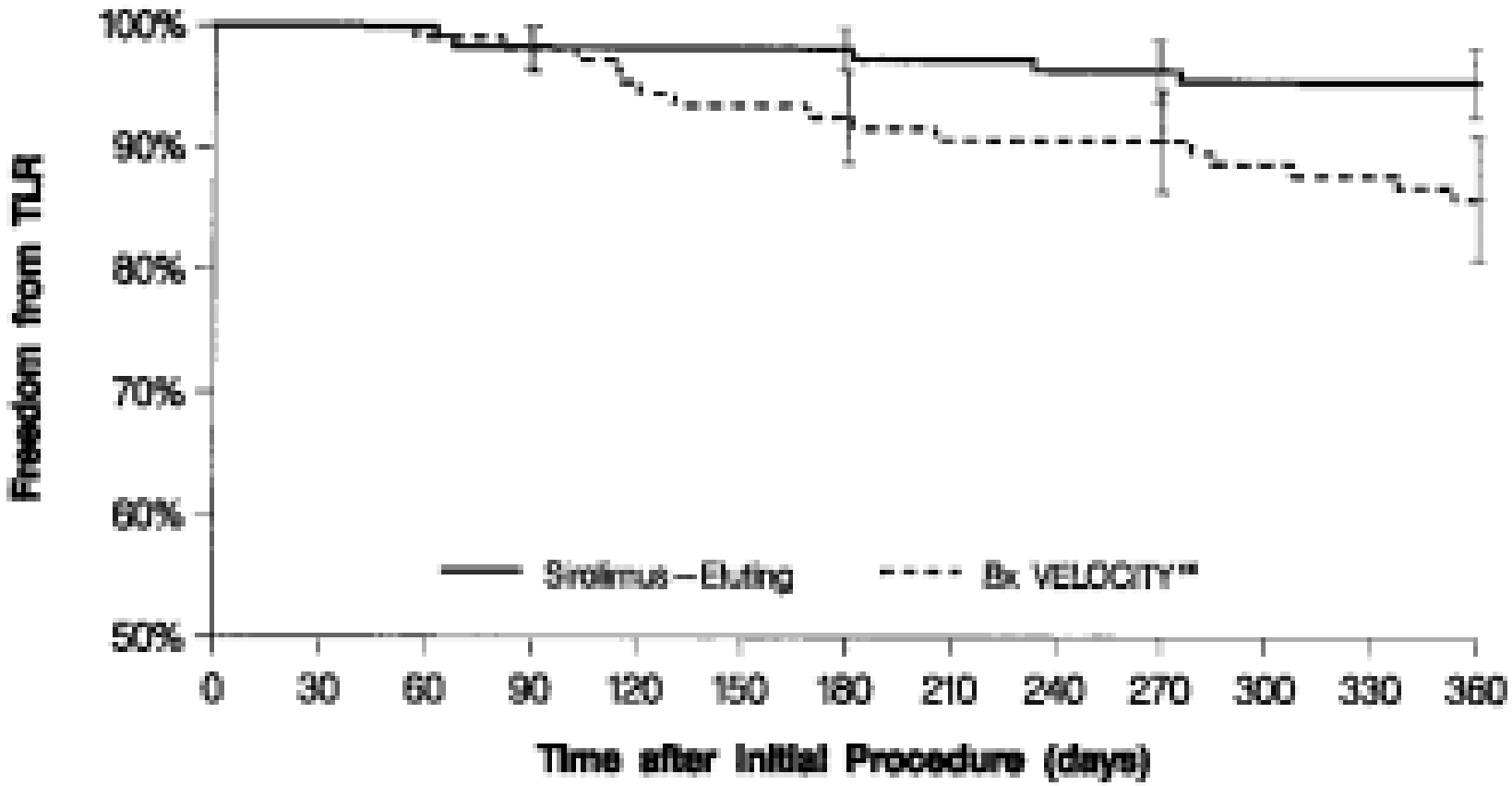
* First Generation
  * Taxus
  * Cypher
* Second Generation
  * Xience
  * Promus
  * Resolute

