International Study Of Comparative Health Effectiveness With Medical And Invasive Approaches (ISCHEMIA):

Primary Report of Clinical Outcomes

Funded by the National Heart, Lung, and Blood Institute

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On behalf of the ISCHEMIA Research Group

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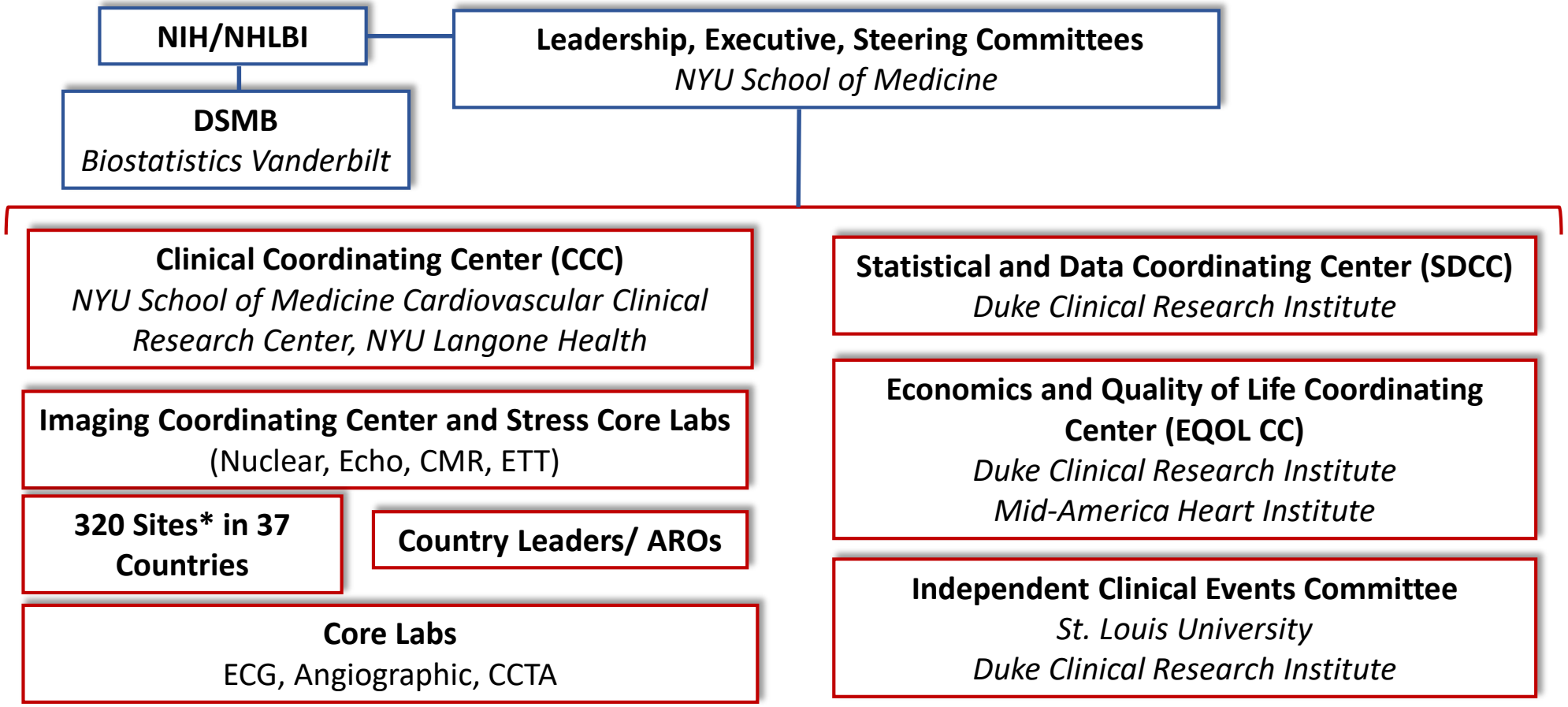
ISCHEMIA Organization



**Specific PCI and CABG volume and quality criteria were required for site participation.*

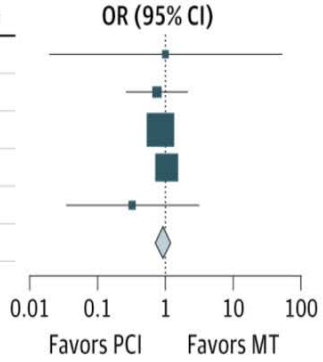
PCI vs Medical Therapy Alone in Patients With Stable Obstructive CAD and Myocardial Ischemia: Meta-analysis of RCTs

Selected for >50% statin use in both groups and >50% stent use
Subset of patients with ischemia documented (4064 of 5286)

A

Death

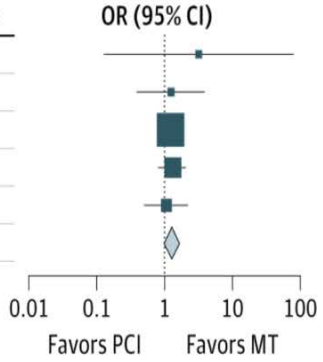
Source	OR (95% CI)	*P* Value
Hambrecht[15]	1.02 (0.02-52.43)	.99
MASS II[13]	0.76 (0.27-2.16)	.60
COURAGE[17]	0.84 (0.61-1.18)	.32
BARI 2D[14]	1.06 (0.71-1.58)	.78
FAME 2[16]	0.33 (0.03-3.16)	.33
Overall	0.90 (0.71-1.16)	.42



B

MI (non-fatal)

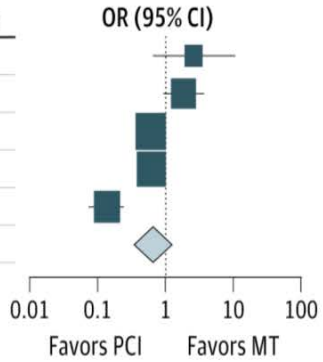
Source	OR (95% CI)	*P* Value
Hambrecht[15]	3.12 (0.12-78.45)	.49
MASS II[13]	1.24 (0.40-3.88)	.71
COURAGE[17]	1.24 (0.94-1.65)	.13
BARI 2D[14]	1.29 (0.82-2.04)	.27
FAME 2[16]	1.06 (0.51-2.22)	.88
Overall	1.24 (0.99-1.55)	.06



C

Unplanned Revascularization

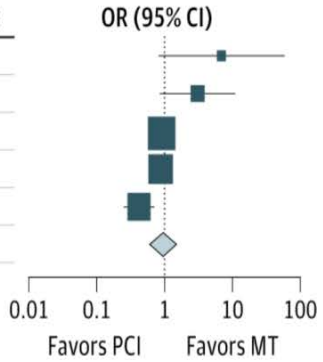
Source	OR (95% CI)	*P* Value
Hambrecht[15]	2.60 (0.63-10.71)	.18
MASS II[13]	1.84 (0.91-3.73)	.09
COURAGE[17]	0.60 (0.48-0.74)	<.001
BARI 2D[14]	0.61 (0.46-0.80)	<.001
FAME 2[16]	0.13 (0.07-0.24)	<.001
Overall	0.64 (0.35-1.17)	.14



