



The Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery: The SYNTAX Study

One Year Results of the PCI and CABG Registries

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On behalf of the SYNTAX investigators

Conflicts of Interest: None



Background I



- In the past five years several studies that have compared contemporary treatment of CAD by CABG and PCI (e.g. New York Registry) have been reported.
- These trials showed a risk-adjusted decrease in 5-year mortality in favor of CABG when the proximal LAD was involved.

Background II



- To demonstrate improvements in current stent therapy, the results of recent PCI studies were compared to previous randomized trials (e.g. ARTS II).
- These studies showed a clear improvement in PCI results but compared to historical CABG data.

SYNTAX Trial Design



62 EU Sites + 23 US Sites

Total enrollment
 $N=3075$

Stratification:
LM and Diabetes

Randomized Arms
 $N=1800$

CABG
 $N=897$

vs.

TAXUS*
 $N=903$

Two Registry Arms

CABG
 $N=1077$

5yr FU $N=649$	No FU $N=428$
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PCI
 $N=198$

*TAXUS Express

Registries Objective



Patients were identified who were not candidates for randomization based on clinical or anatomical characteristics and formed the basis for the registry experience:

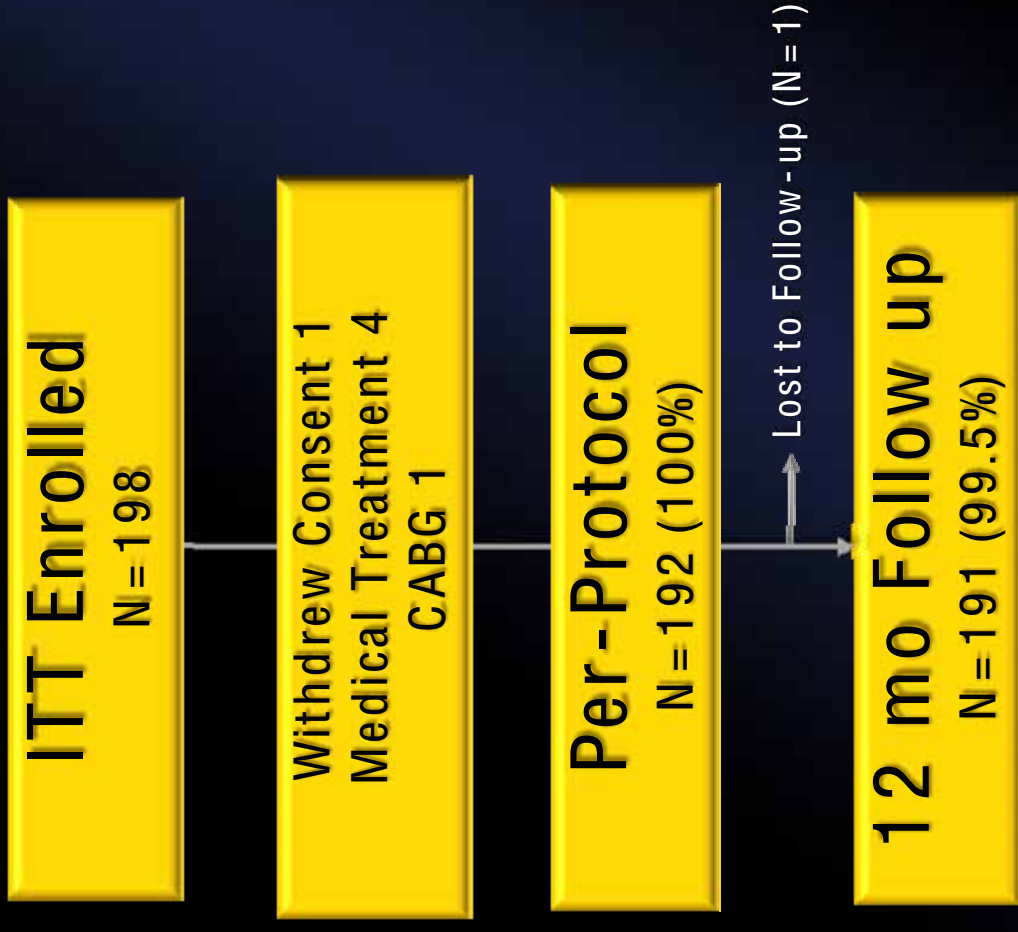
- Who were not candidates for CABG (inoperable patients)
- Who were not candidates for PCI (technically not feasible)

Registries Methodology



- Treatment schedule and follow up visits identical with RCT
- Major adverse cardiac and cerebrovascular events 100% monitored
- 20% of patient data at each site (every fifth patient) was fully monitored
- No statistical comparisons between randomized and registry were performed

Patient Disposition: PCI Registry



Patient Disposition: CABG Registry



ITT Enrolled

N = 1077

Randomly assigned to 5y Follow-up

N = 649

No Treatment 3
Medical Treatment 2

Per-Protocol

N = 644 (100%)

Lost to Follow-up (N = 10)
Withdrew Consent (N = 1)

12 mo Follow up

N = 633 (98.2%)



Reasons for Registry Allocation



PCI Registry - CABG ineligible due to:

