ORBITAL ATHERECTOMY IN CORONARY ARTERIES

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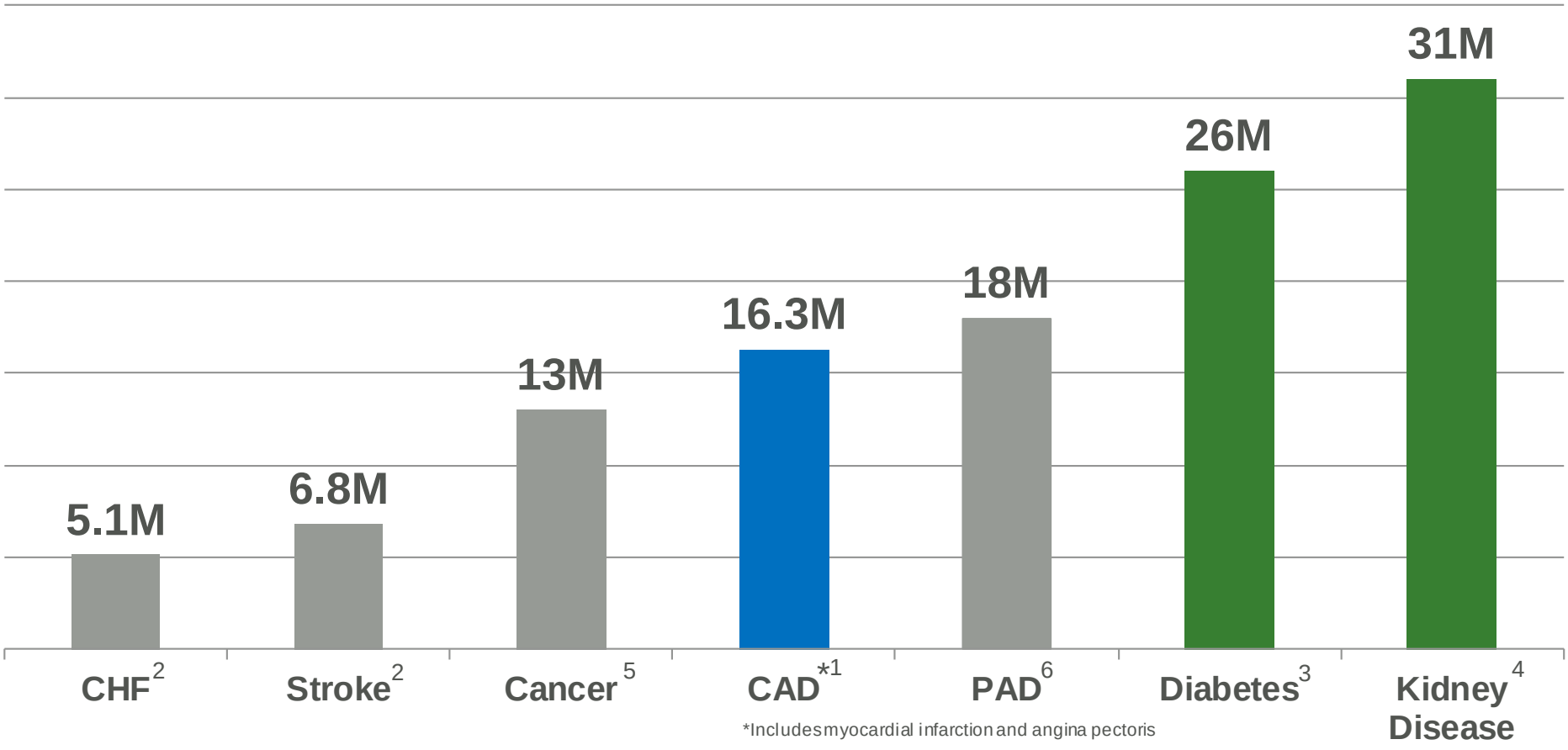
DISEASE STATE PREVALENCE

Coronary artery disease – large and growing problem in the US



1. Dolor RJ, et al. Comparative Effectiveness Reviews, No. 66. 2012 Aug.
2. Go AS, et al. *Circulation*. 2014;129:e28-292.
3. American Diabetes Association Diabetes Fact Sheet. Accessed April 21, 2014.
4. American Kidney Fund Website. Accessed July 30, 2013.
5. Howlader N, et al. SEER Cancer Statistics Review, 1975-2010. Accessed April 17, 2014.
6. Schiavetta A, et al. *StemCells Translational Medicine*. 2012;1:572-578.

RISKS FACTORS FOR CORONARY CALCIFICATION

Advanced Age

41.4M 65+yrs old in U.S.[2]

85+ age group is the fastest growing in the U.S.

Diabetes

Up to 26M in U.S.[1]

New epidemic,

the fastest growing health problem in the U.S.

Kidney Disease

Up to 31M in U.S.[3]

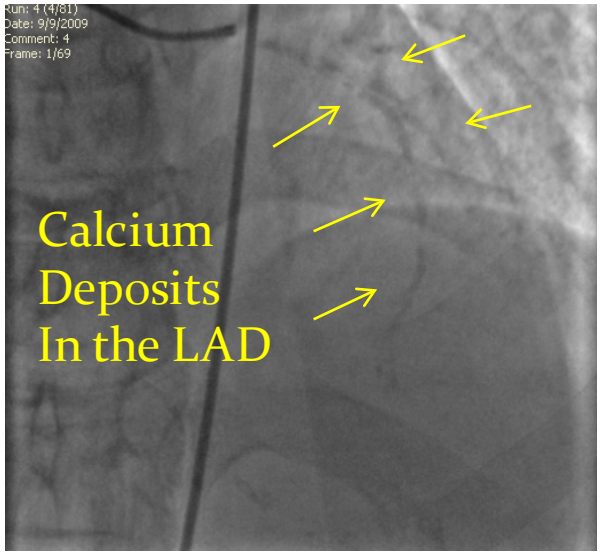
Diabetes is leading cause of kidney disease

Calcium Deposits in the Coronary Arteries

1. American Diabetes Association Diabetes Fact Sheet. March, 2013 Accessed on April 21, 2014.
2. U.S. DHHS. Administration on Aging. Accessed Nov. 24, 2014.
3. American Kidney Fund. Accessed July 30, 2013.

WHAT IS CORONARY ARTERY CALCIFICATION AND HOW DO WE DEFINE IT?

- Two definitions of coronary calcification as proposed to the ICD-10-CM/PCS Committee: angiographic or IVUS
  - NONE or MILD calcification
    – Radiopacities barely visible in close examination before contrast injection[1] or IVUS reveals arc of calcium less than 90 degrees or no calcium arc[4]
  - MODERATE calcification
    – Radiopacities noted only during the cardiac cycle before contrast injection[1,2,3] or IVUS reveals arc of calcium 90 to 180 degrees[4,5]
  - SEVERE calcification
    – Radiopacities noted without cardiac motion before contrast injection generally compromising both sides of the arterial lumen[1,2,3] or IVUS reveals arc of calcium greater than 180 degrees[4,5,6]
- Incidence of severe calcification: 6%[7] to 20%[8]