D

Angina

Source	OR (95% CI)	*P* Value
Hambrecht[15]	6.82 (0.79-58.85)	.08
MASS II[13]	3.06 (0.83-11.29)	.09
COURAGE[17]	0.91 (0.74-1.10)	.33
BARI 2D[14]	0.87 (0.59-1.28)	.47
FAME 2[16]	0.42 (0.25-0.72)	<.001
Overall	0.90 (0.57-1.44)	.67

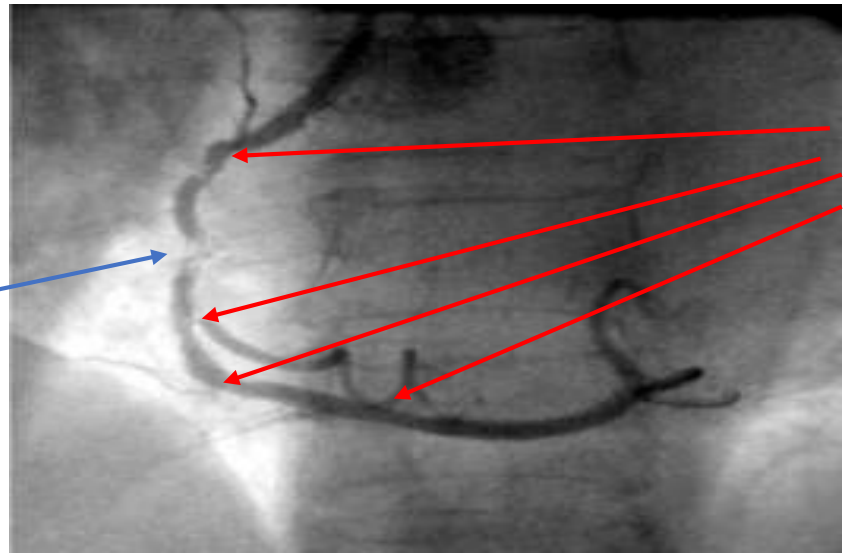


Stergiopoulos et al. JAMA Intern Med. 2014;174:232-40.

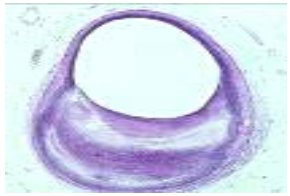
A paradigm that suggests why randomized trials have not demonstrated a survival benefit for revascularization in SIHD

Severe Obstruction (angina, no rupture) vs Mild Obstruction (no angina, likely to rupture)

Severe fibrotic plaque
- **Severe obstruction**
- **No lipid**
- **Fibrosis, Ca^{2+}**



Vulnerable plaque
- **Minor obstruction**
- **Eccentric plaque**
- **Lipid pool**
- **Thin cap**

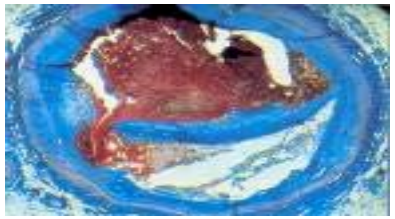


Plaque rupture
- **Acute MI**
- **Unstable angina**
- **Sudden death**

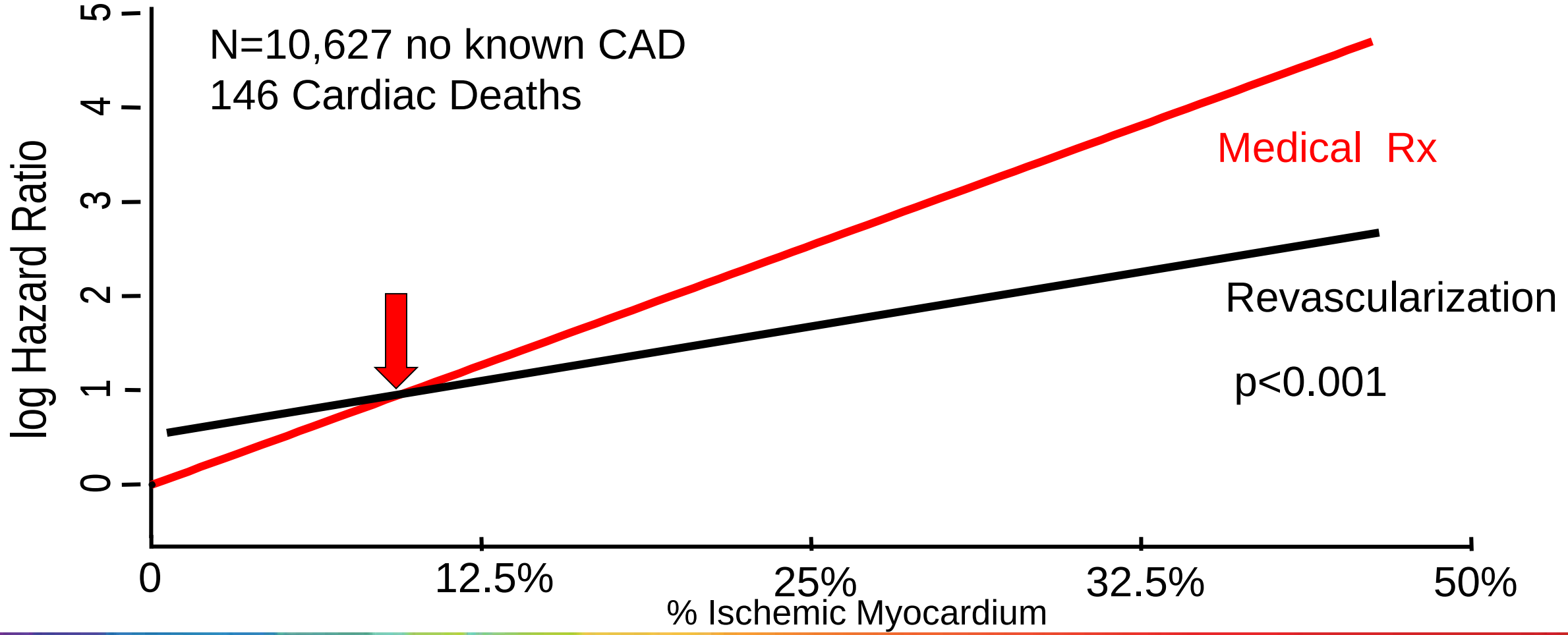
Exertional angina
- **(+) ETT**

Revascularization
Anti-anginal Rx

Pharmacologic stabilization
Early identification of high-risk?