Drug Eluting Stents

* Components of DES
  * Scaffold
  * Polymer
  * Drug

First Generation Drug Eluting Stents

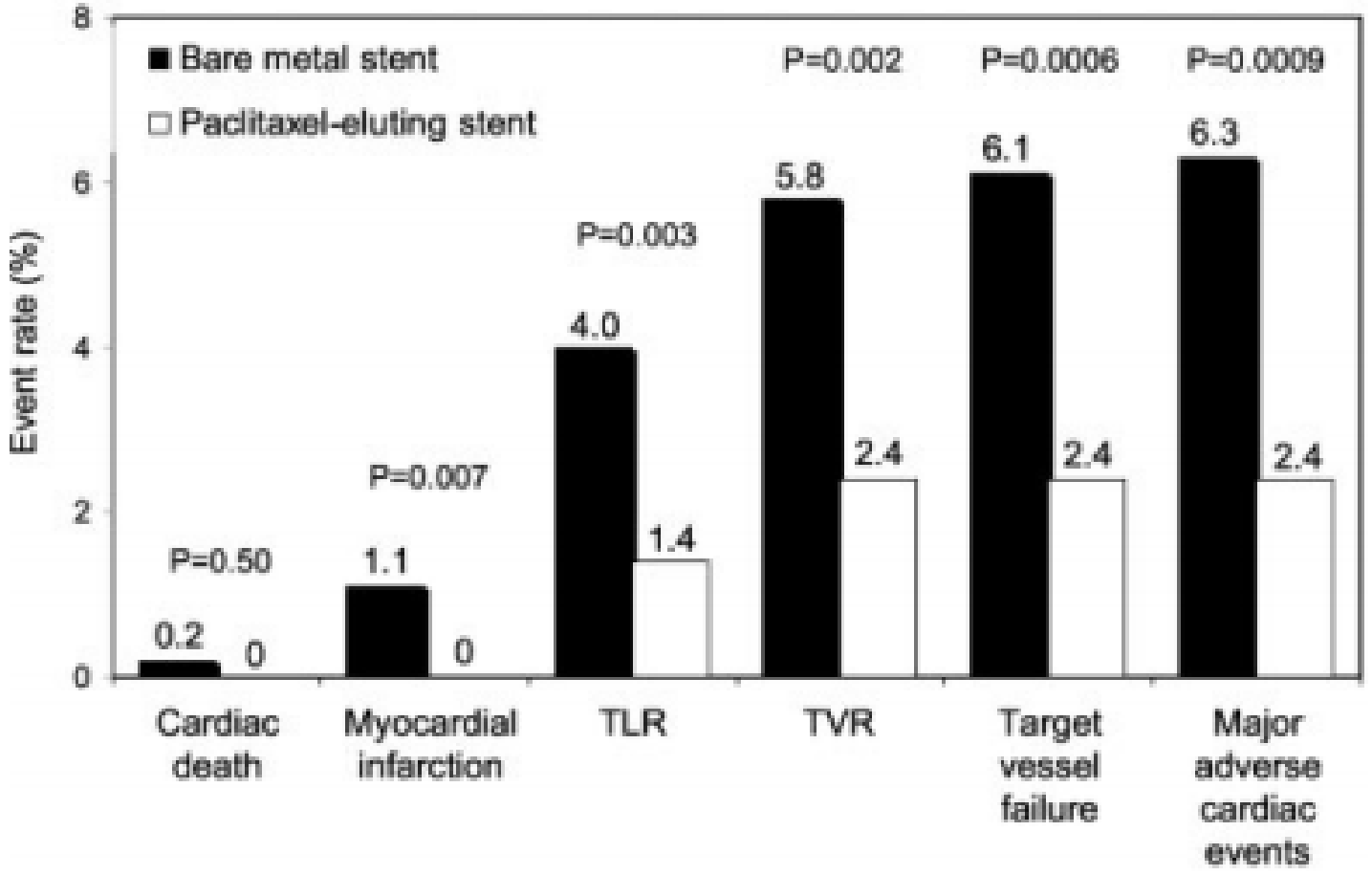
TABLE 3. SIRIUS: Cumulative Clinical Events



MACE	8.3 (44)	22.3 (117)	<0.001
TVF	9.8 (52)	24.8 (130)	<0.001
Stent thrombosis	0.4 (2)	0.8 (4)	0.448