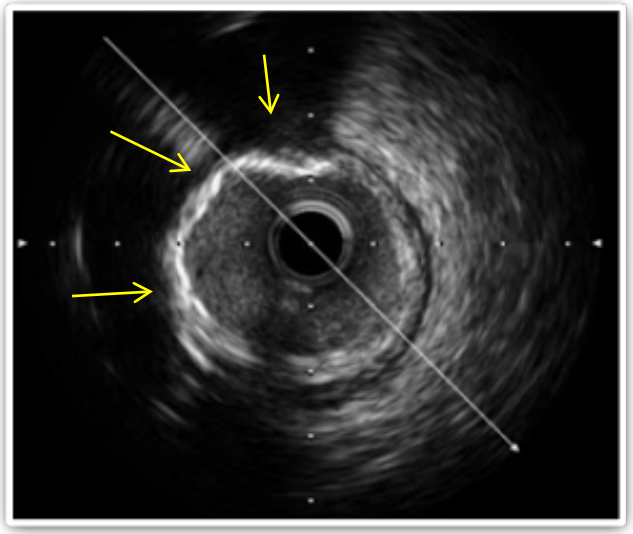
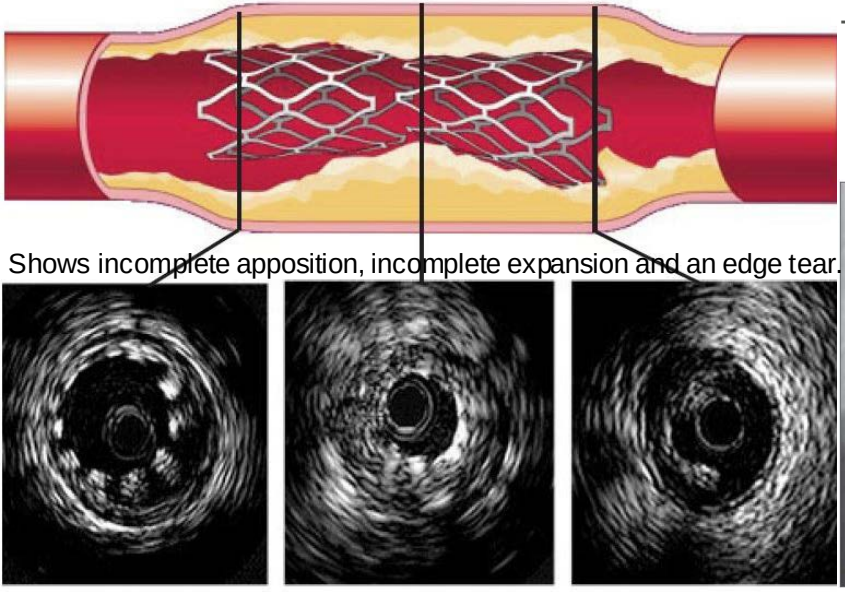


Image courtesy of Nabil Dib, MD

1. Torre Hernandez JM, et al. *J Invasive Cardiol*. 2005;17:365-368.
2. Mintz GS, et al. *Circulation*. 1995;91:1959-1965.
3. Nishida K, et al. *AmJ Cardiol*. 2013;112:647-655.
4. Hony e J, et al. *Circulation*. 1992;85:1012-1025.
5. Rathore S, et al. *CCI*. 2010;75:919-927.
6. Kume T, et al. *Circ J*. 2007;71:643-647.
7. Genereux P, et al. *J AmColl Cardiol*. 2014;63:1845-54.
8. Bourantas CV, et al. *Heart*. 2014;100:1158-64.

WHY DO WE CARE ABOUT CORONARY CALCIFICATION?

- Respond poorly to angioplasty[1]
- Difficult to completely dilate[2]
- Prone to dissection during balloon angioplasty or predilatation[1]
- Preclude stent delivery to the desired location[2,3]
- Can prevent adequate stent expansion[4] → restenosis, stent thrombosis, readmissions
- May result in stent malapposition[5]
- Insufficient drug penetration and subsequent restenosis[6]



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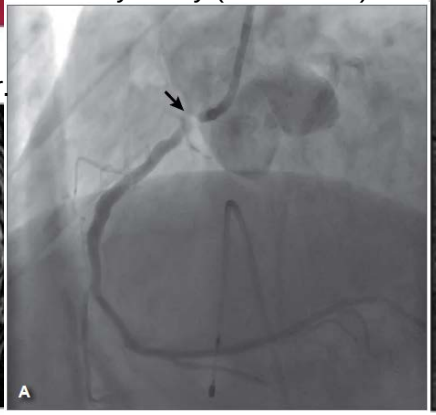
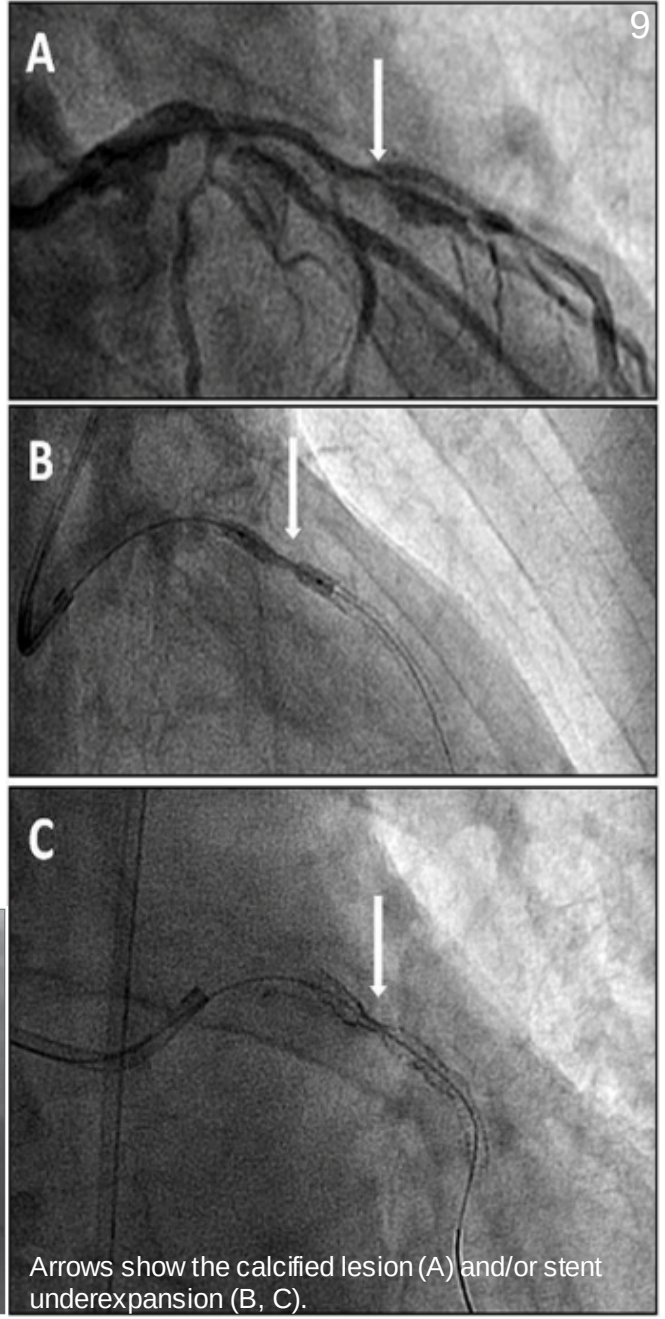
Shows incomplete apposition, incomplete expansion and an edge tear.

Calcified ostial lesion in the right coronary artery (black arrow). 8





9

Arrows show the calcified lesion (A) and/or stent underexpansion (B, C).

1. Fitzgerald PJ, et al. *Circulation*. 1992;86:64-70.
2. Cavusoglu E, et al. *Cathet Cardivasc Intervent*. 2004;62:485-498.
3. Gilutz H, et al. *Cathet Cardiovasc Intervent*. 2000;50:212-214.
4. Moussa I, et al. *Circulation*. 1997;96:128-136.
5. Mosseri M, et al. *Cardiovasc Revasc Med*. 2005;6:147-53.
6. Ichihashi S & Kichikawa K. *Ther Clin Risk Manag*. 2014;10:467-474.
7. Buckley CJ. *Vascular Disease Management*. 2011;8:87-92.
8. Dardas P, et al. *Hellenic J Cardiol*. 2011;52:399-406.
9. Hernandez J, et al. *J Invasive Cardiol*. 2014;26:E122-E123.