- Co-morbidities (70.7%)
- No graft material (9.1%)
- Small or poor quality of distal vessel (1.5%)
- Patient refused CABG (5.6%)
- Other (13.1%)

CABG Registry- PCI ineligible due to:

- Complex anatomy (70.9%)
- Untreatable CTO (22.0%)
- Unable to take anti-platelet medications (0.9%)
- Patient refused PCI (0.5%)
- Other (5.7%)

Patient Characteristics

Notable Differences PCI RCT + Registry



	TAXUS RCT n = 903	PCI Reg n = 192
Age, mean \pm SD (y)	65.2 \pm 9.7	71.2 \pm 10
Male, %	76.4	70.3
SYNTAX score	28.4 \pm 11.5	31.6 \pm 12.3
Diabetes, %	28.2	35.4
Hyperlipidemia, %	78.7	67.5
Current smoker, %	18.5	11.2
Prior MI, %	31.9	40.4
Unstable angina, %	28.9	38.0
Add. EuroSCORE, mean \pm SD	3.8 \pm 2.6	5.8 \pm 3.1
Total Parsonnet score, mean \pm SD	8.5 \pm 7.0	14.4 \pm 9.5

*For descriptive purposes only; no statistical comparisons done

Procedural Characteristics

Notable Differences: PCI RCT + Registry



	TAXUS RCT* n = 903	PCI Reg n = 192
Staged Procedure, %	14.1	13.0
Bi/trifurcation lesions treated, %	24.8	64.4
Lesions treated, mean \pm SD	3.6 \pm 1.6	2.5 \pm 1.3
Stents implanted, mean \pm SD	4.6 \pm 2.3	3.1 \pm 1.8
Total length implanted, mm	86.1 \pm 47.9	58.5 \pm 41.2
Range, mm	8.0 - 324.0	8.0 - 252.0
Long stenting (>100 mm), %	33.2	12.2

*For descriptive purposes only; no statistical comparisons done

Patient Characteristics

Notable Differences CABG RCT + Registry



	CABG RCT N = 897	CABG Reg N = 644
Age, mean \pm SD (y)	65.0 \pm 9.8	65.7 \pm 9.4
Male, %	78.9	80.7
SYNTAX score, mean \pm SD	29.1 \pm 11.4	37.8 \pm 13.3
Diabetes, %	28.5	29.7
Hypertension, %	77.0	73.5
Hyperlipidemia, %	77.2	76.4
Current smoker, %	22.0	21.9
Prior MI, %	33.8	33.5
Unstable angina, %	28.0	21.6
Add. EuroSCORE, mean \pm SD	3.8 \pm 4.4	3.9 \pm 2.7
Total Parsonnet score, mean \pm SD	8.4 \pm 6.8	9.0 \pm 7.1