First Generation Drug Eluting Stents

TABLE 2. Cumulative Adverse Event Rates at 12 Months

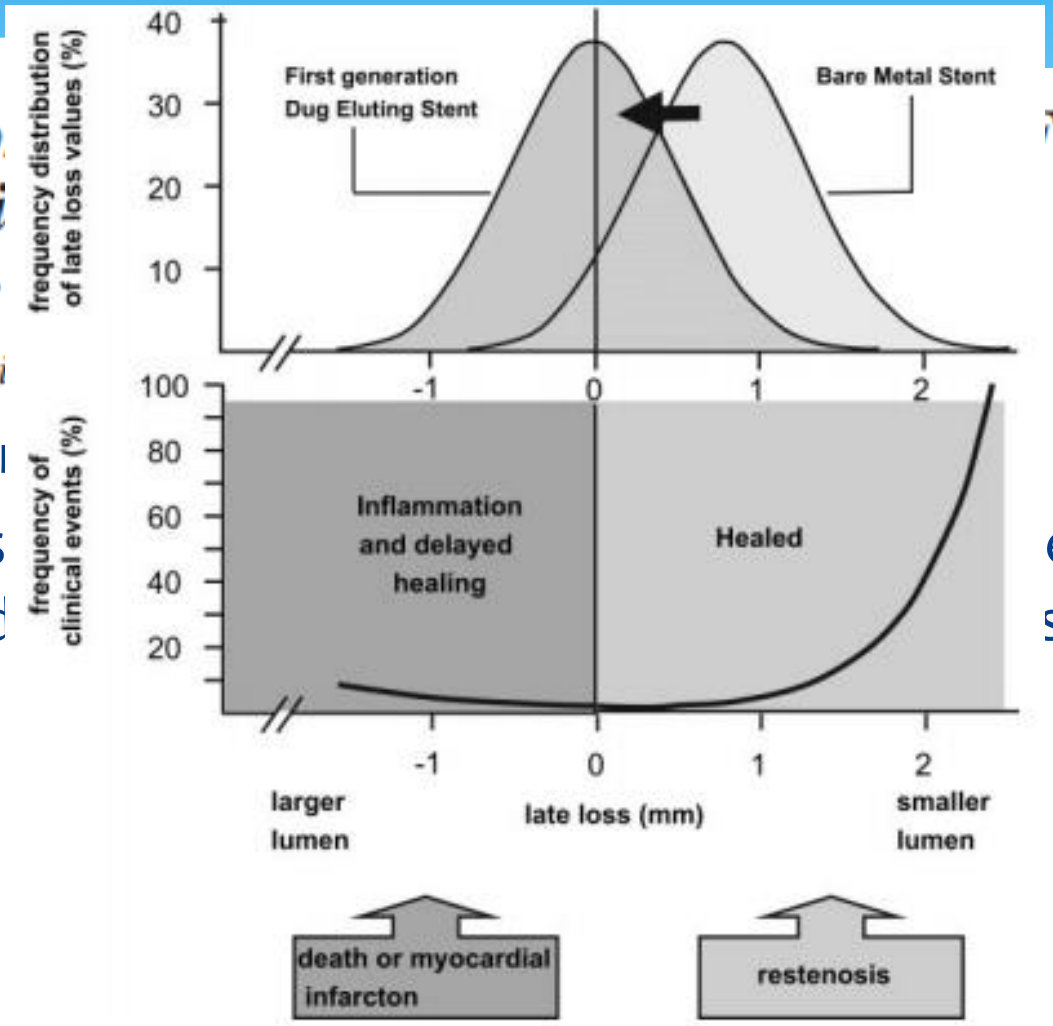


	P
Cardiac	0.83
Myocar	0.31
Stent t	0.72
TLR	<0.0001
Repe	<0.0001
Bypa	0.0003
TVR (n	0.72
TVR	<0.0001
Repe	<0.0001
Bypa	0.01
Target-	<0.0001
Major a	<0.0001