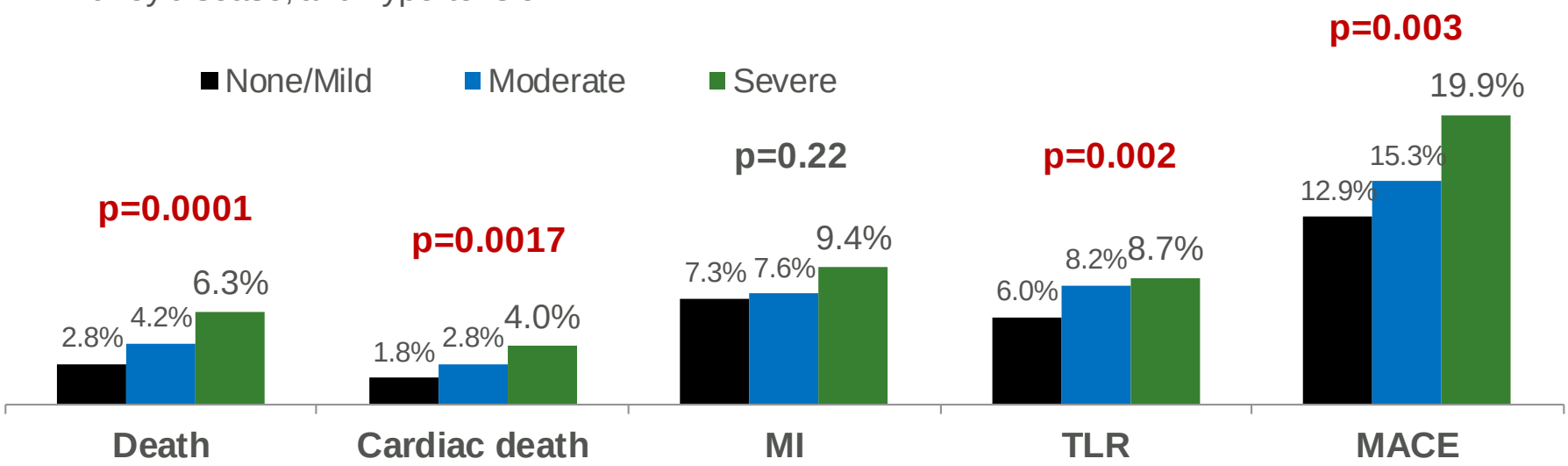
WHAT IS THE CURRENT STANDARD OF CARE TO TREAT CORONARY CALCIFICATION?

Balloon Angioplasty

Coronary stents

CLINICAL OUTCOMES IN PATIENTS WITH SEVERE CALCIUM

- Severe calcium results in higher procedural complication rates and higher incidence of major adverse cardiac events[1-3]
- Patients with severely calcified coronary arteries tend to be older with higher prevalence of diabetes, kidney disease, and hypertension[4-6]



Genereux P, et al. 2014 – ACUITY/HORIZONS

- Requires more time and equipment to treat[7,8]
- More costly to treat[7,8]

Patients with Severe Calcification have worse outcomes. [1,9-12]

1. Fitzgerald PJ, et al. *Circulation*. 1992;86:64-70.
2. Kawaguchi R, et al. *Cardiovasc Revasc Med*. 2008;9:2–8.
3. Genereux P, et al. *J AmColl Cardiol*. 2014;63:1845-54.
4. Won KB, et al. *Diabetol Metab Syndr*. 2014;6:134.
5. Shemesh J, et al. *AmJ Cardiol*. 2012;109:844-850.
6. Kramer H, et al. *J AmSoc Nephrol*. 2005;16:507-513.
7. Meerkin D, et al. *J Invasive Cardiol*. 2002;14:547-551.
8. Parikh K, et al. *Catheter Cardiovasc Interv*. 2013;81:1134-1139.
9. Bangalore S, et al. *Catheter Cardiovasc Interv*. 2011;77:22-28.
10. Kocka V, et al. *Eur Heart J*. 2014;35:787-94.
11. Ullah M, et al. *Cardiovasc J*. 2014;6:149-163.
12. Camnitz WM & Keeley EC. *J Interv Cardiol*. 2010;23:254-255.

OTHER OPTIONS FOR TREATING CALCIFIED CORONARY ARTERIES

- Atherectomy
  - modify calcified deposits and plaques[1]
  - may change artery compliance[2]
  - low rate of dissections and perforations[3]
  - facilitate stent delivery and expansion[1]

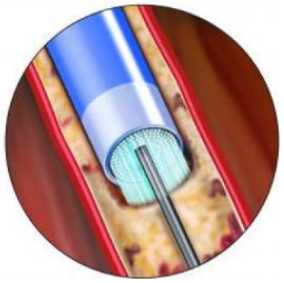
Adequate lesion preparation with atherectomy appears to help stent implantation in severely calcified lesions.[4,5]

1. Abdel-Wahab M, et al. *JACC Cardiovasc Interv.* 2013;6:10-9.
2. Parikh K, et al. *Catheter Cardiovasc Interv.* 2013;81:1134-1139
3. Chambers JW, et al. *J Am Coll Cardiol Intv.* 2014;7:510-8.
4. Ullah M, et al. *Cardiovasc J.* 2014;6:149-163.
5. Moussa I, et al. *Circulation.* 1997;96:128-36.

CONVENTIONAL ATHERECTOMY PROCEDURES

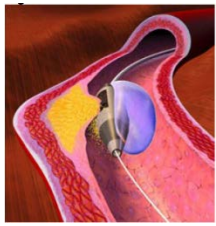
❑ Laser

- Utilizes pulsed laser energy to vaporize the plaque into particles
- Suited for removal of soft or medium plaque



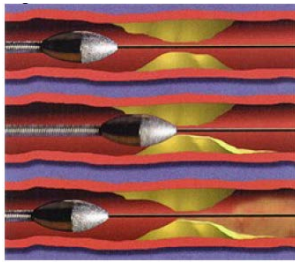
❑ Directional

- Direct and orient the cutting blade to plaque for removal
- Does not discriminate between diseased plaque and arterial tissue
- Suited for removal of soft or medium plaque

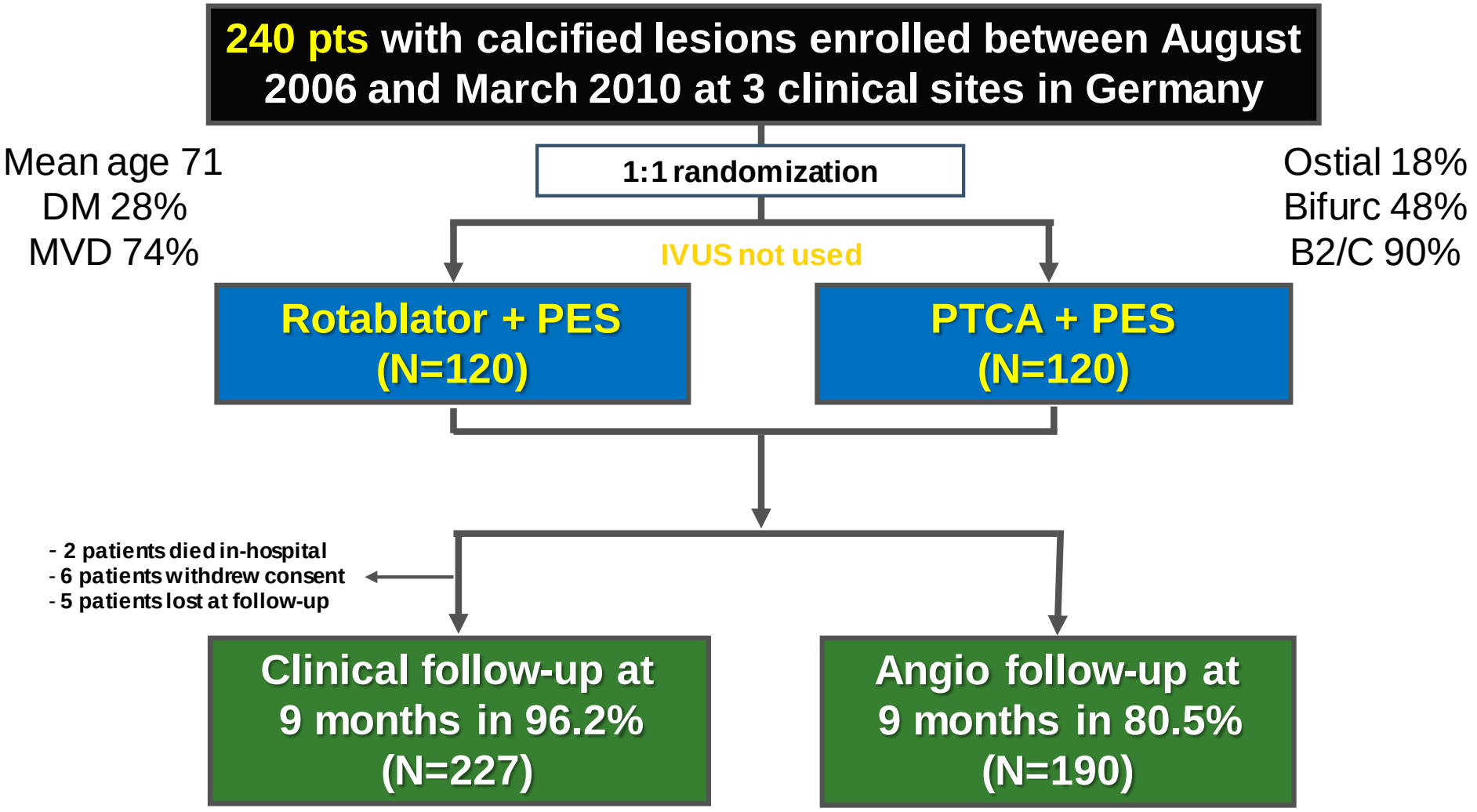


❑ Rotational

- Forward drill-like mechanism
- Rotating burr in constant contact with the lesion circumference
- Not indicated for calcified lesions

