A Prospective "All Comers" Cypher non-Randomized Registry in Complex Patients from MATRIX

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MATRIX: Goals and Design

- Post-marketing surveillance prospective registry initiated in 2004 as a 3,500 patient trial under a physician driven IDE
- Is designed to evaluate the safety and efficacy of SES in consecutive "real world" population undergoing PCI with SES
- Both on- and off-label SES use
- Clinical follow-up at 1 month, 6 months, 1 year and 2 years
- Angiographic follow-up at 6 months in patients undergoing PCI for CTO and Acute MI

Study Organization

- Data management: Cardiovascular Research Foundation
- Independent CEC
- 100% monitoring of the first 1,000 pts
- Independent QCA lab

MATRIX Registry: Sub-Studies

- Bifurcation lesions
- CTO
- Acute MI
- Diabetic patients
- Multivessel disease
- SVGs

Medication Regimen

Pre-procedure :

- Aspirin 325 mg
- Clopidogrel loading dose of 300 to 600 mg within 24 hours followed by 75 mg once daily or Ticlopidine loading dose of 500 mg within 24 hours, followed by 250 mg twice a day.

During procedure:

- Angiomax or Heparin ± GP IIb/IIIa inhibitors

Post-procedure and after discharge:

- Aspirin 325 mg for 1 months, thereafter ASA 81 mg indefinitely
- Clopidogrel 75 mg once daily for at least 1 year or Ticlopidine 250 mg twice a day for at least 1 year

Results

Enrollment As of 4/24/06

- # of patients: 1777
- Data available on: 921 patients:
  - CTO-268, CTO w/ angio FU=35
  - Acute MI-37, AMI with angio FU=8
  - Bifurcation-181
  - Failed Brachytherapy-26
  - SVG-60

Baseline Clinical Characteristics

	N = 921 patients
Age, mean±SD (years)	64.7±10.9
Male gender	74.1%
Diabetes mellitus	35.7%
Hyperlipidemia	83.2%
Hypertension	82.4%
History of CVA/TIA	9.0%
Prior MI	35.4%
Prior CABG	20.5%
Smoking within 30 days	11.7%
Unstable angina	35.0%

Baseline Angiographic Characteristics (1)

	N = 1,398 lesions
Target vessel	
Unprotected LM	1.3%
LAD	37.1%
LCX	27.5%
RCA	29.5%
SVG	3.8%
Arterial conduit	0.5%
Target lesion location	
Ostial	8.7%
Proximal	30.0%
Chronic total occlusion	4.6%
Bifurcation	12.4%
De novo lesion	90.7%
Restenotic lesion	9.3%

Baseline Angiographic Characteristics (2)

	N = 1,398 lesions
Multivessel CAD	67.7%
Ejection fraction, mean±SD (%)	50.5±10.7
Lesion length, mean±SD (mm)	22±13
TIMI flow grade 0 to 2	10.4%
TIMI flow grade 3	89.6%
Moderate/severe calcification	24.3%
Moderate/severe tortuosity	2.5%
Lesion type B2/C by ACC/AHA	69.3%
RVD, mean±SD (mm)	2.78±0.43
MLD, mean±SD (mm)	0.68±0.40
Diameter stenosis, mean±SD (%)	75.9±9.8

Final Angiographic Characteristics

	N = 1,398 lesions
RVD, mean±SD (mm)	2.86±0.44
MLD, mean±SD (mm)	2.34±0.44
Diameter stenosis, mean±SD (%)	5.8±8.8
Acute gain in segment, mean±SD (mm)	1.66±0.48
TIMI flow grade 3	99.6%

Procedural Characteristics

	N = 1,398 lesions
Direct stenting	33.2%
Total stent length, mean±SD (%)	21.2±7.4
Overlapping stents	18.1%
Angiomax used	82.2%
IIb/IIIa inhibitors administered	7.5%
Device success	98.3%
Angiographic success	99.9%
Procedure success	94.8%

In-hospital Outcomes

	N=921 patients
Death	0.1%
Myocardial infarction	3.4%
Q wave	0
Non-Q wave	3.4%
TLR	0.1%
TVR	0.8%
Stent thrombosis	0.1%
TVF*	3.5%