*For descriptive purposes only; no statistical comparisons done

Procedural Characteristics

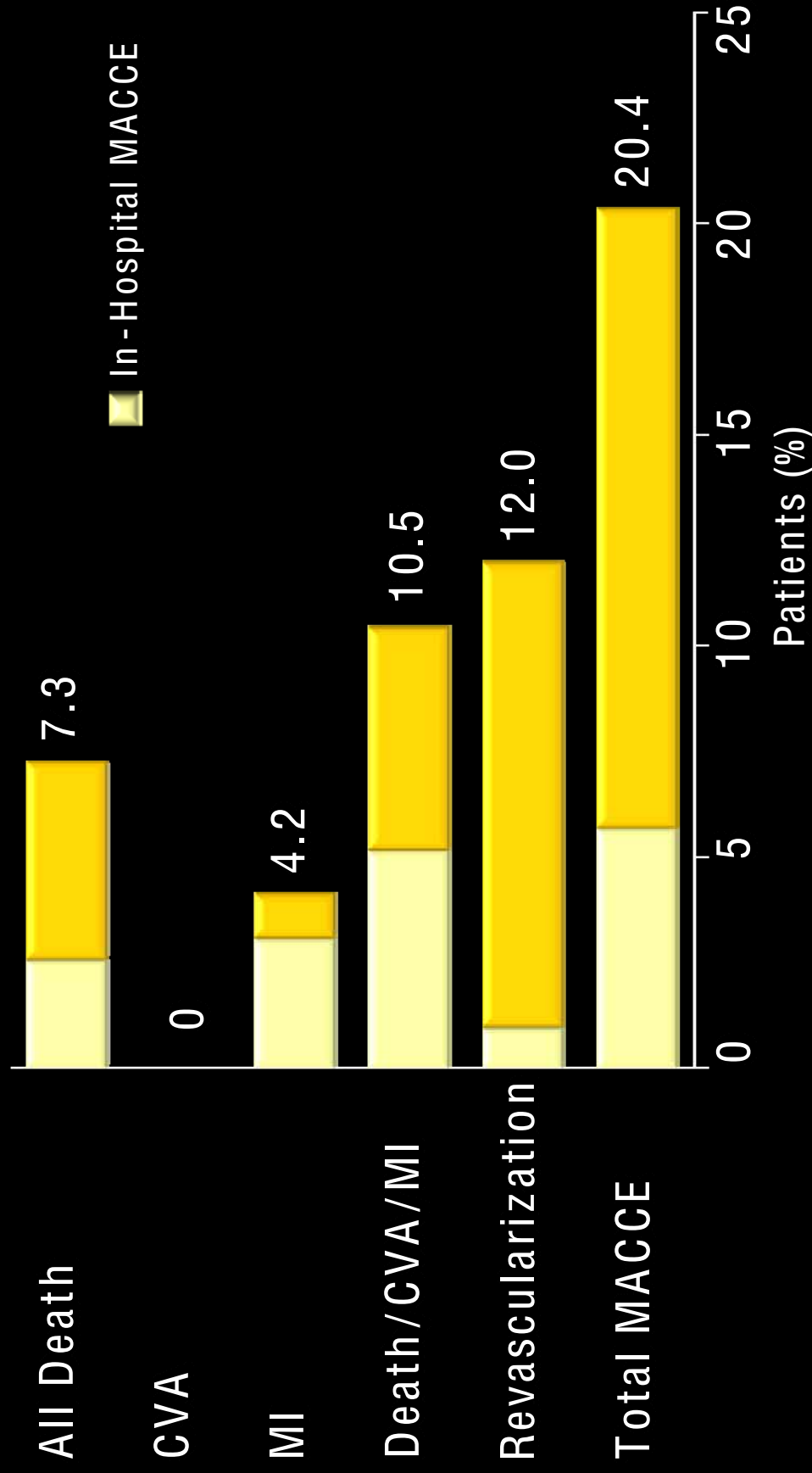
Notable Differences CABG RCT + Registry



	CABG RCT* n = 897	CABG Reg n = 644
<i>Procedure-related</i>		
Off-pump surgery, %	15.0	18.6
Graft revascularization, %		
At least one arterial graft	97.3	96.7
Arterial graft to LAD	95.6	94.7
LIMA + venous	78.1	85.1