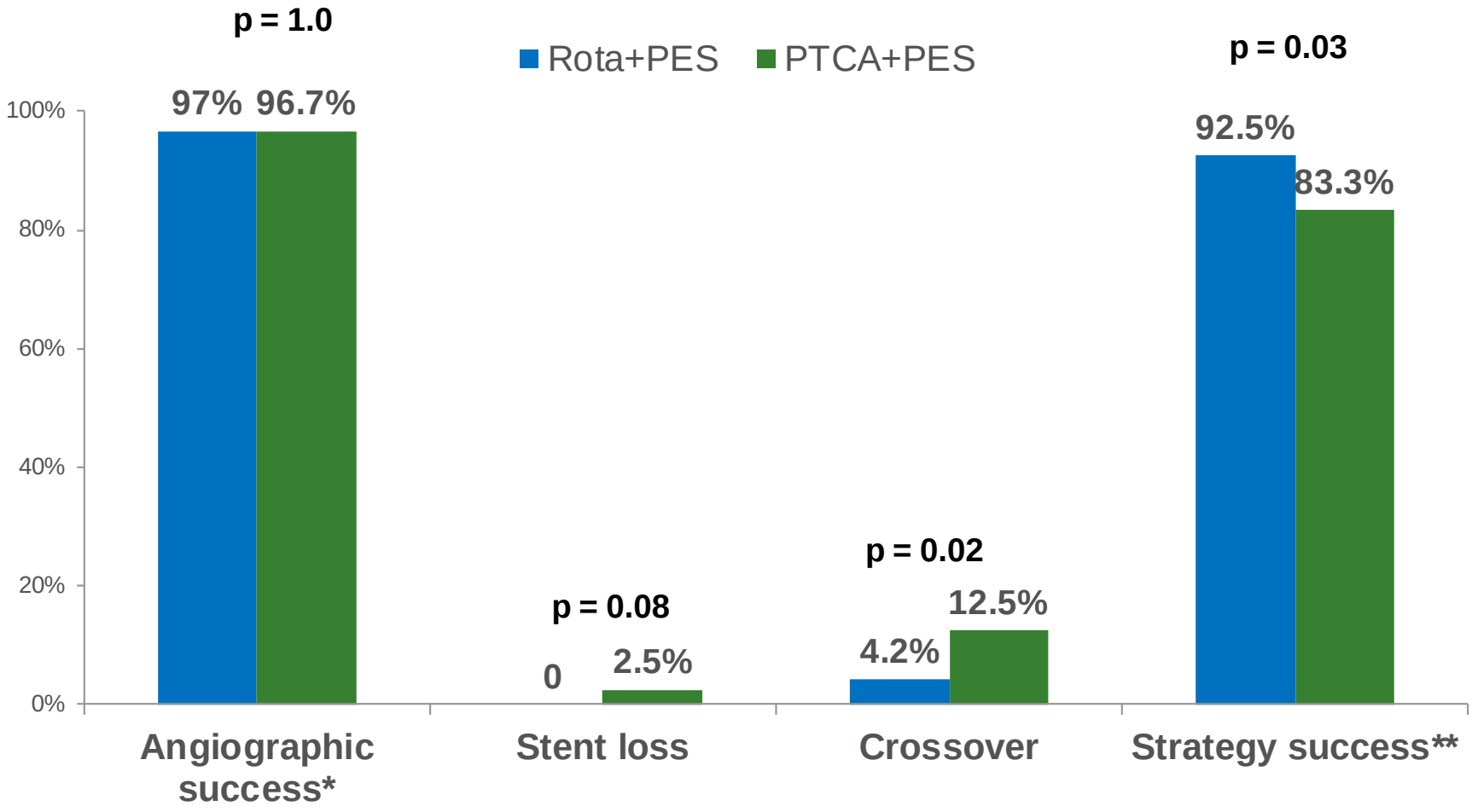


ROTAXUS



*Primary endpoint: In-stent late loss

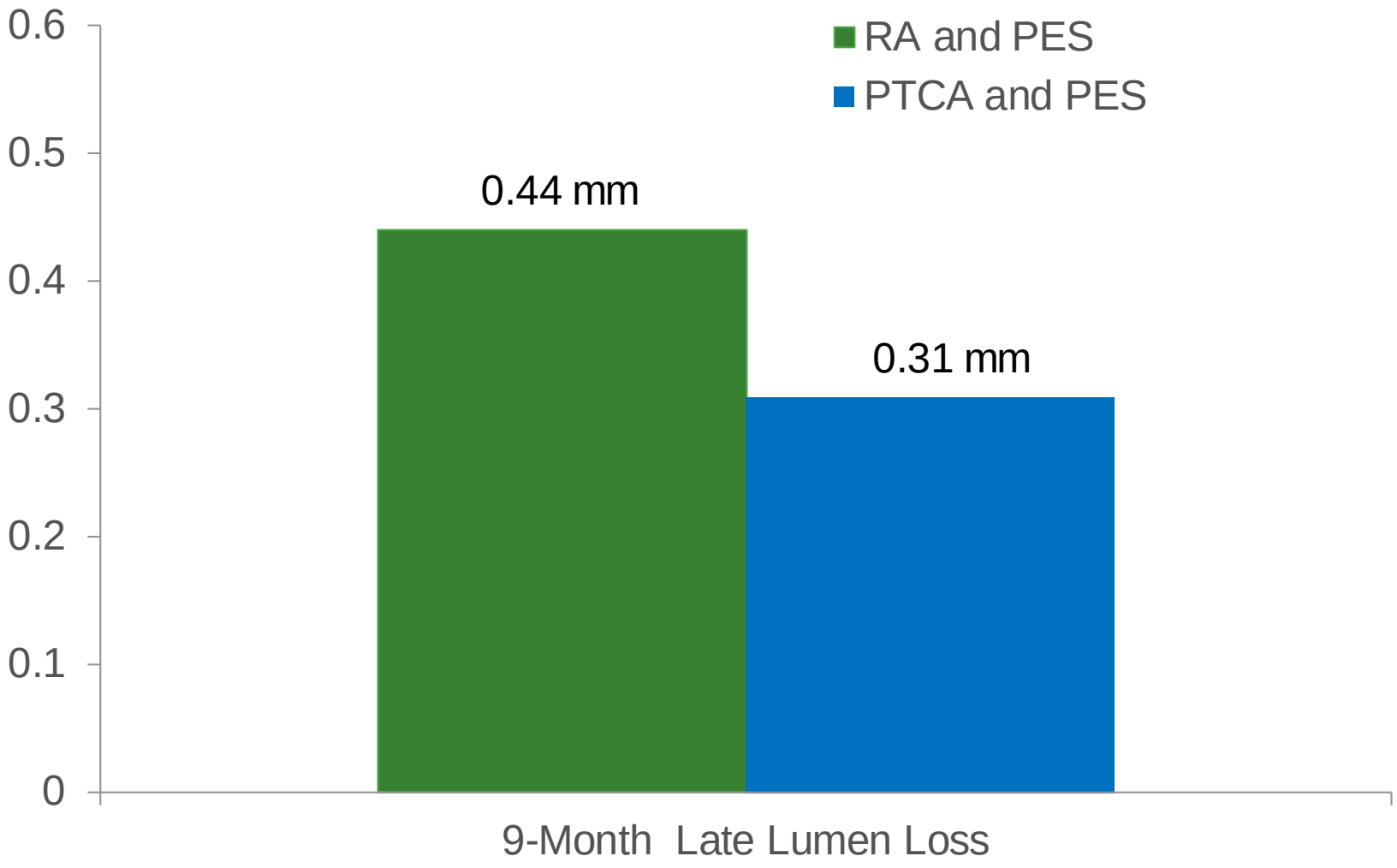
ROTAXUS: Procedural Outcomes



* Defined as <20% residual stenosis + TIMI 3 flow
** Defined as angiographic success with no crossover or stent loss