Observational study: Revascularization was associated with lower risk of cardiac death only in those with >10% ischemia on perfusion imaging

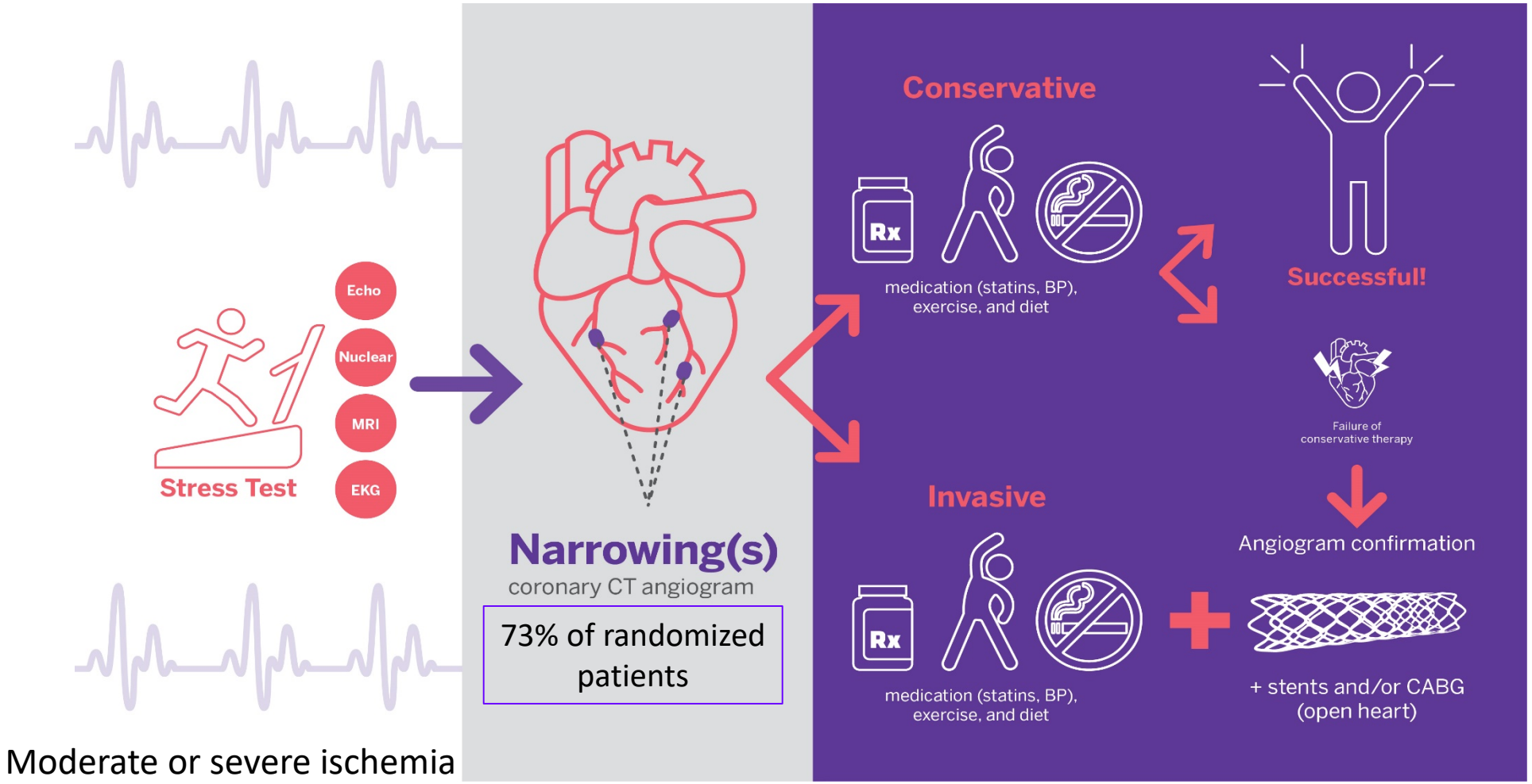


Source: Hachamovitch Circulation 2003;107:2900-2907.

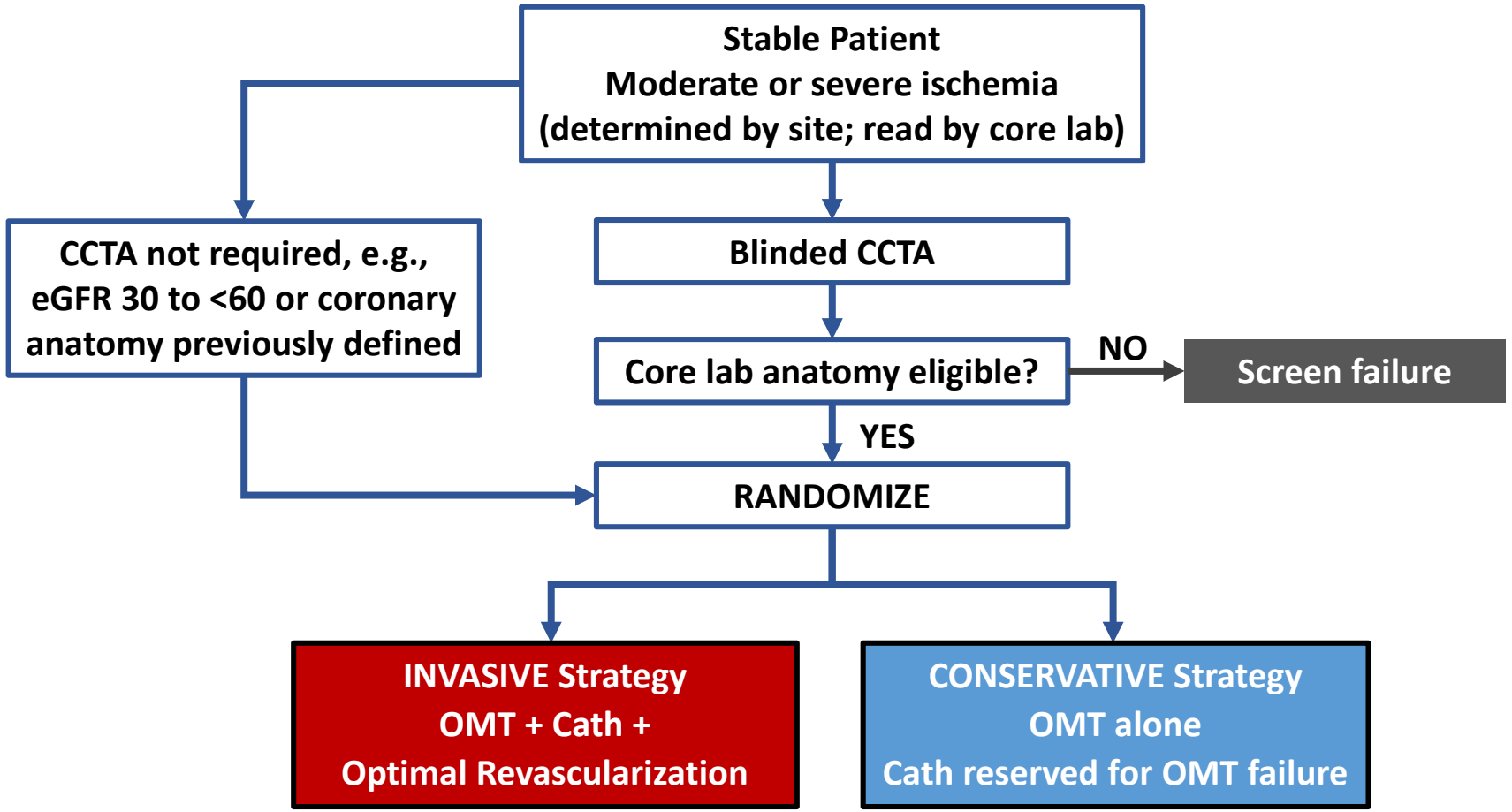
ISCHEMIA Research Question

- In stable patients with at least moderate ischemia on a stress test, is there a benefit to adding cardiac catheterization and, if feasible, revascularization to optimal medical therapy?

ISCHEMIA design overview



Study Design



Maron DJ, et al. American Heart Journal. 2018; 201;124-135.