Double LIMA/RIMA	27.6	16.1
Complete arterial revascularization	18.9	11.2
Venous graft only	2.6	3.3
Grafts per patient, mean ±SD	2.8 ± 0.7	3.0 ± 0.9
Distal anastomoses, mean ±SD	3.2 ± 0.9	3.5 ± 1.0

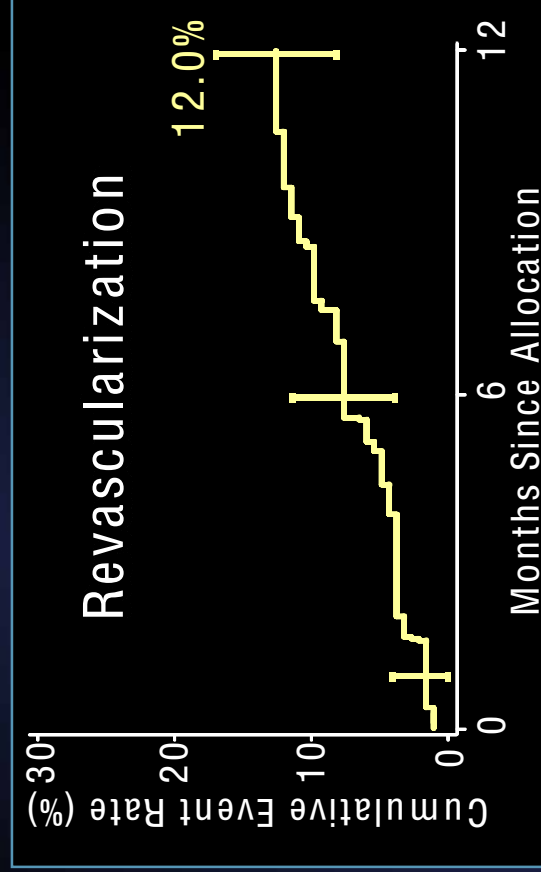
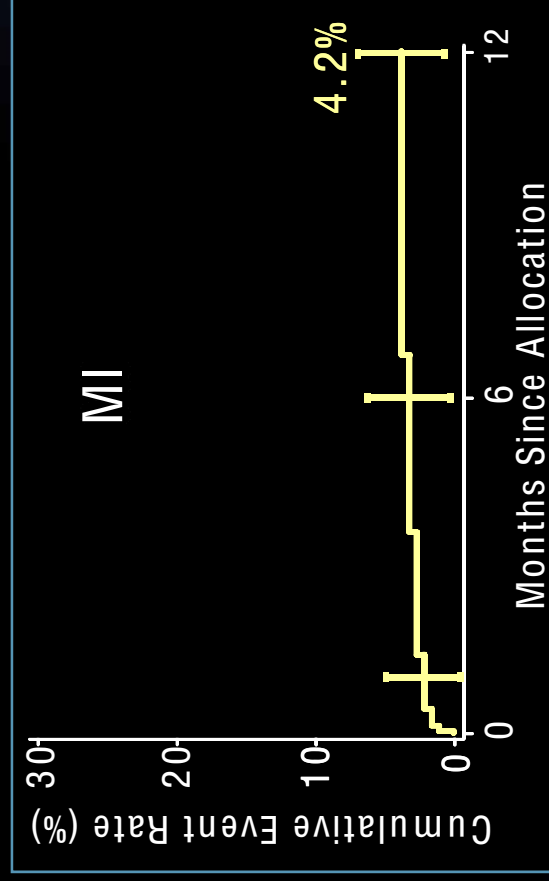
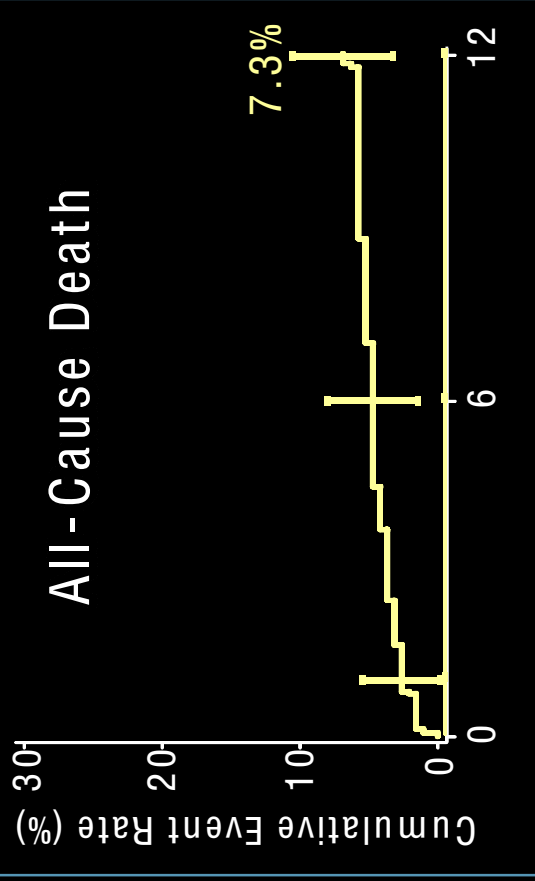
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12 Month MACCE Rates PCI Registry (N = 192)