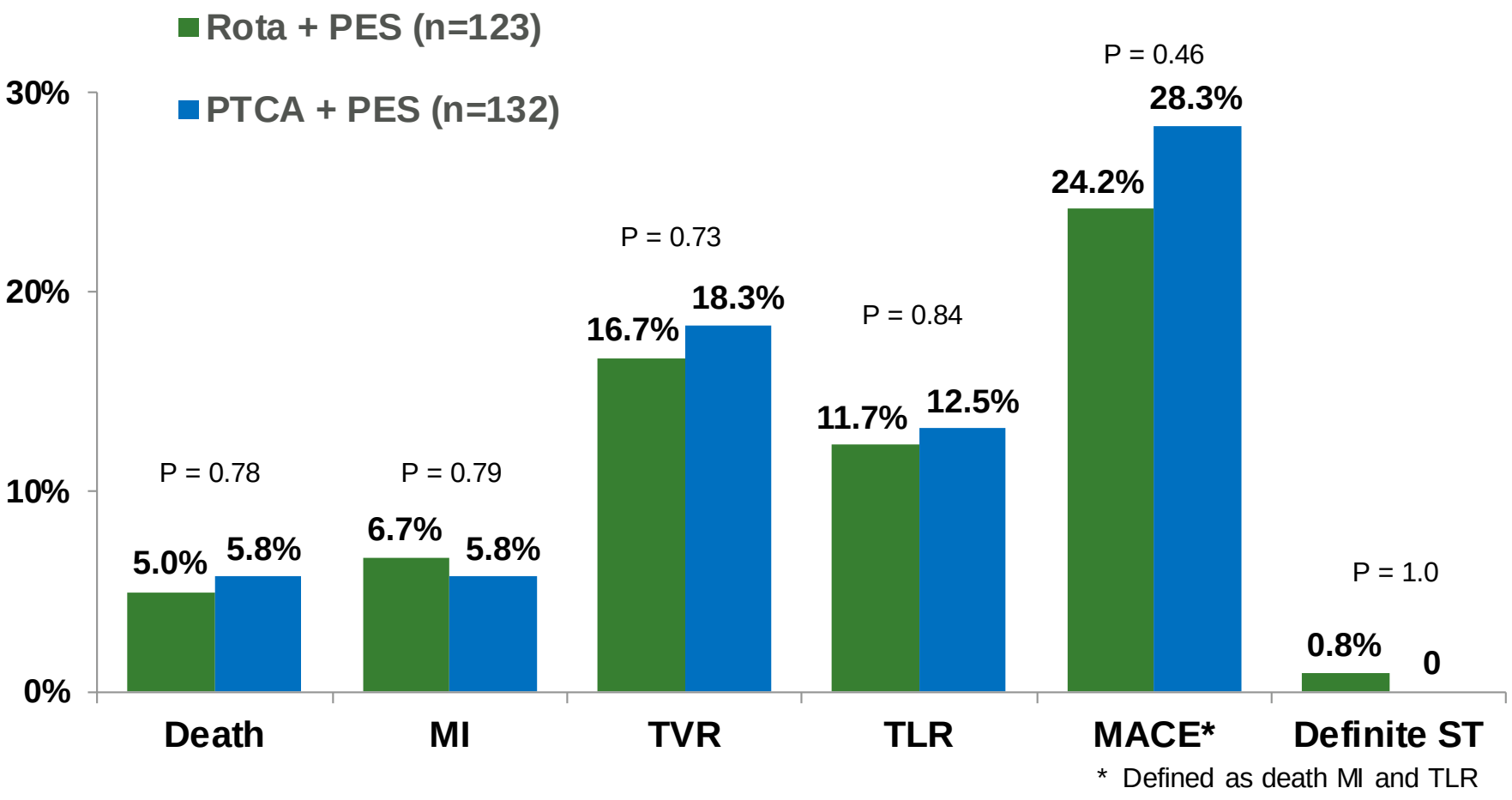
Abdel-Wahab M, et al. *JACC Cardiovasc Interv*. 2013;6:10-9.

ROTAXUS PRIMARY ENDPOINT



Abdel-Wahab M, et al. *JACC Cardiovasc Interv*. 2013;6:10-9.

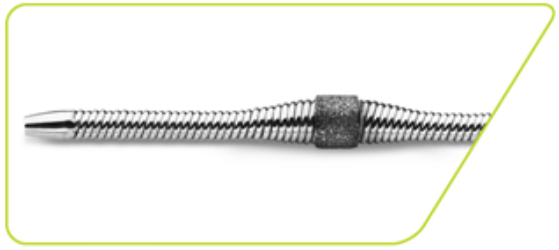
ROTAXUS: 9-MONTH FOLLOW-UP



Diamondback 360° Coronary Orbital Atherectomy System (OAS)

The first and only FDA approved atherectomy device specifically indicated for severe calcium

Diamondback 360°Coronary Orbital Atherectomy System



Diamond-coated Crown

ViperWire Advance® Coronary Guide Wire
Designed to enhance navigation

ViperSlide® Coronary Lubricant
Designed for smooth operation

Saline Infusion Pump
Infuse fluidity into every procedure

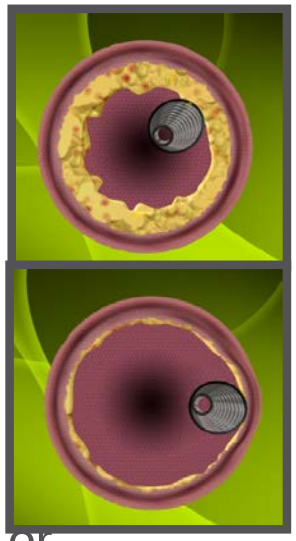
DIAMONDBACK 360 CORONARY OAS

https://www.youtube.com/watch?v=PVr7Ftzl5Mc

UNIQUE MECHANISM OF ACTION

Coronary Orbital Atherectomy utilizes an **orbiting mechanism of action**:

- Differential, circumferential (orbital) sanding mechanism
  - Differentiates between hard, calcified plaques and healthy arterial tissue
- Variable size of lumen modification
  - Higher speed, larger treatment area (speed controlled by the operator) – one device treat multiple vessel sizes
- Non-occlusive
  - Continuous flow of blood during orbit – constant cooling of minimizes thermal injury
- Bi-directional treatment
  - The device circumferentially sands plaque when pushed forward or pulled back



ORBIT II Study Design

To evaluate the safety and efficacy of the coronary Orbital Atherectomy System (OAS) to prepare *de novo*, severely calcified coronary lesions for stent placement

- Prospective, multi-center trial
- Single arm trial *as there are no FDA-approved percutaneous treatments for patients with severely calcified lesions*

443 patients enrolled in 49 U.S. sites

30-day follow-up – published[1]

1 year follow-up – published[2]

2-year data – published[3]

1. Chambers JW, et al. *J Am Coll Cardiol Intv*. 2014;7:510-8.
2. Chambers JW. Presented at SCAI 2014.
3. Chambers JW. Presented at CRT 2015.

ORBIT II
Patient Demographics & Lesion Characteristics

76.1% 65 years or older

Real-world patients

Demographics	ORBIT II (N=443)
Age (yrs)	**71.4**
Male	**64.6%**
History of diabetes mellitus	**36.1%**
History of hypertension	**91.6%**
History of dyslipidemia	**91.9%**
Prior CABG	**14.7%**
Vessel & Lesion Characteristics	N=440
Severe calcification	**100%**
Mean pre-procedure target lesion length	**18.9 mm**
Mean pre-procedure minimum lumen diameter	**0.5 mm**
Mean pre-procedure percent stenosis	**84.4%**

Real-world patients are older, more often females, with higher predicted risk of mortality, and have substantially more comorbidities such as diabetes, hypertension or dyslipidemia.[1-6]

1. Udell JA, et al. *JAMA*. 2014;312:841-843.
2. Zulman DM, et al. *J Gen Intern Med*. 2011;26:783-90.
3. Cherubini A, et al. *Arch Intern Med*. 2011;171:550-556.
4. Niederseer D, et al. *International Journal of Cardiology*. 2013;168:1859–1865.
5. Lind KD. AARP Public Policy Institute. 2011
6. Lempereur M, et al. *EuroIntervention*. 2014; doi: 10.4244/EIJY14M12_11. [Epub ahead of print]