Endpoints

Primary Endpoint:

- Time to CV death, MI, hospitalization for unstable angina, heart failure or resuscitated cardiac arrest

Major Secondary Endpoints:

- Time to CV death or MI
- Quality of Life (separate presentation)

Other Endpoints include:

- All-Cause Death
- Net clinical benefit (stroke added to primary endpoint)
- Components of primary endpoint

Maron DJ, et al. American Heart Journal. 2018; 201;124-135.

Statistical Considerations

Power and Precision (N = 5,179)

- Power: >80% power to detect 18.5% relative reduction in primary endpoint assuming an aggregate 4-year cumulative rate of approximately 14%
- Precision: 95% confidence interval around primary endpoint treatment effect hazard ratio will extend from 15% lower to 17% higher than point estimate

Pre-Specified Statistical Analysis

- Intention-to-treat
- Model-free: Cumulative event rates accounting for competing risks
- Model-based: Cox regression (covariate adjusted)
  - Emphasize nonparametric event rates if proportional hazards assumption is violated
- Bayesian analysis of Cox model
  - Evaluate the probability of a small or large hazard ratio in light of minimally informative prior probabilities and the current study data

Eligibility Criteria

Clinical and Stress Test Eligibility Criteria

Inclusion Criteria

- Age ≥21 years
- Moderate or severe ischemia*
  - Nuclear ≥10% LV ischemia (summed difference score ≥7)
  - Echo ≥3 segments stress-induced moderate or severe hypokinesis, or akinesis
  - CMR
    - Perfusion: ≥12% myocardium ischemic, and/or
    - Wall motion: ≥3/16 segments with stress-induced severe hypokinesis or akinesis
  - Exercise Tolerance Testing (ETT) ≥1.5mm ST depression in ≥2 leads or ≥2mm ST depression in single lead at <7 METS, with angina

Major Exclusion Criteria

- NYHA Class III-IV HF
- Unacceptable angina despite medical therapy
- EF < 35%
- ACS within 2 months
- PCI or CABG within 1 year
- eGFR <30 mL/min or on dialysis

CCTA Eligibility Criteria

Inclusion Criteria

- ≥50% stenosis in a major epicardial vessel (stress imaging participants)
- ≥70% stenosis in a proximal or mid vessel (ETT participants)

Major Exclusion Criteria

- ≥50% stenosis in unprotected left main

**Ischemia eligibility determined by sites. All stress tests interpreted at core labs.*

Maron DJ, et al. American Heart Journal. 2018; 201;124-135.

Endpoint Definitions and Adjudication

- Many methods were used to assure complete ascertainment and reporting of events
- All 5 primary endpoint events and stroke were adjudicated by an independent CEC comprised of senior experts from around the world

Cardiovascular Death | **Myocardial Infarction** | **Unstable Angina** | **Heart Failure** | **Resuscitated Cardiac Arrest**

Cardiovascular Death

Proximate or underlying cardiac or vascular cause

Maron DJ, et al. AHJ. 2018; 201;124-135.

MI Endpoint Definitions

Cardiovascular Death	**Myocardial Infarction**	Unstable Angina	Heart Failure	Resuscitated Cardiac Arrest

Universal Definition of MI *except*

- **Spontaneous MIs (types 1, 2, 4b, 4c)**
  - site-reported MI decision limits for troponin (upper limit of normal [ULN], not 99th percentile URL)
- **Procedural MI**
  - more **stringent** biomarker and supporting criteria for procedural MI (similar to SCAI definition)

Maron DJ, et al. American Heart Journal. 2018; 201;124-135.

Procedural Myocardial Infarction Definitions

PCI-related MI (Type 4a)

Markers: CK-MB preferred over troponin

- **CK-MB >5X ULN**
- **Troponin >35X ULN** when CK-MB is unavailable

PLUS at least one of the following:

New ECG changes

- ST segment elevation or depression >0.1 mV in 2 contiguous leads
- New pathologic Q-waves in ≥2 contiguous leads or
- New persistent LBBB

Angio

- Reduced flow in major coronary
- Type C or greater dissection

Or stand-alone biomarker definition

- **CK-MB to >10-fold** the ULN (or when CK-MB is unavailable, a rise in **troponin to >70 fold** the MI Decision Limit/ULN)

CABG-Related MI (Type 5)

Markers: CK-MB preferred over troponin

- **CK-MB to >10X ULN**
- **Troponin to >70X ULN** when CK-MB is unavailable

PLUS at least one of the following:

Imaging

- A new substantial wall motion abnormality by (CEC assessed), except new septal and apical abnormalities

New ECG changes

- New pathologic Q-waves in ≥2 contiguous leads or
- New persistent LBBB present on day 3 post CABG or hospital discharge

Or stand-alone biomarker definition

- **CK-MB to >15-fold** the ULN (or when CK-MB is unavailable a rise in **troponin to >100 fold** the MI Decision Limit/ULN)

Elements in common with SCAI definition of clinically relevant MI

Maron DJ, et al. American Heart Journal. 2018; 201;124-135.

Endpoint Definitions

Unstable Angina

Prolonged ischemic symptoms at rest or accelerating pattern resulting in hospitalization

AND at least 1 of the following (core laboratory assessed):

- **New or worsening ST or T wave changes**
- **Angiographic evidence of a ruptured/ulcerated plaque, or thrombus**

Heart Failure

- **≥24 hour hospitalization for HF**

AND all of the following:

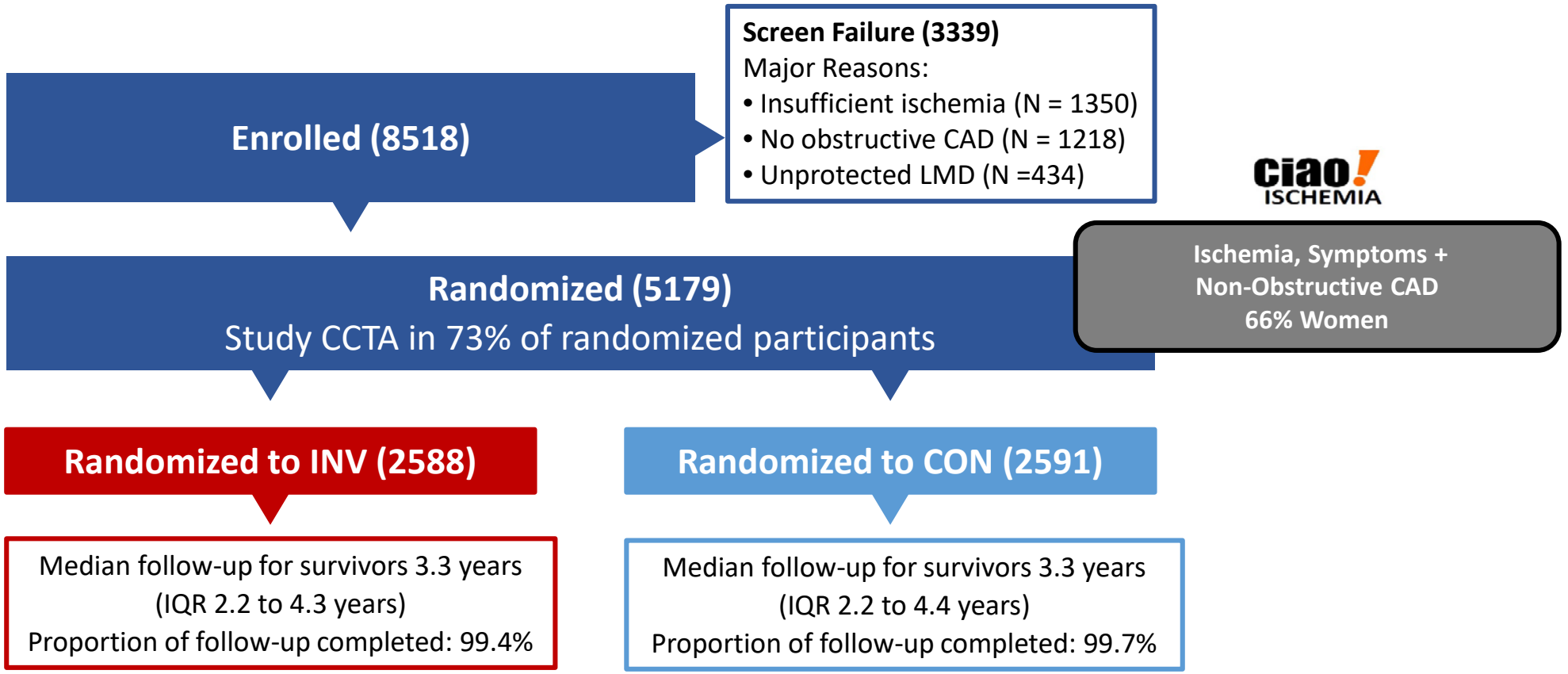
- **Symptoms** New/worsening dyspnea, orthopnea, PND, fatigue, reduced exercise tolerance AND
- **Signs** of HF AND
- **Increased pharmacologic** Rx or initiation of **mechanical** or surgical intervention AND
- No other cause identified