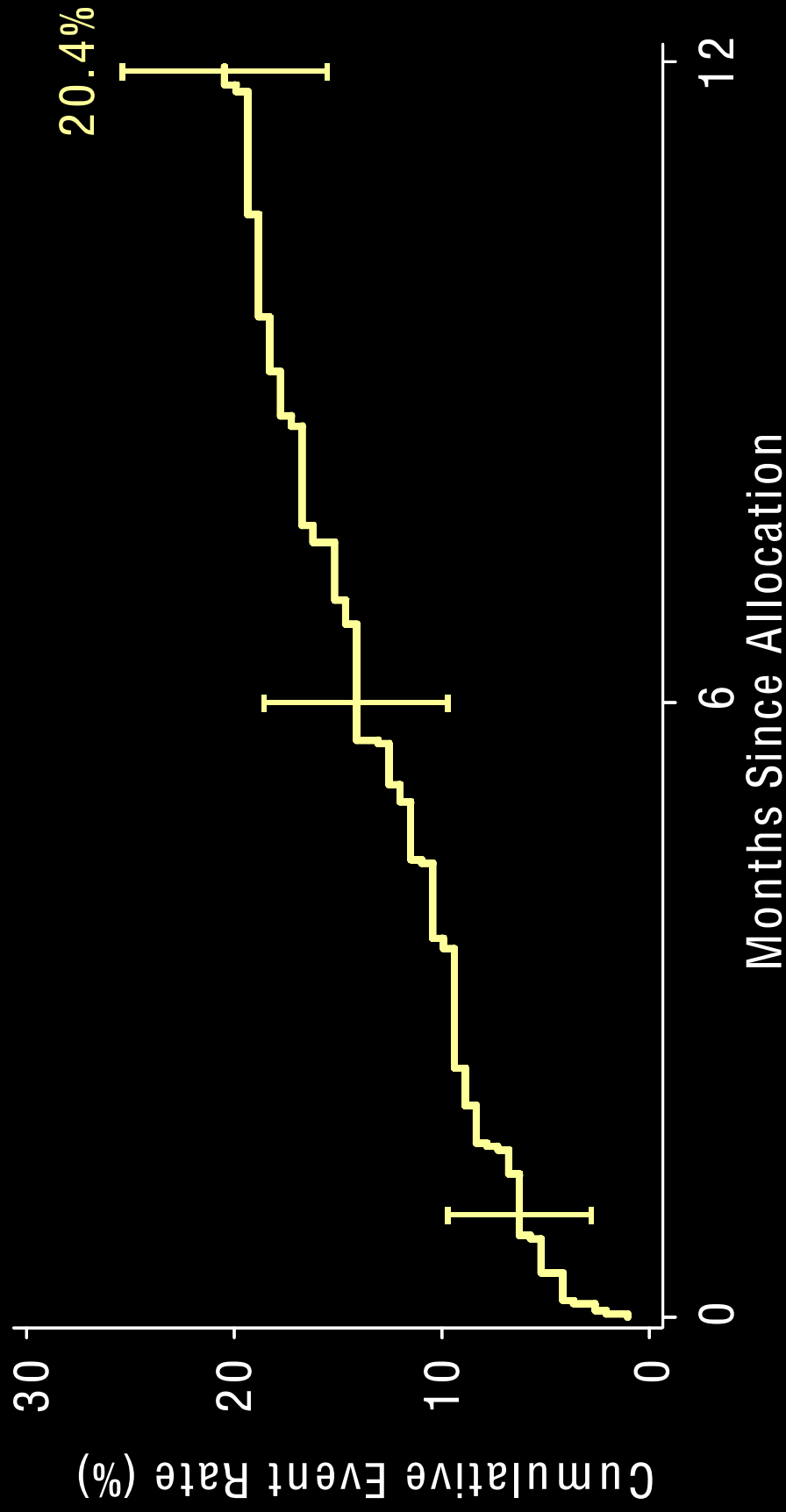


Per-protocol population

Event Rates to 12 Months: PCI Registry



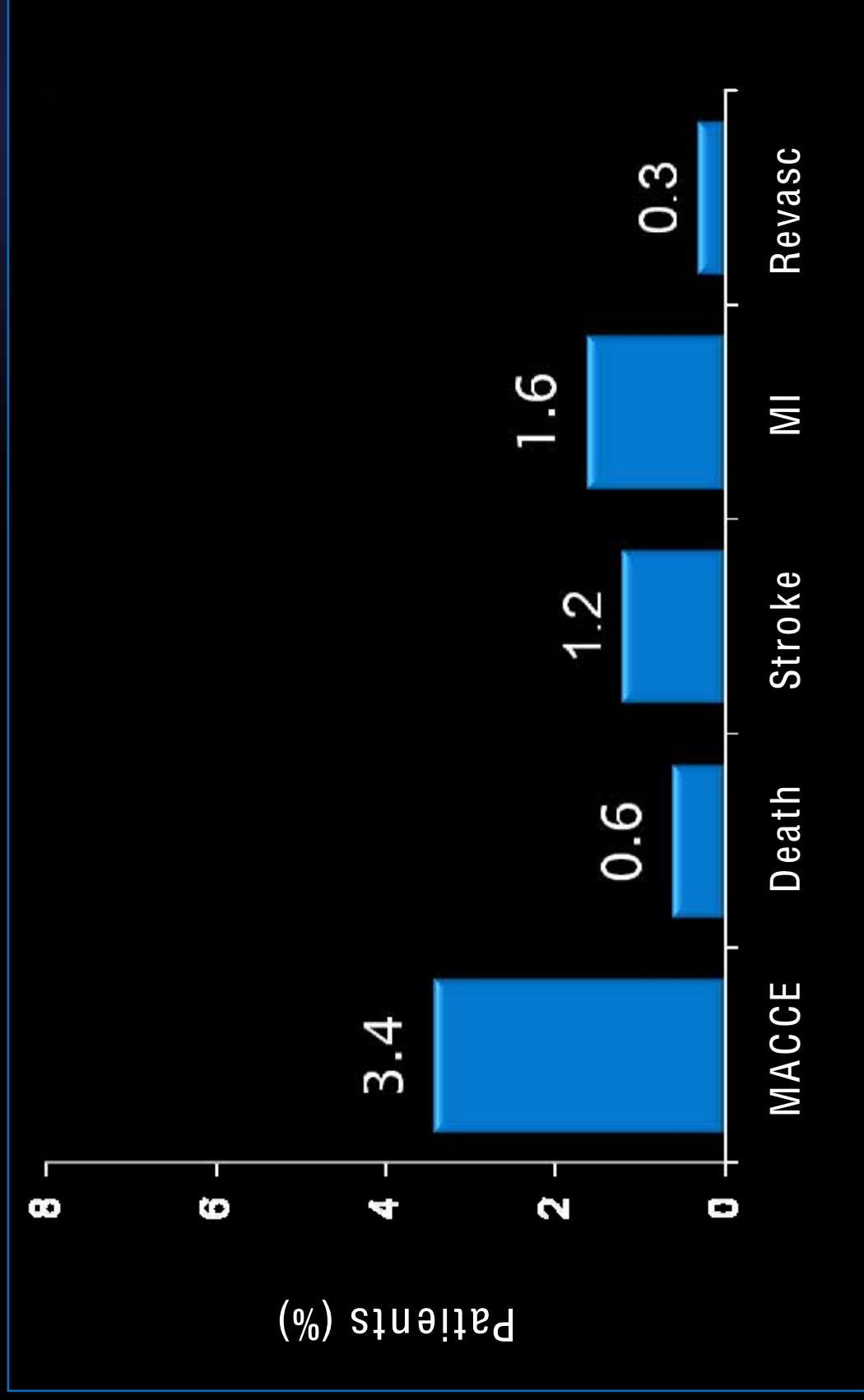
Overall MACCE to 12 Months *PCI Registry*