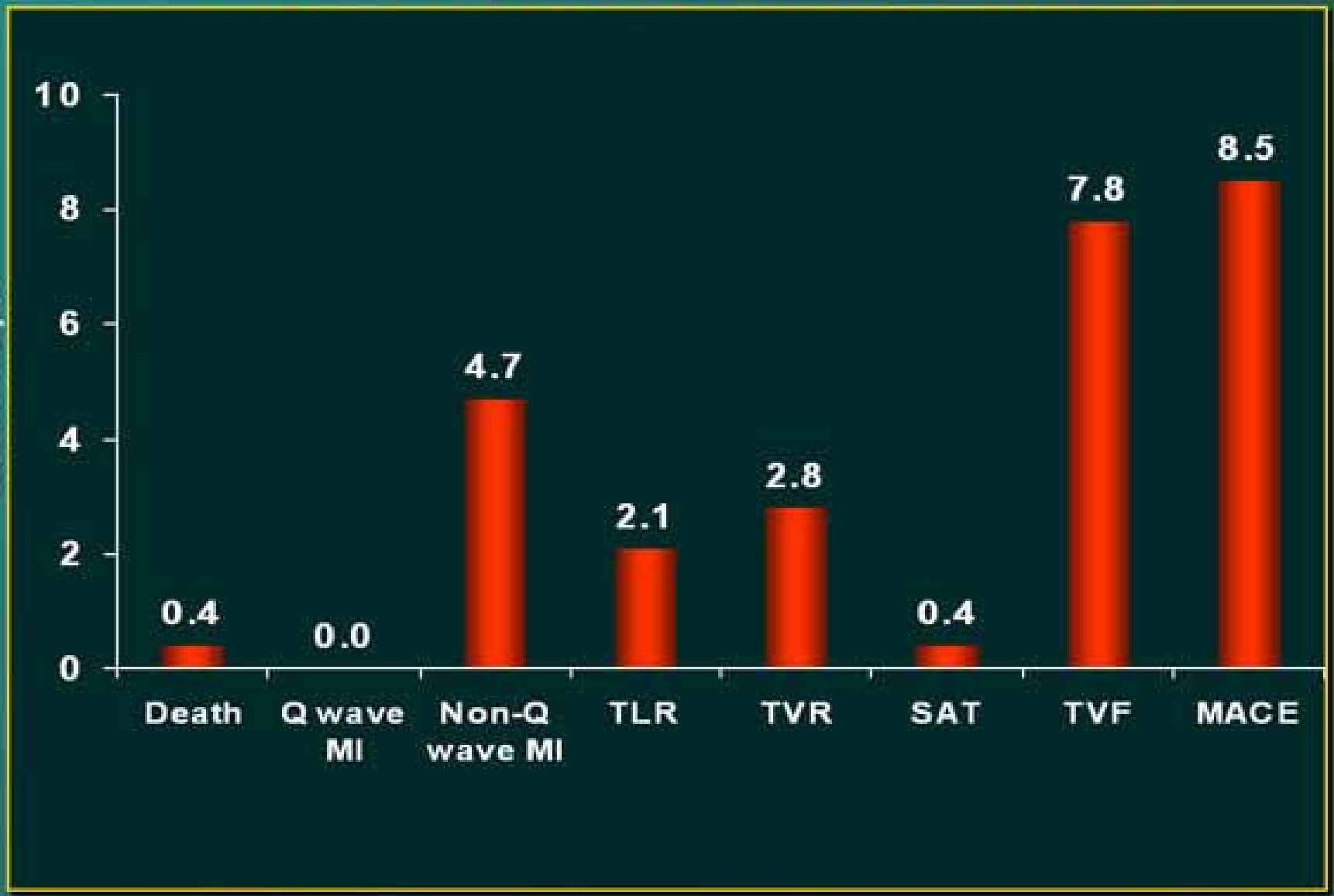
**TVF = cardiac death, MI or TVR*

Outcomes to 6 months

	N=702 patients
Death	0.4%
Myocardial infarction	4.7%
Q wave	0
Non-Q wave	4.7%
TLR	2.1%
TVR	2.8%
Stent thrombosis	0.4%
TVF*	7.8%

**TVF = cardiac death, MI or TVR*

Outcomes at Six Months



MATRIX - Conclusions (1)

In this preliminary interim analysis of the first 921 patients from the MATRIX registry which included patients with complex coronary artery disease treated with the sirolimus-eluting Bx VELOCITY™ stent (Cypher stent)

- In comparison to previous sirolimus randomized trials (RAVEL, SIRIUS, C-SIRIUS, and E-SIRIUS), enrollment included consecutive patients with "real life" characteristics that include sicker patients, multi-vessel stenting, longer lesions, and more complex lesions, like bifurcations, CTO's, LMCA, and SVG's

MATRIX - Conclusions

- The frequency of in-hospital and early (30 days) out-of-hospital adverse events was low, and similar to those previously reported with simple low-risk lesions
- The frequency of stent thromboses was low, 0.4%
- The use of cypher stent in "real life" clinical practice, that includes high rate of multivessel and complex lesions, is safe.
- Long term follow-up is ongoing and will explore the effectiveness of the cypher stent in real-life PCI practice