Resuscitated Cardiac Arrest

- Successful resuscitation for documented cardiac arrest **out-of-hospital** (or ER), discharged from hospital alive

Maron DJ, et al. American Heart Journal. 2018; 201;124-135.

Study Flow


Enrolled (8518)
Screen Failure (3339)
Major Reasons:
• Insufficient ischemia (N = 1350)
• No obstructive CAD (N = 1218)
• Unprotected LMD (N =434)
ciao! ISCHEMIA
Ischemia, Symptoms + Non-Obstructive CAD 66% Women
Randomized (5179)
Study CCTA in 73% of randomized participants
Randomized to INV (2588)
Randomized to CON (2591)
Median follow-up for survivors 3.3 years (IQR 2.2 to 4.3 years)
Proportion of follow-up completed: 99.4%
Median follow-up for survivors 3.3 years (IQR 2.2 to 4.4 years)
Proportion of follow-up completed: 99.7%

Prior Strategy Trials

- Landmark trials (BARI 2D, COURAGE)
  - Major contribution
- Considerations to address in further studies
  - Will higher risk patients based on substantial ischemia benefit?
  - Eliminate referral bias by randomizing before cardiac catheterization
  - Use newer stents and FFR as needed

Limitations of Prior Trials

- Selection bias (randomization occurred after cath)
- No minimum threshold of ischemia required
- DES not used in COURAGE and BARI 2D*
- PCI not FFR-guided in COURAGE and BARI 2D
- CABG not done in COURAGE or FAME 2

* DES only used in a small percentage of participants.

Remaining Gap

- Is there any high risk group of SIHD patients, (other then LM) in whom a strategy of routine revascularization improves outcomes in the era of modern medical therapy?

Baseline Characteristics

Characteristic	Total	INV	CON
Clinical			
Age at Enrollment (yrs.)			
Median	64 (58, 70)	64 (58, 70)	64 (58, 70)
Female Sex (%)	23	23	22
Hypertension (%)	73	73	73
Diabetes (%)	42	41	42
Prior Myocardial Infarction (%)	19	19	19
Ejection Fraction, Median (%) (n=4637)	60 (55, 65)	60 (55, 65)	60 (55, 65)
Systolic Blood Pressure, Median (mmHg)	130 (120, 142)	130 (120, 142)	130 (120, 142)
Diastolic Blood Pressure, Median (mmHg)	77 (70, 81)	77 (70, 81)	77 (70, 81)
LDL Cholesterol, Median (mg/dL)	83 (63, 111)	83 (63, 111)	83 (63, 109.5)
History of Angina	90%	90%	89%
Angina Began or Became More Frequent Over the Past 3 Months	29%	29%	29%
Stress Test Modality			
Stress Imaging (%)	75	75	76
Exercise Tolerance Test (ETT) (%)	25	25	24

Median values reported with 25th and 75th percentiles

Hochman JS et al. JAMA Cardiology. 2019 Mar 1;4(3):273-86.

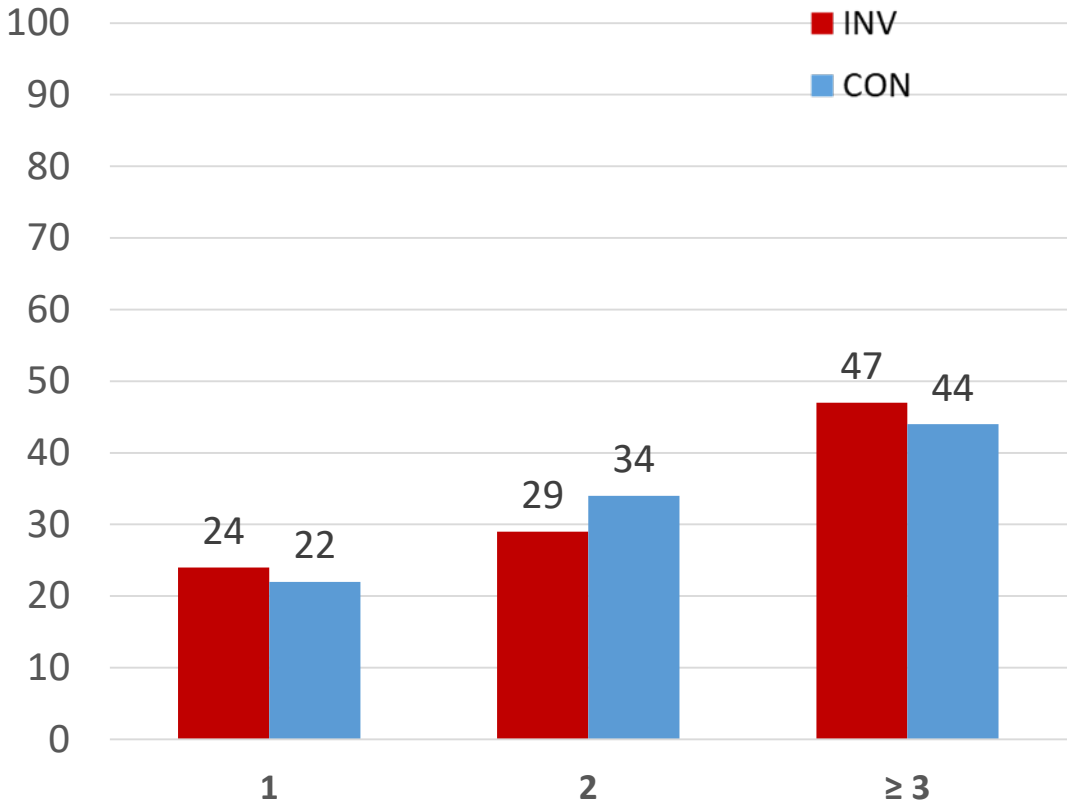
Qualifying Stress Test: Core Lab Interpretation