First Generation Drug Eluting Stents

Stent Thro… …irst-Generation Drug-Eluti… A Cause for…

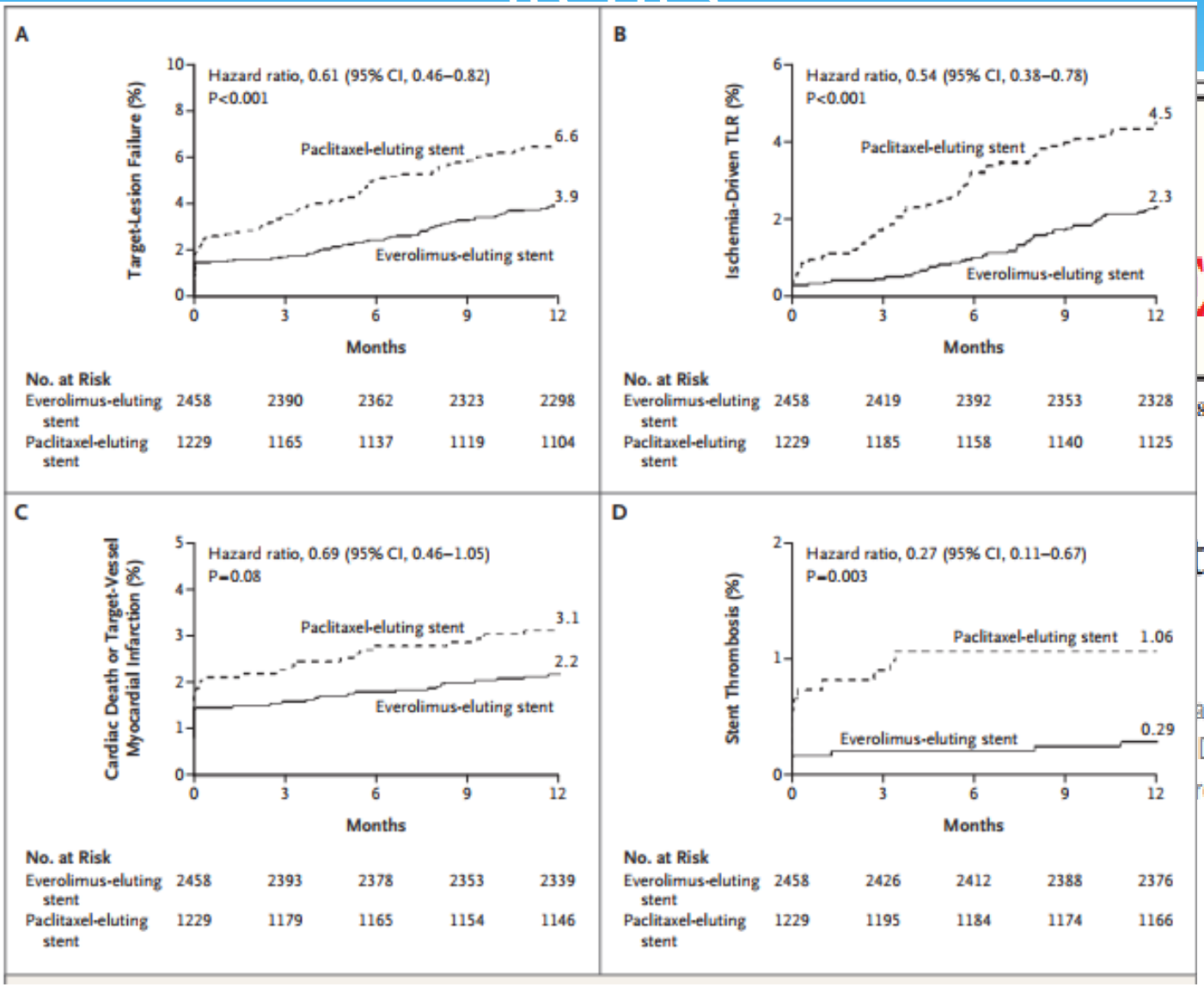
Edoardo Camenzi…



tl…

* Sus… …elialization and… …stream

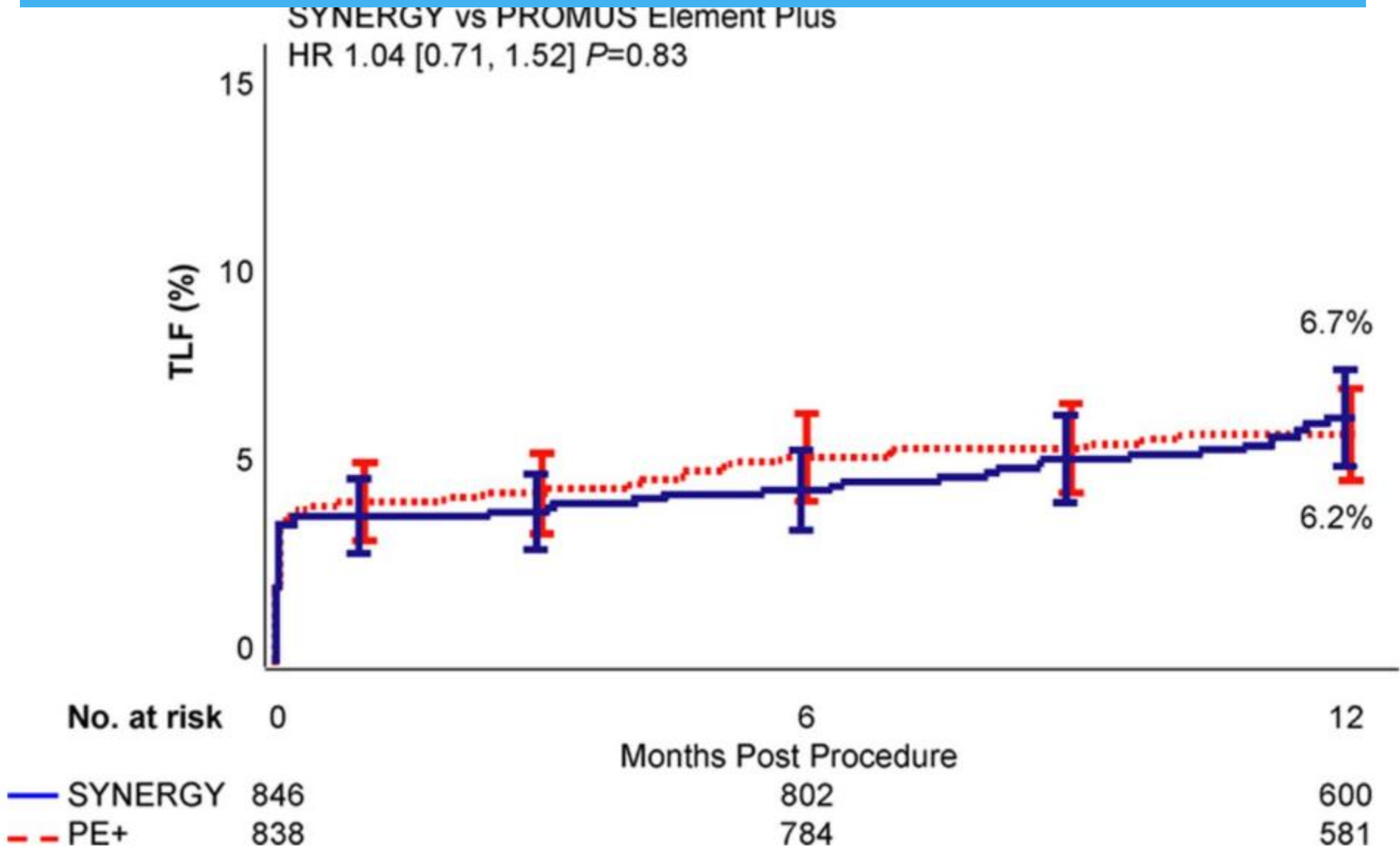
Second Generation Drug Eluting Stents



Third Generation Drug Eluting Stents

* Synergy stent
  * PtCr based stent with a new bioresorbable polymer for delivering drug to abluminal surface only
  * Reduced time to elute drug leading to quicker endotheliaization with reduced neo-intimal thickening.
  * Best of both worlds theory.

Third Generation Drug Eluting Stents



Stent Issues

* Continue to have permanent metal scaffold in vessel
  * Vessel reactivity is negated
  * prevention of late vessel adaptive or expansive remodeling
* Need for re-intervention leads to higher risks
  * More layers = faster restenosis
* Drug Eluting stents have lower rate of TLR, but higher rate of ST
* Hindrance of surgical revascularization
* Impairment of imaging with multislice CT

Bio-resorbable scaffolds

* Most notably: Absorb – Abbott Vascular
* Also multiple iron, magnesium or zinc based metallic absorbable stents under development.