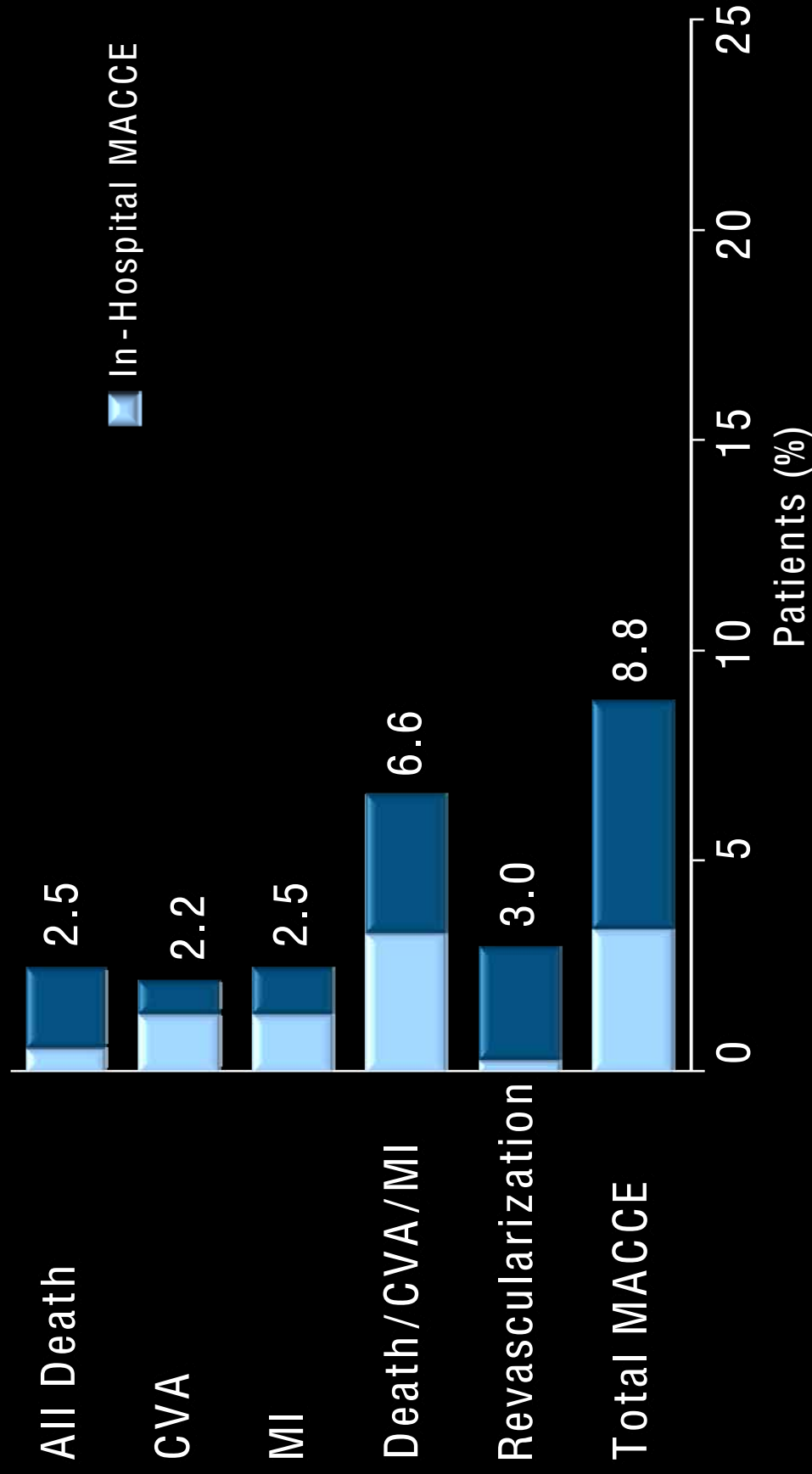
Event Rate \pm 1.5 SE

Per-protocol population

30 Day MACCE Post-Procedure CABG Registry (N=644)