ORBIT II - Results

PRIMARY EFFICACY ENDPOINT

Performance goal: 82%

Procedural Success: 88.9%*

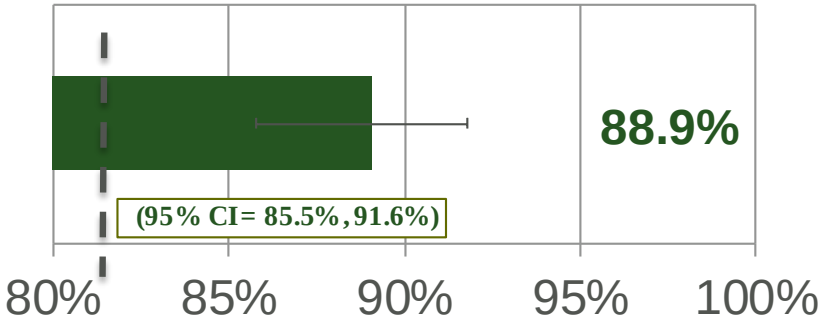
Successful Stent Delivery		97.7%
Residual Stenosis < 50%		98.6%
Freedom from MI (CK-MB>3x ULN)		90.7%
Non Q-wave	91.4%	
Q-wave	99.3%	
Freedom from TVR/TLR		99.3%
Freedom from Cardiac Death		99.8%

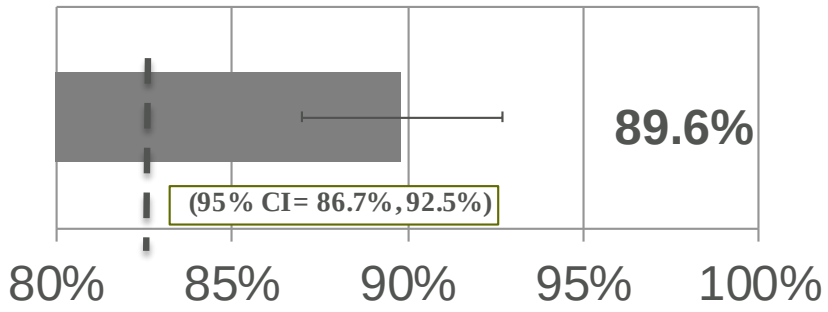
PRIMARY SAFETY ENDPOINT

Performance goal: 83%

Freedom from 30 day MACE: 89.6%

Freedom from MI (CK-MB>3x ULN)		90.3%
Non Q-wave	91.2%	
Q-wave	99.1%	
Freedom from TVR/TLR		98.6%
Freedom from Cardiac Death		99.8%

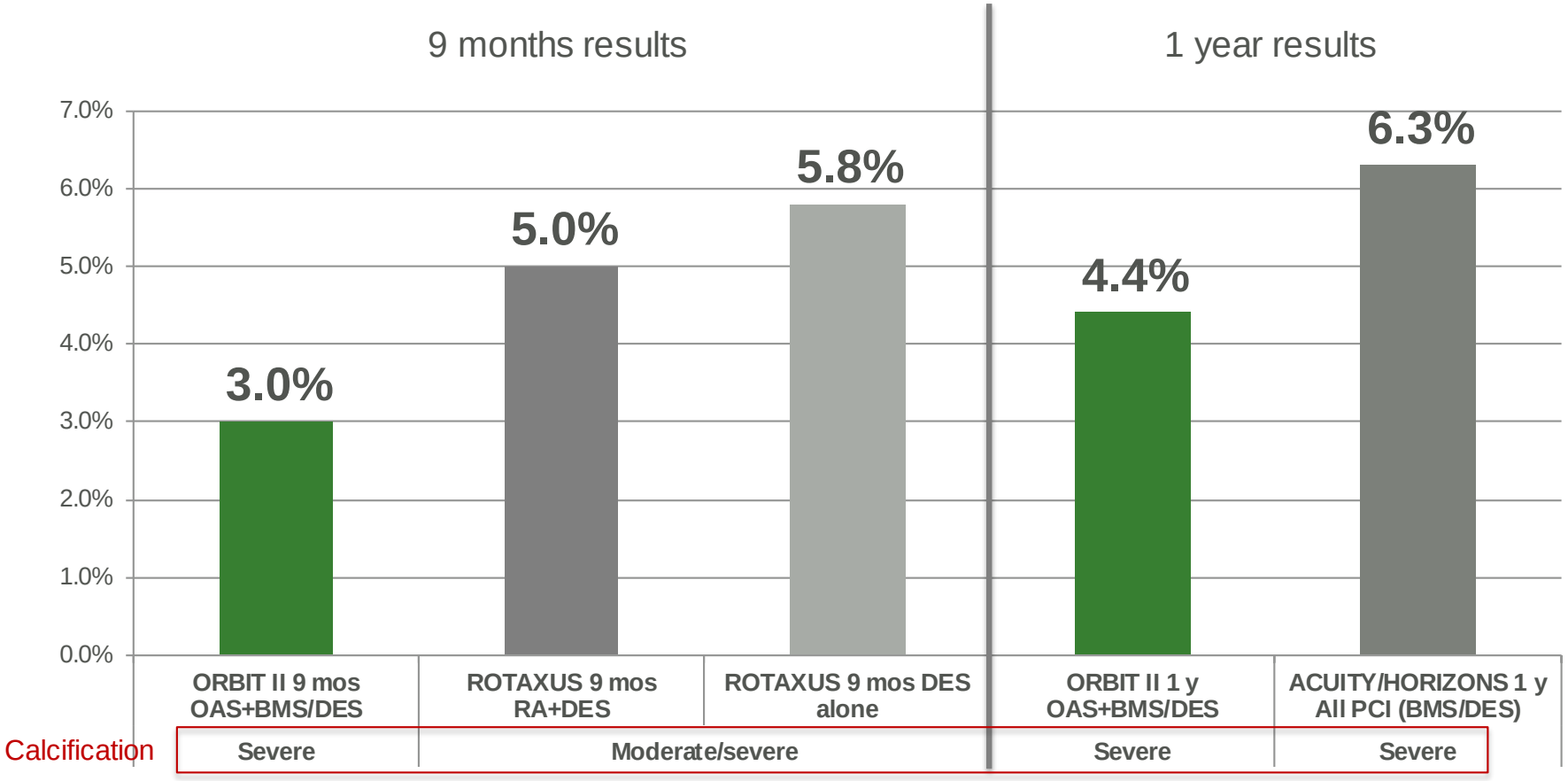




*Subjects may have more than one event.

MORTALITY

OAS has demonstrated substantial clinical improvement in reducing mortality rates in treating severely calcified lesions.