Absorb BRS

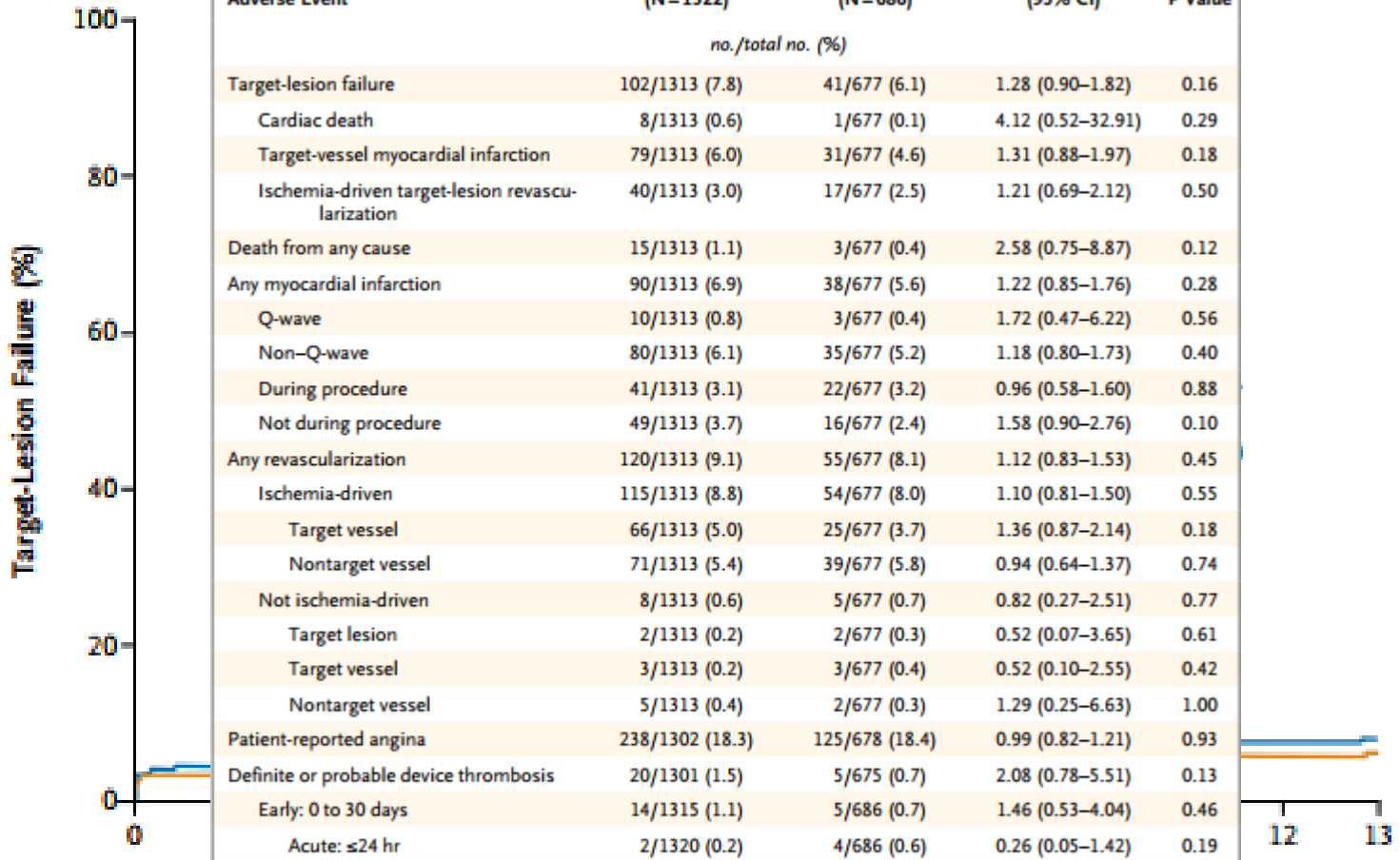
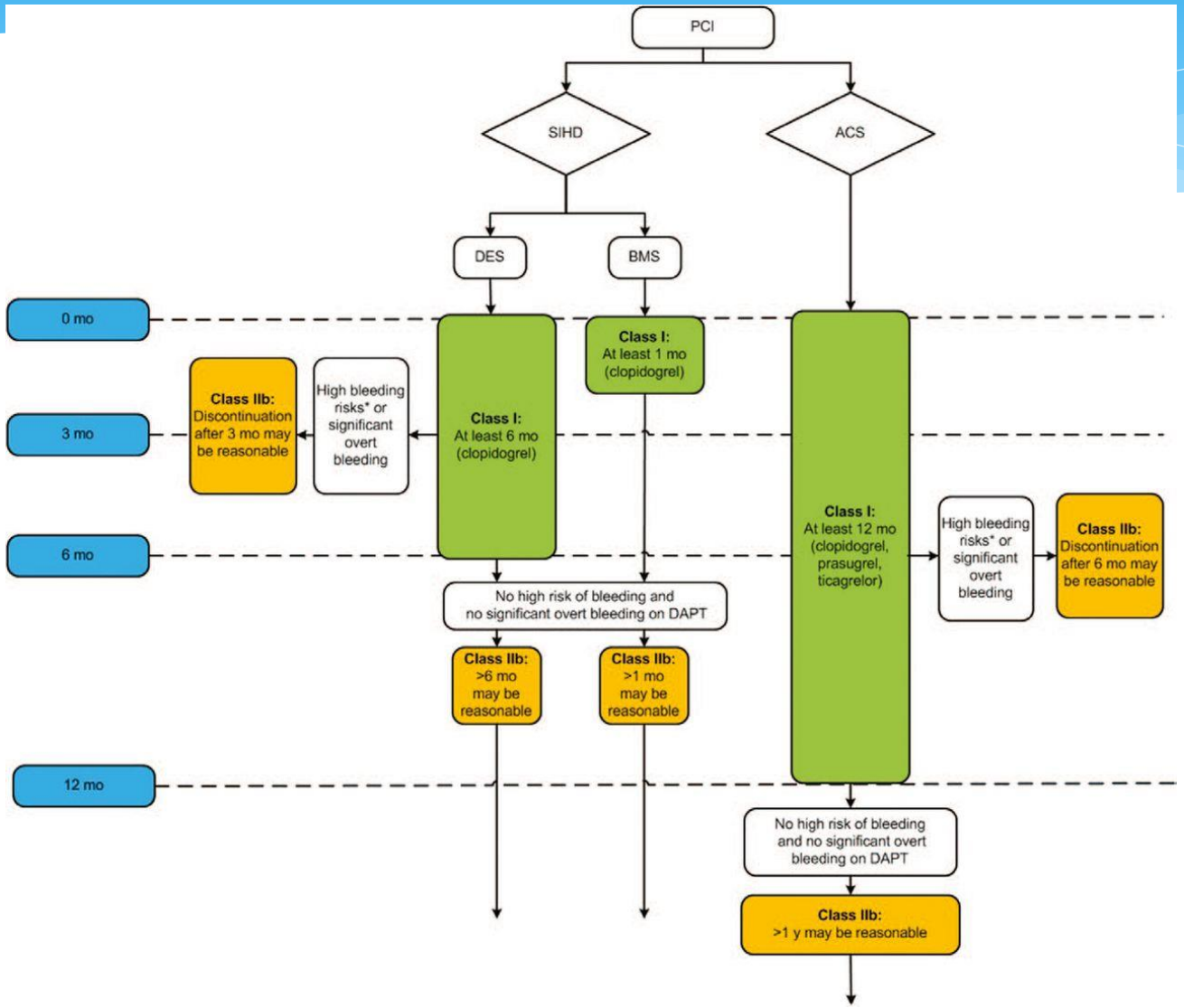