Characteristic	Total	INV	CON
Baseline Inducible Ischemia*			
Severe	54%	53%	55%
Moderate	33%	34%	32%
Mild/None	12%	12%	12%
Uninterpretable	1%	1%	1%

*Only severe qualified by ETT

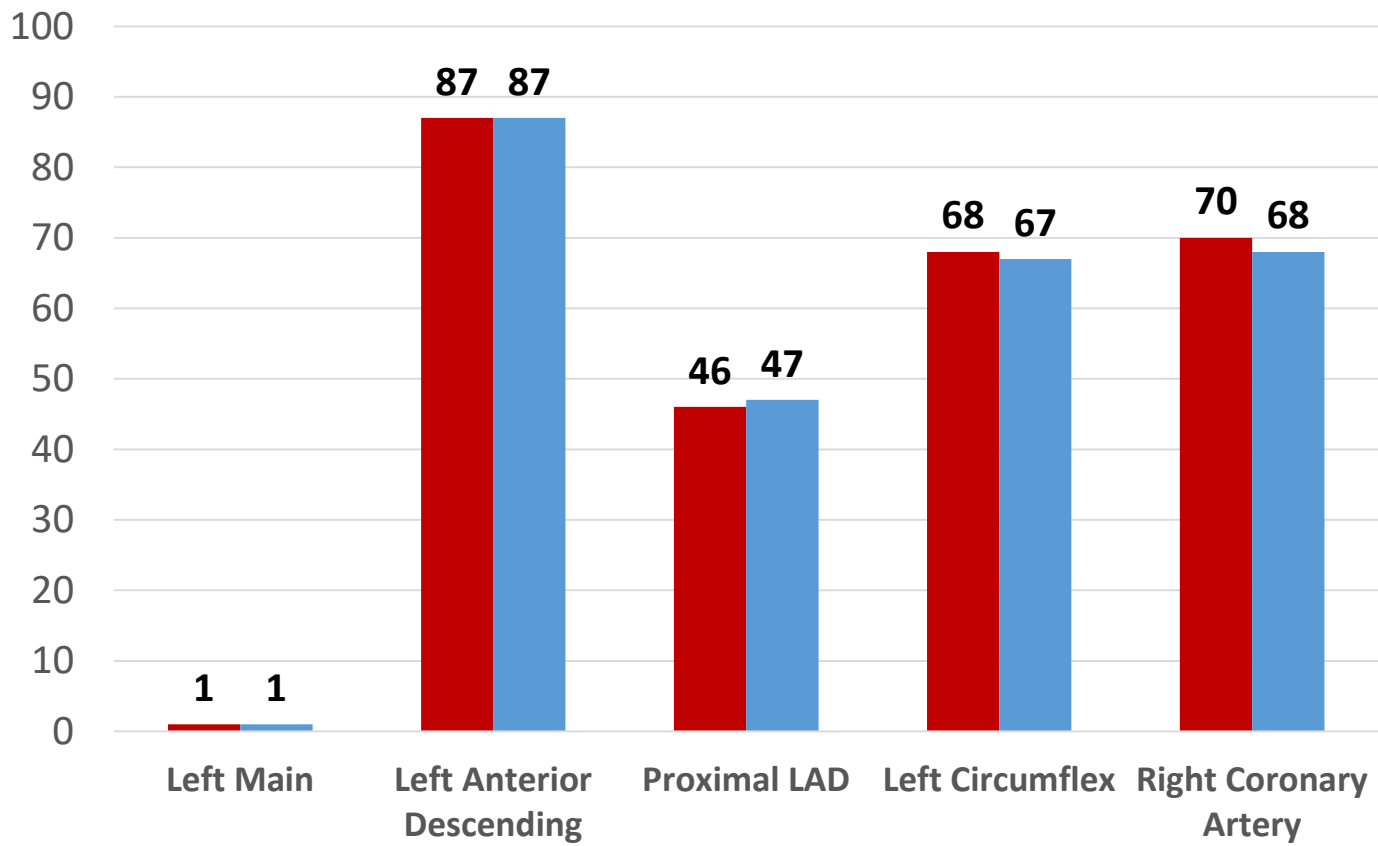
Hochman JS et al. JAMA Cardiology. 2019 Mar 1;4(3):273-86.

Baseline Coronary Artery Anatomy by CCTA



# of Vessels with ≥50 % Stenosis (%)

N=2982



Specific Vessels with ≥50% Stenosis (%)

N=3739

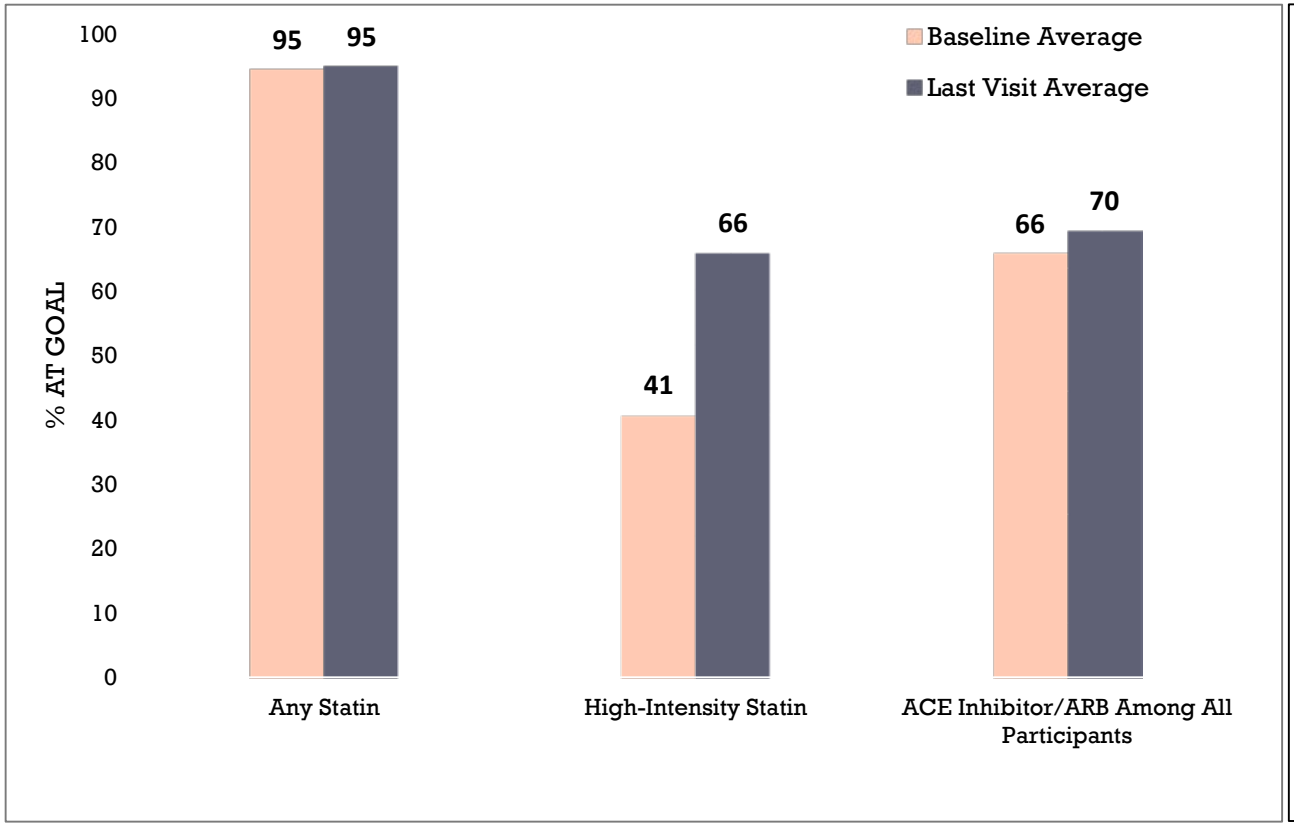
(% of total)