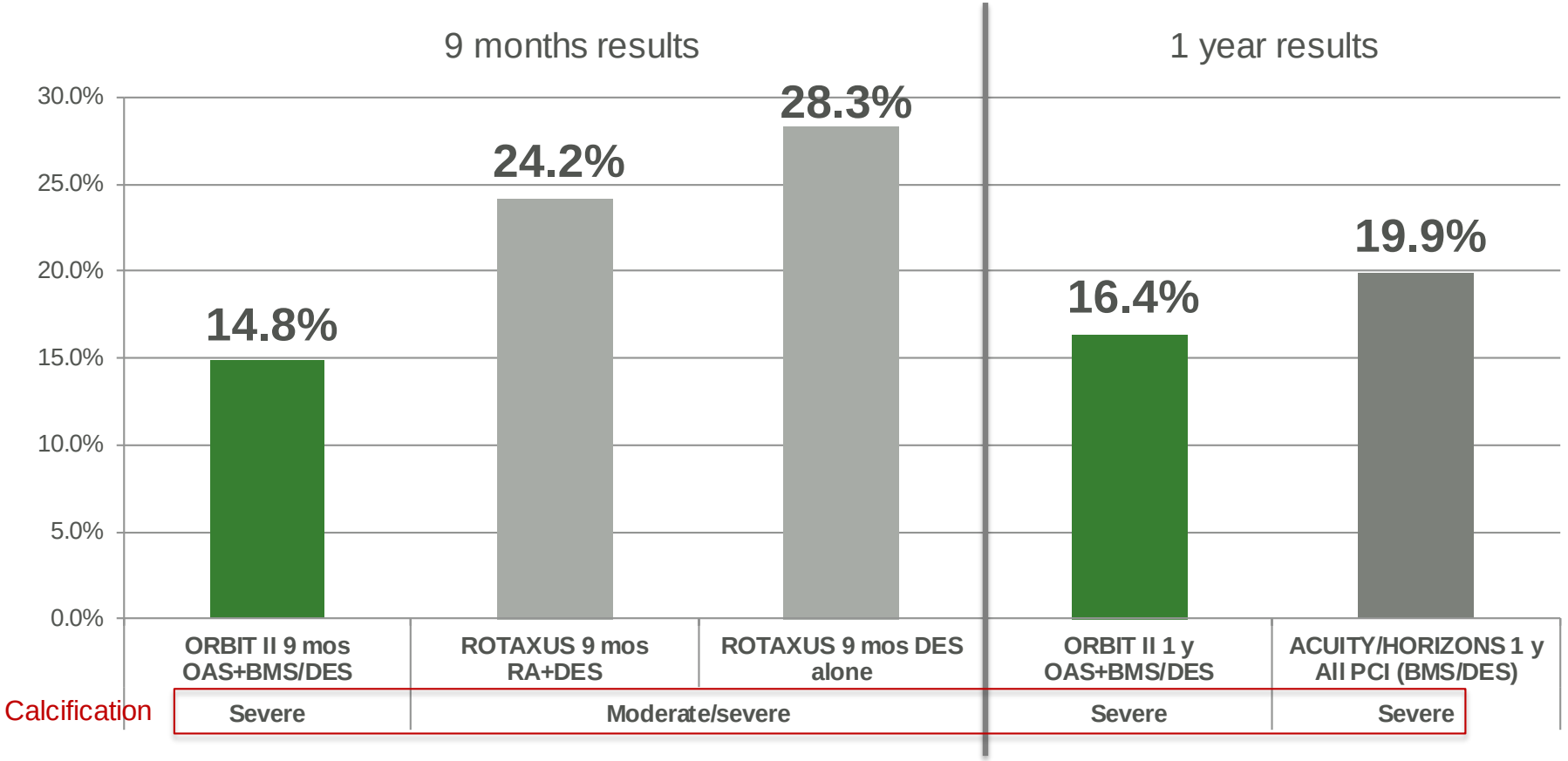


ORBIT II, 100% severely calcified lesions – Chambers JW, et al. *J Am Coll Cardiol Intv*. 2014;7:510-8.
ROTAXUS, ~50%/50% moderate/severely calcified lesions – Abdel-Wahab M, et al. *J Am Coll Cardiol Intv*. 2013;6:10-9.
ACUITY/HORIZONS, 100% severe calcified lesions – Genereux P, et al. *J Am Coll Cardiol*. 2014;63:1845-54.

*The cited clinical trials did not involve direct device-to-device comparison and they varied in study design. The comparison shown is based upon peer-reviewed reports of the studies and is intended to show differences in classes of adverse events to support CMS need for data showing clinical improvement.

MACE Rates

OAS has demonstrated substantial clinical improvement in reducing MACE rates in treating severely calcified lesions.



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ROTAXUS, ~50%/50% moderate/severely calcified lesions – Abdel-Wahab M, et al. *J Am Coll Cardiol Intv*. 2013;6:10-9.
ACUITY/HORIZONS, 100% severe calcified lesions – Genereux P, et al. *J Am Coll Cardiol*. 2014;63:1845-54.

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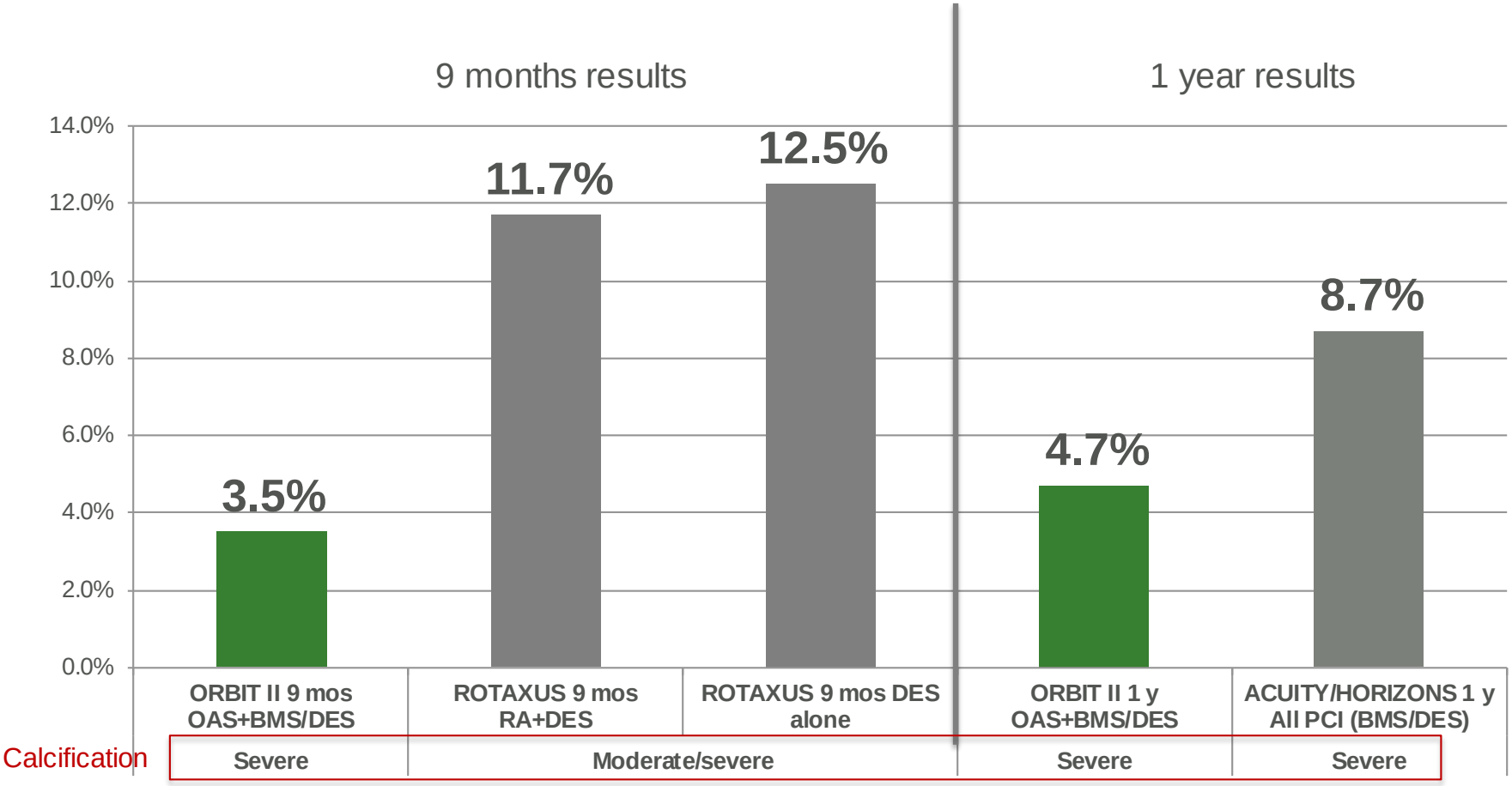
Target Lesion Revascularization Rates

OAS has demonstrated substantial clinical improvement in reducing TLR rates in treating severely calcified lesions.