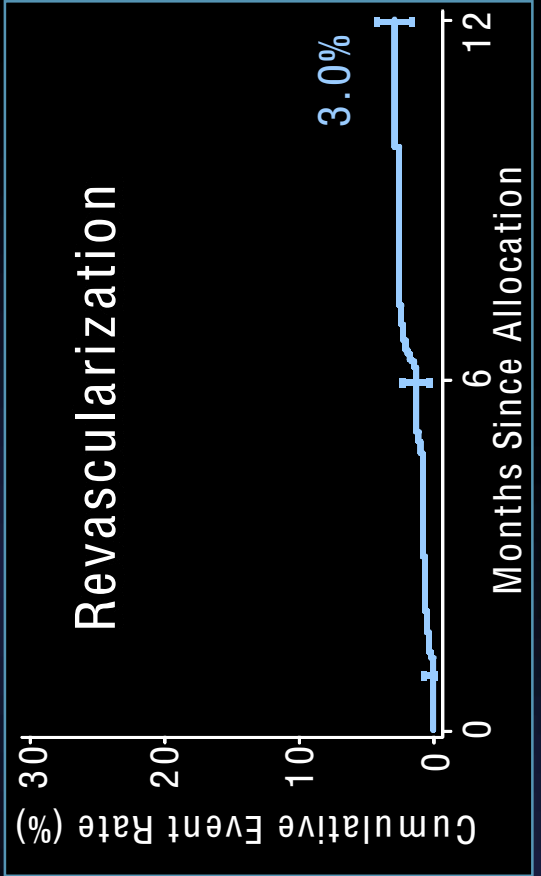
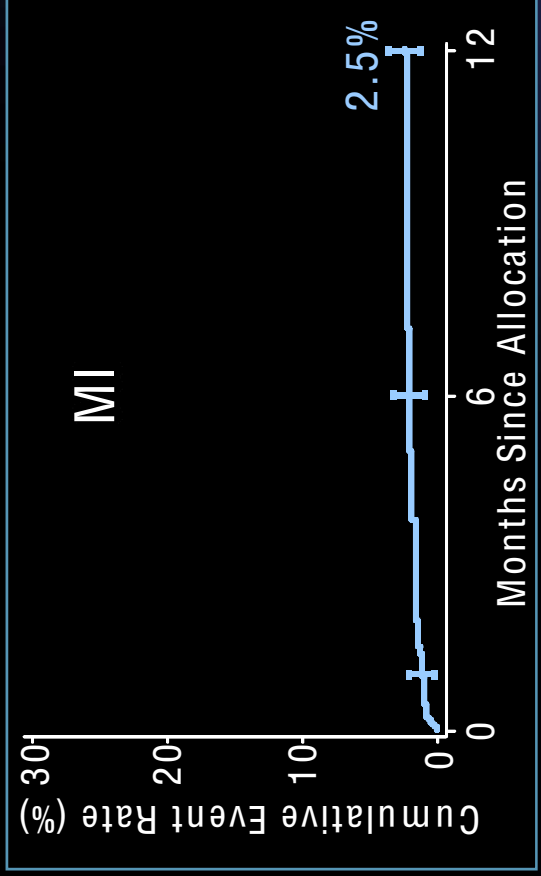
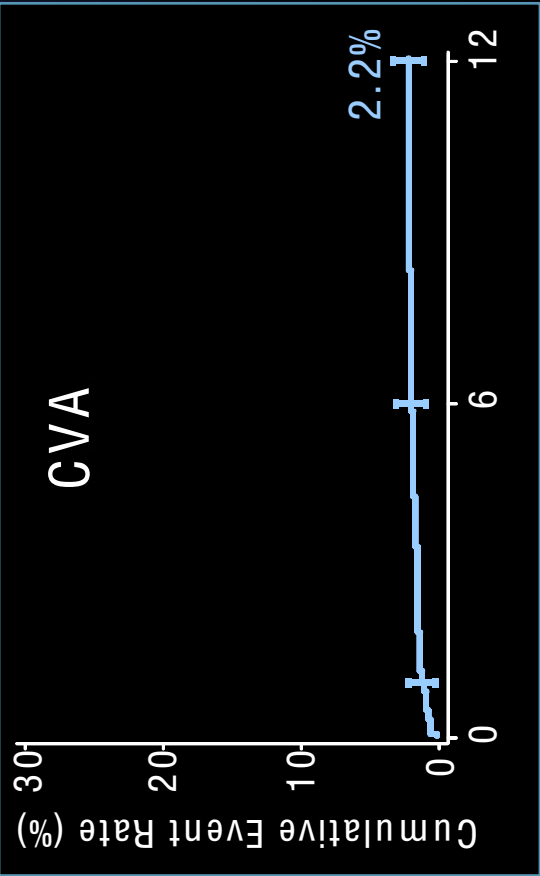
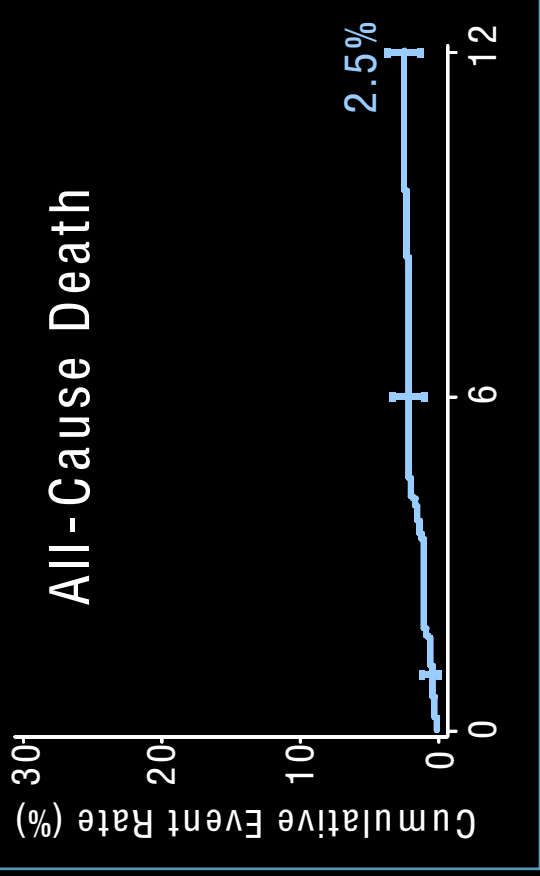