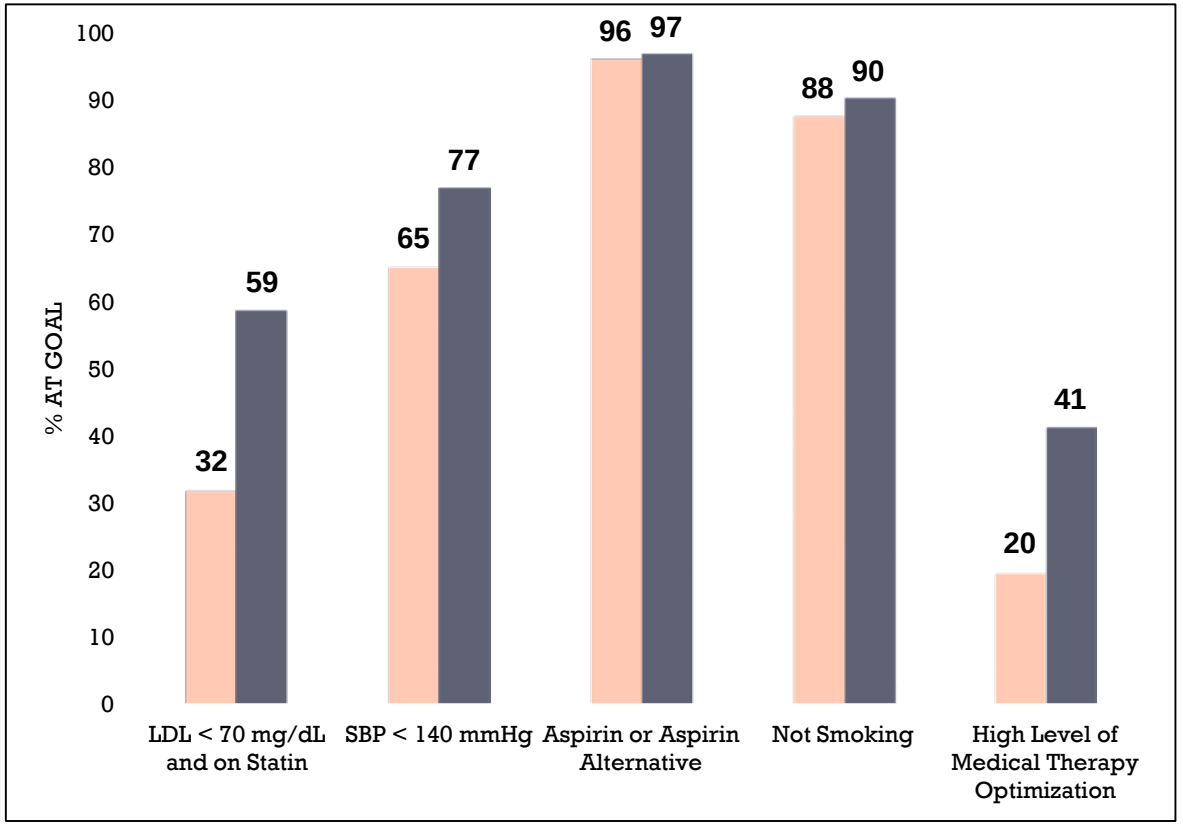
Hochman JS et al. JAMA Cardiology. 2019 Mar 1;4(3):273-86.