ORBIT II, 100% severely calcified lesions – Chambers JW, et al. *J Am Coll Cardiol Intv*. 2014;7:510-8.
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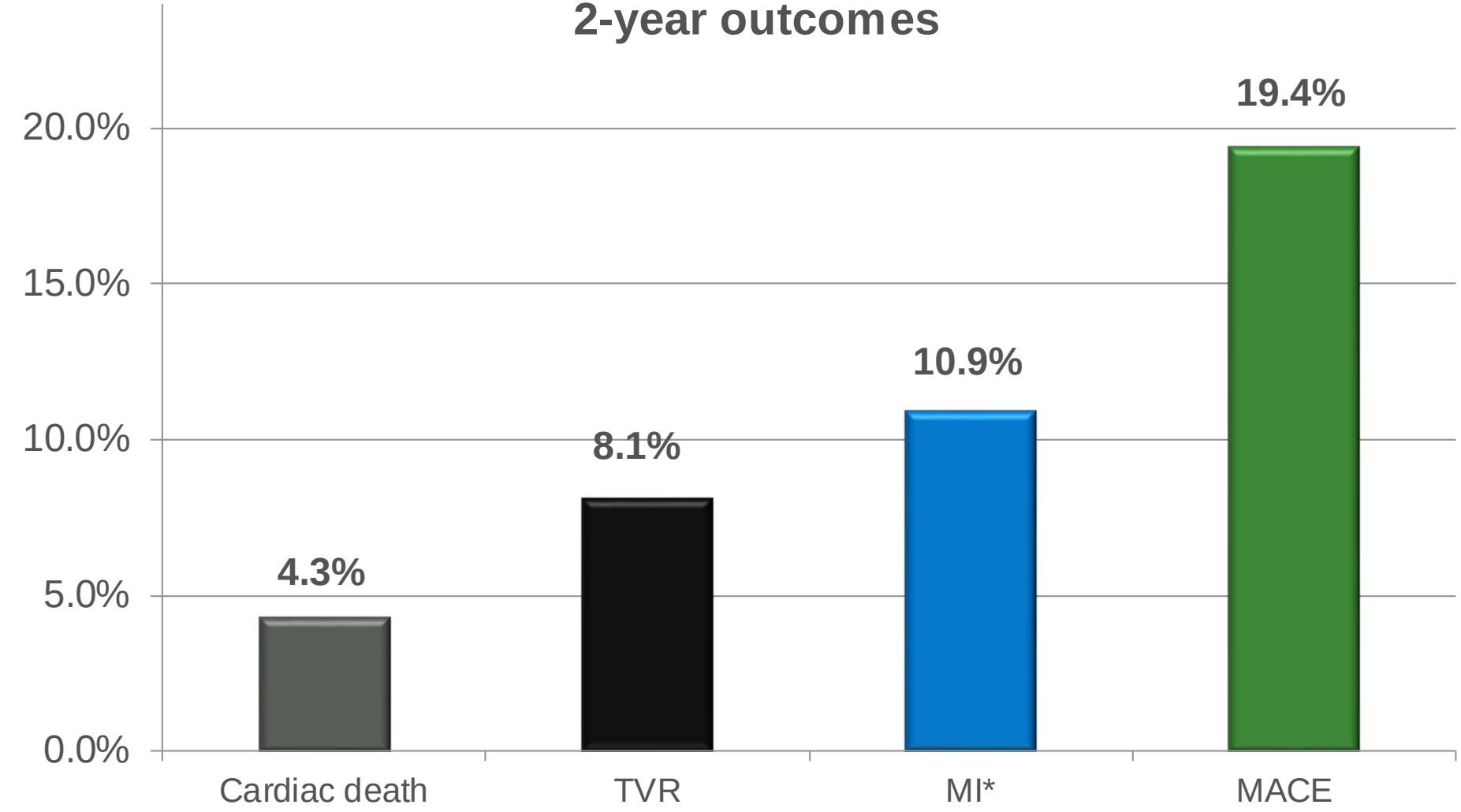
ACUITY/HORIZONS, 100% severe calcified lesions – Genereux P, et al. *J Am Coll Cardiol*. 2014;63:1845-54.

*The cited clinical trials did not involve direct device-to-device comparison and they varied in study design. The comparison shown is based upon peer-reviewed reports of the studies and is intended to show differences in classes of adverse events to support CMS need for data showing clinical improvement.

ORBIT II STUDY OBJECTIVE – SAFETY

OAS has demonstrated that is safe in treating de novo, severely calcified coronary lesions.



*Not per protocol analysis. Clinically driven evaluation based on CEC adjudication of MI.

ORBIT II 1 AND 2 YEAR TVR/TLR RATES WITHIN RANGE OF DES LITERATURE*

	1-year		2-year	
	TVR	TLR	TVR	TLR
ORBIT II—all stent types	1.9%	4.7%	2.9%	6.2%
ORBIT II—DES only	1.6%	3.4%	2.7%	5.2%
ROTAXUS—RA + DES[1]	NR	NR	19.6%	NR
DES RCT—severe Ca^{2+} included	0.7-7.6%[2]	0.0-7.8%[3]	3.7-14.9%[4]	3.5%-11.0%[5]

*Literature search of coronary drug eluting stent (DES) randomized controlled trials (RCT) is on file at CSI. This summary table shows the TVR/TLR events as presented in the literature, but is not a direct device-to-device comparison since the studies described vary in design.

1. Abdel-Wahab M, et al. Rotational atherectomy before paclitaxel-eluting stent implantation in complex coronary lesions: Two-year clinical outcome of the randomized ROTAXUS trial. Presented at EuroPCR 2013--Paris, France.
2. COMPARE (Lancet. 2010;375:201-9.), DESSERT (Am J Cardiol. 2008;101:1560-6.), ESSENCE-DIABETES (Circulation. 2011;124:886-92.), EXAMINATION (Lancet. 2012;380:1482-90.), EXCELLENT (J Am Coll Cardiol. 2011;58:1844-54.), LONG-DES III (JACC Cardiovasc Interv. 2011;4:1096-103.), MISSION (Am J Cardiol. 2010;106:4-12.), PRISON II (Circulation. 2006;114:921-8.), RESET (Circulation. 2012;126:1225-36.), RESOLUTE (J Am Coll Cardiol. 2011;57:2221-32.), SESAMI (J Am Coll Cardiol. 2007;49:1924-30.),TWENTE (J Am Coll Cardiol. 2012;59:1350-61.), ZEST (J Am Coll Cardiol. 2010;56:1187-95.)
3. COMPARE (Lancet. 2010;375:201-9.), DESSERT (Am J Cardiol. 2008;101:1560-6.), ESSENCE-DIABETES (Circulation. 2011;124:886-92.), EXAMINATION (Lancet. 2012;380:1482-90.), EXCELLENT (J Am Coll Cardiol. 2011;58:1844-54.), ISAR Left Main (J Am Coll Cardiol. 2009;53:1760-8.), KOMER-AMI (EuroIntervention. 2011;7:936-43.), LONG-DES III (JACC Cardiovasc Interv. 2011;4:1096-103.), MISSION (Am J Cardiol. 2010;106:4-12.), PASEO (JACC Cardiovasc Interv. 2009;2:515-23.), PRISON II (Circulation. 2006;114:921-8.), PROSIT (Catheter Cardiovasc Interv. 2008;72:25-32.), RESET (Circulation. 2012;126:1225-36.), RESOLUTE (J Am Coll Cardiol. 2011;57:2221-32.), SESAMI (J Am Coll Cardiol. 2007;49:1924-30.), TWENTE (J Am Coll Cardiol. 2012;59:1350-61.), ZEST (J Am Coll Cardiol. 2010 ;56:1187-95.)
4. BASKET-PROVE (N Engl J Med. 2010;363:2310-9.), DES-Diabetes (JACC Cardiovasc Interv. 2011;4:310-6.), GISSOC II-GISE (Eur Heart J. 2010;31:2014-20.)
5. DES-Diabetes (JACC Cardiovasc Interv. 2011;4:310-6.), GISSOC II-GISE (Eur Heart J. 2010 ;31:2014-20.), ISAR Left Main (J Am Coll Cardiol. 2009;53:1760-8.), PASEO (JACC Cardiovasc Interv. 2009;2:515-23.)

SUMMARY OF CLINICAL DATA

- Calcified vessels are technically challenging to treat, requiring more time and resources.

- Using the DIAMONDBACK Coronary OAS, the first and only device approved by FDA specifically to treat severely calcified lesions, offers an effective method to treat calcified coronary lesions to facilitate stent placement in these difficult-to-treat patients.

- Compared to the currently available treatments coronary orbital atherectomy has demonstrated substantial clinical improvement in treating severely calcified coronary lesions as shown by reduced rates of cardiac death, mortality, MACE, and TLR, as well as by reduced length of stay and costs.

NEED FOR CHANGES TO THE CODE STRUCTURE

- Current coding does not have a means of identifying the use of orbital atherectomy in coronary artery interventions
- Establishing a unique qualifier will identify coronary orbital atherectomy from other currently available atherectomy treatments
- A unique qualifier will provide the ability to collect and track:
  - clinical data for treatment of severely calcified lesions
  - utilization and resource costs
  - more accurate coding for reimbursement

MEDICAL RECORD DOCUMENTATION

Orbital atherectomy procedures are typically described within the Medical Record as:

- DIAMONDBACK 360®
- Orbital Atherectomy System (OAS)
- Coronary orbital atherectomy with severely calcified lesions
- Coronary orbital atherectomy with DES/BMS delivery
- Coronary orbital atherectomy with PTCA