Table 3. Safety and Efficacy Outcomes at 1 Year.*

Adverse Event	Absorb Scaffold (N=1322)	Xience Stent (N=686)	Relative Risk (95% CI)	P Value
	no./total no. (%)			
Target-lesion failure	102/1313 (7.8)	41/677 (6.1)	1.28 (0.90–1.82)	0.16
Cardiac death	8/1313 (0.6)	1/677 (0.1)	4.12 (0.52–32.91)	0.29
Target-vessel myocardial infarction	79/1313 (6.0)	31/677 (4.6)	1.31 (0.88–1.97)	0.18
Ischemia-driven target-lesion revascularization	40/1313 (3.0)	17/677 (2.5)	1.21 (0.69–2.12)	0.50
Death from any cause	15/1313 (1.1)	3/677 (0.4)	2.58 (0.75–8.87)	0.12
Any myocardial infarction	90/1313 (6.9)	38/677 (5.6)	1.22 (0.85–1.76)	0.28
Q-wave	10/1313 (0.8)	3/677 (0.4)	1.72 (0.47–6.22)	0.56
Non–Q-wave	80/1313 (6.1)	35/677 (5.2)	1.18 (0.80–1.73)	0.40
During procedure	41/1313 (3.1)	22/677 (3.2)	0.96 (0.58–1.60)	0.88
Not during procedure	49/1313 (3.7)	16/677 (2.4)	1.58 (0.90–2.76)	0.10
Any revascularization	120/1313 (9.1)	55/677 (8.1)	1.12 (0.83–1.53)	0.45
Ischemia-driven	115/1313 (8.8)	54/677 (8.0)	1.10 (0.81–1.50)	0.55
Target vessel	66/1313 (5.0)	25/677 (3.7)	1.36 (0.87–2.14)	0.18
Nontarget vessel	71/1313 (5.4)	39/677 (5.8)	0.94 (0.64–1.37)	0.74
Not ischemia-driven	8/1313 (0.6)	5/677 (0.7)	0.82 (0.27–2.51)	0.77
Target lesion	2/1313 (0.2)	2/677 (0.3)	0.52 (0.07–3.65)	0.61
Target vessel	3/1313 (0.2)	3/677 (0.4)	0.52 (0.10–2.55)	0.42
Nontarget vessel	5/1313 (0.4)	2/677 (0.3)	1.29 (0.25–6.63)	1.00
Patient-reported angina	238/1302 (18.3)	125/678 (18.4)	0.99 (0.82–1.21)	0.93
Definite or probable device thrombosis	20/1301 (1.5)	5/675 (0.7)	2.08 (0.78–5.51)	0.13
Early: 0 to 30 days	14/1315 (1.1)	5/686 (0.7)	1.46 (0.53–4.04)	0.46
Acute: ≤24 hr	2/1320 (0.2)	4/686 (0.6)	0.26 (0.05–1.42)	0.19
Subacute: >24 hr to 30 days	12/1315 (0.9)	1/686 (0.1)	6.26 (0.82–48.04)	0.04
Late: 31 days to 1 yr	6/1299 (0.5)	0/675	NA	0.10
Definite	18/1301 (1.4)	5/675 (0.7)	1.87 (0.70–5.01)	0.21
Probable	2/1301 (0.2)	0/675	NA	0.55

Post Stenting Care



Post Stenting Care

* DAPT
  * Ticagrelor and Prasugrel have increased efficicacy with increased bleeding risk in comparison with Clopidogrel
    * Prasugrel should be avoided in patient with history of stoke or the elderlyl
  * Benefit out to 30 months balanced by increase in bleeding risk

Post Stenting Care

* In patients on therapeutic anticoagulation:
  * DAPT leads to 2-3 fold increase in bleeding risk
  * If low bleeding risk triple therapy is currently recommended.
  * If bleeding risk higher (elderly, fall risk, etc)
    * Consider use of P2Y12 inhibitor with therapeutic oral anticoagulation with either Warfarin or DOAC

Access Site

* Radial vs Femoral
  * The USA continues to have about 30% of cases by radial approach over the past few years.
  * Recent urge for radial approach due to patient preference, comfort and risk of vascular complications.
  * Mortality benefit of radial approach during ACS due mostly to decreased bleeding complications.