12 Month MACCE Rates CABG Registry (N=644)

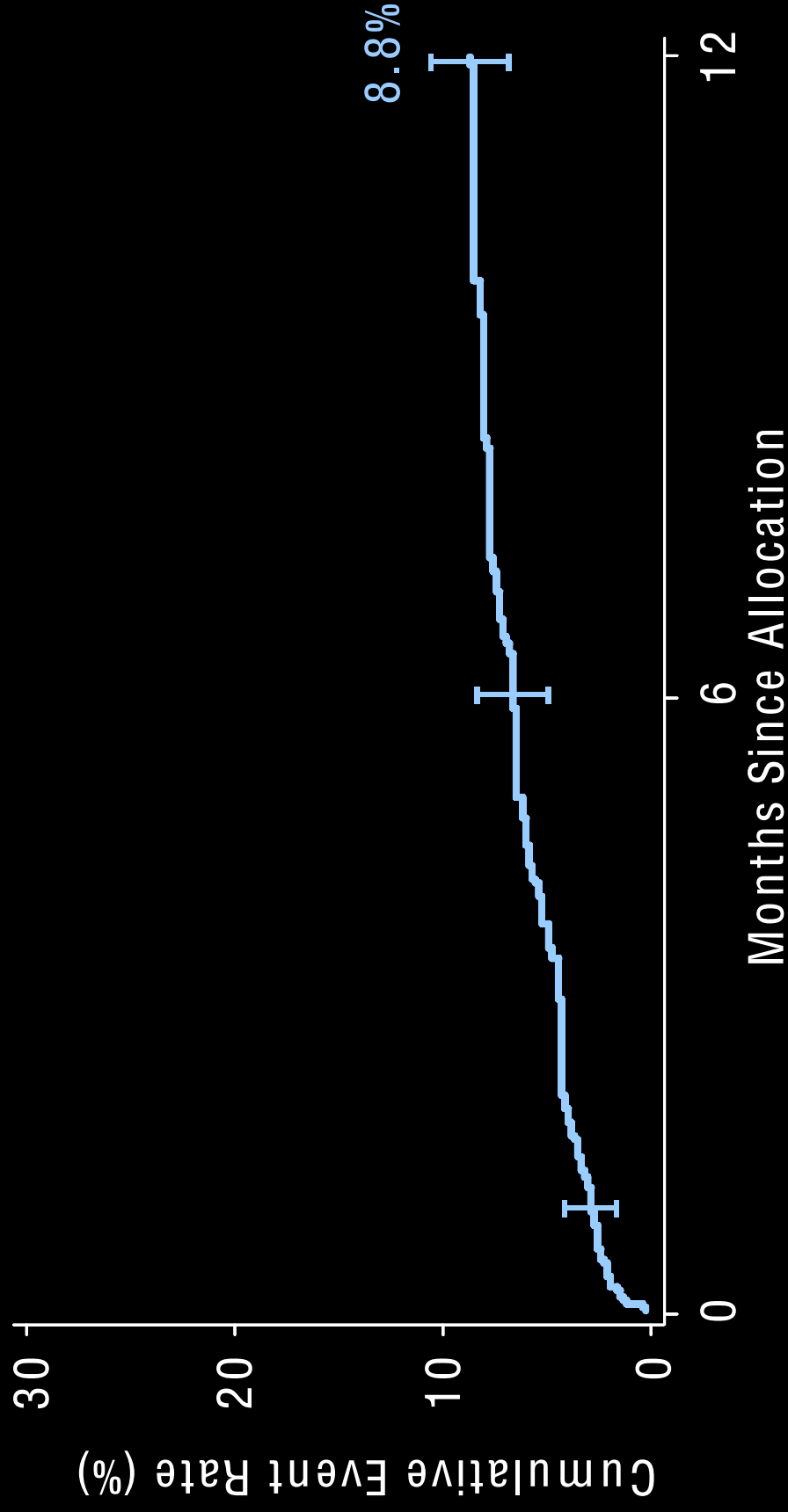


Per-protocol population

Event Rates to 12 Months: CABG Registry SYNTAX



Overall MACCE to 12 Months *CABG Registry*



Event Rate \pm 1.5 SE

Per-protocol population

Conclusions Registries



- Patients (N = 1275) were identified as unsuitable candidates for randomization based on clinical or anatomical characteristics, and formed the basis for the registry experience
- Patients (N = 198) who were not candidates for CABG form a small population to study the outcomes of inoperable patients
- Patients (N = 1077) who were not candidates for PCI form an ideal population to study the results of current surgical practice

Conclusions *PCI Registry*



- PCI registry patients have the highest co-morbidity as expressed by highest EuroSCORE & Parsonnet scores
- In this surgically inoperable PCI registry the 12 month outcomes are:
 - All Cause Death 7.3%
 - CVA 0.0%
 - MI 4.2%
 - Repeat Revascularization 12.0%
 - MACCE 20.4%

Conclusions *CABG Registry*



- The CABG registry patients who are technically unsuitable for PCI have the most complex lesion anatomy as expressed by a higher SYNTAX score
- In the CABG registry the 12 month outcomes are:
 - All Cause Death 2.5%
 - CVA 2.2%
 - MI 2.5%
 - Repeat Revascularization 3.0%
 - MACCE 8.8%

General Conclusions SYNTAX Trial



- The SYNTAX trial has enrolled a large number of patients with LM and/or 3 VD to evaluate optimal strategies of care. In these patients we can conclude:
- The Primary Endpoint (12 months MACCE) in this non-inferiority trial for PCI was not met.
- PCI continues to improve as do surgical techniques
- In this trial the Heart Team concluded that CABG remains the only treatment option for at least 1/3 of the patients screened
- In patients who are not candidates for PCI, surgical results are excellent
- In patients who are not candidates for CABG, PCI is a viable option