Access Site - Care

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Access Site - Care

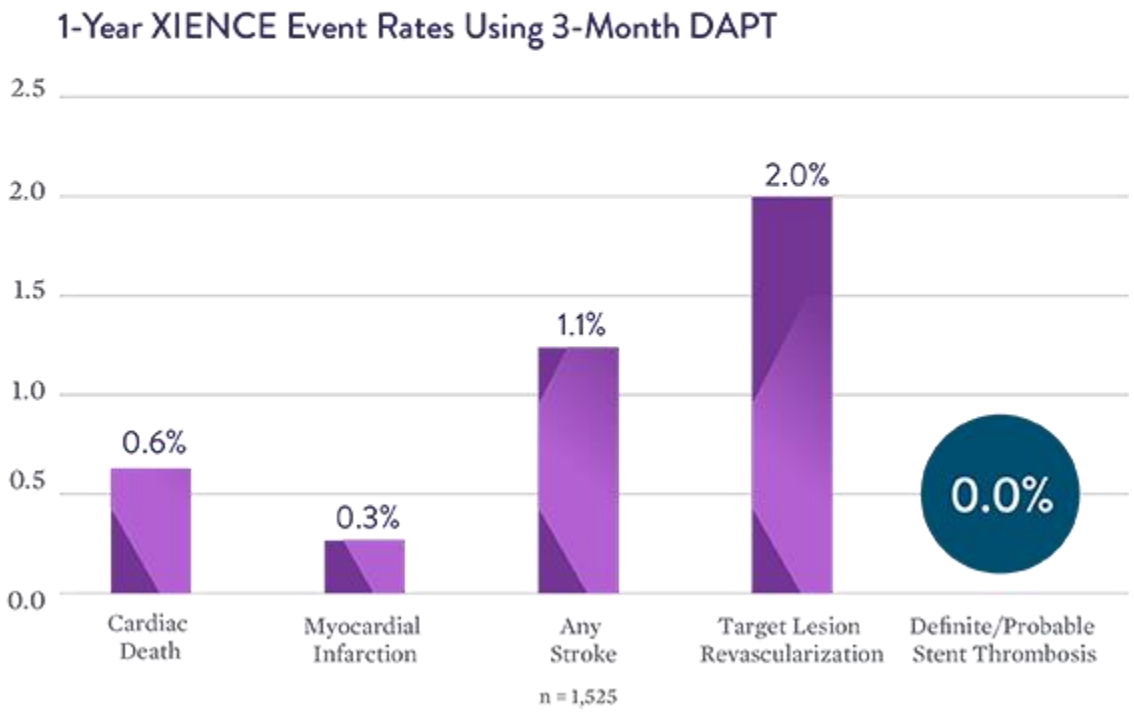
* Femoral access:
  * Depending on closure method the period of bedrest will vary, however, at least 2 hours of bedrest
  * After bedrest period, patient will have HOB elevated.
  * Then legs dangling over side of bed hours later
  * Then ambulation.

Access Site - Care

* Regardless of access site:
  * No lifting more than 10lb for one week
  * No Tennis
  * No Golf
  * No soaking (bath, pool, beach, dishes, or mopping)
  * No driving (time limit depends on cardiologist and access site)
  * Showering is OK.

Future Developments

STOPDAPT Study Demonstrates XIENCE's Safety with 3-Month DAPT[8]



Future Developments

* Several Major short DAPT trials
  * XIENCE Short Dual Antiplatelet Therapy (DAPT) Study – 3 month DAPT trial - Enrolling
  * Resolute – one month DAPT trial – enrolling
  * Synergy – SENIOR trial – one month DAPT trial – data collection phase
  * Synergy – EVOLVE short DAPT – 3 months - enrolling

Future Developments

* Drug Coated balloons.
  * Intended to address issues of stents:
    * Treatment of small vessel disease
    * Issues related to the duration of dual antiplatelet therapy (DAPT)
    * Treatment failure leading to restenosis
    * Late stent thrombosis
  * Promising results peripherally and in some trial.
  * Multiple trials ongoing

Open Forum for Questions