Risk Factor Management

Baseline vs last visit

No between group differences INV vs CON

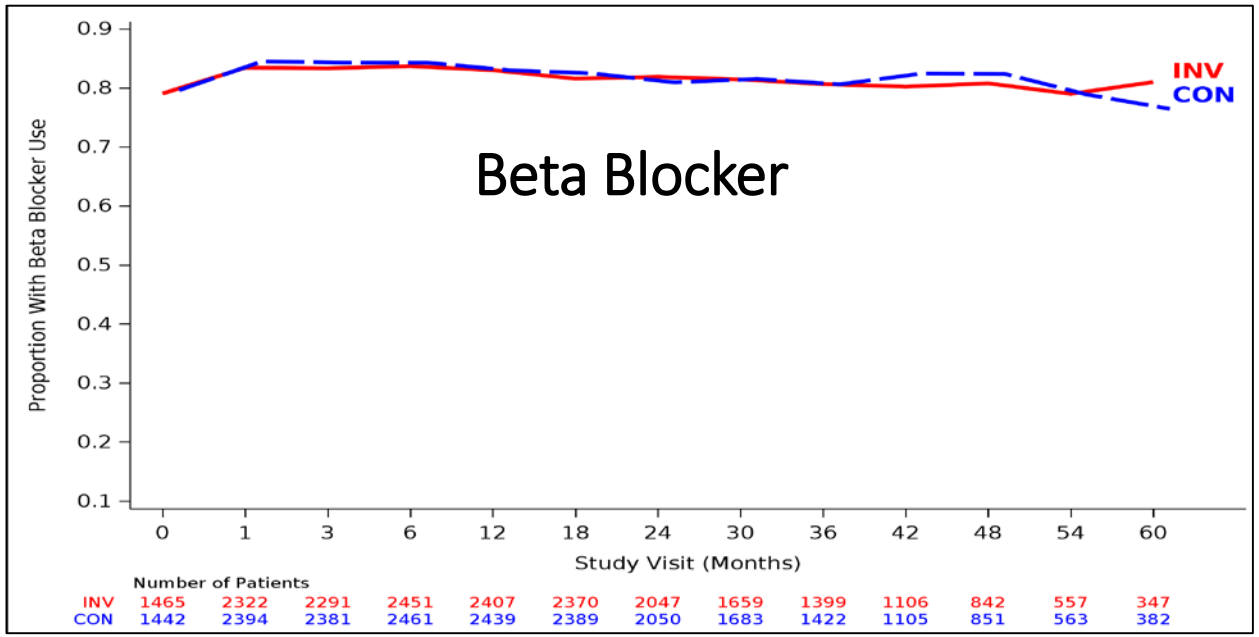


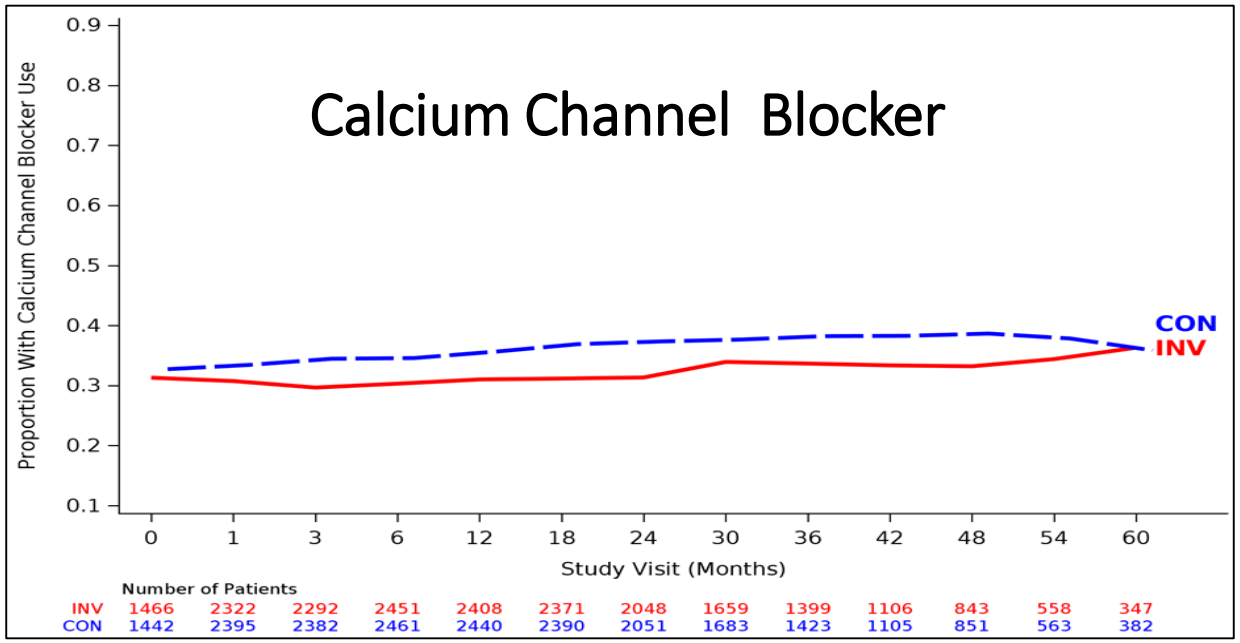


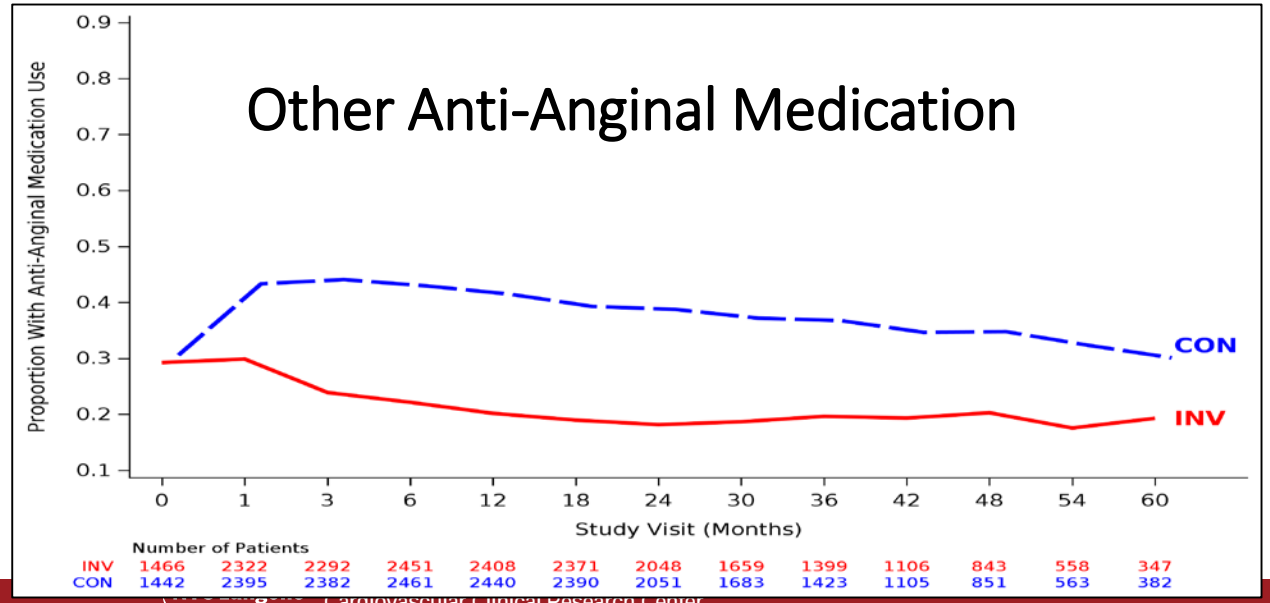
High Level of Medical Therapy Optimization is defined as a participant meeting all of the following goals: LDL < 70 mg/dL and on any statin, systolic blood pressure < 140 mm/Hg, on aspirin or other antiplatelet or anticoagulant, and not smoking. High level of medical therapy optimization is missing if any of the individual goals are missing.

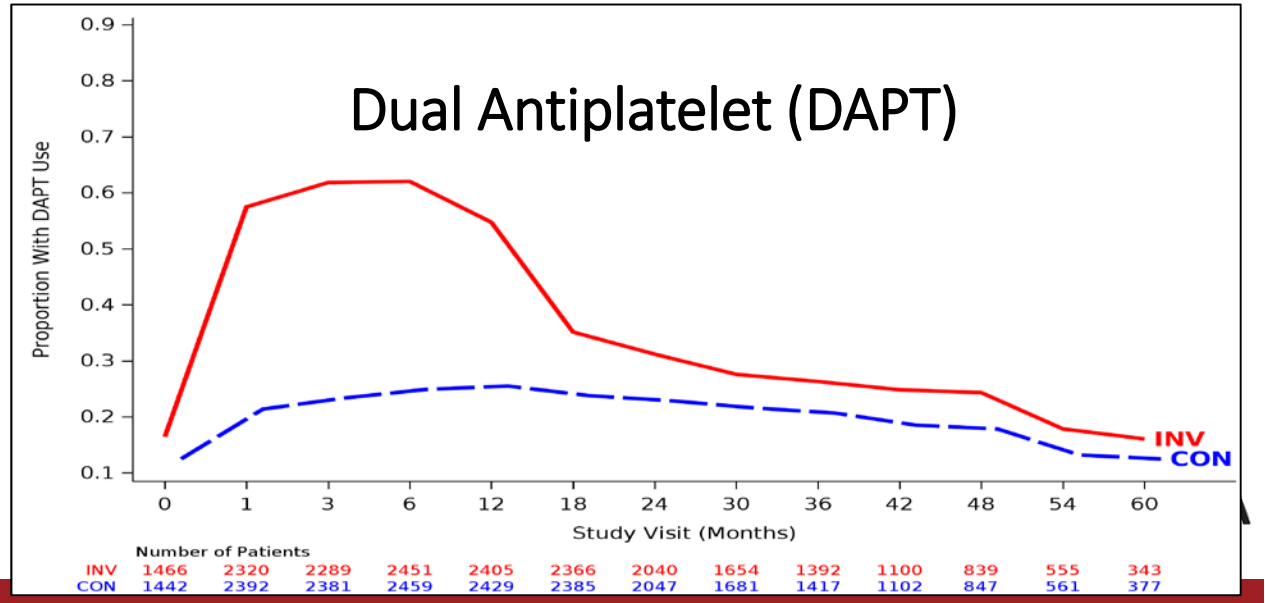
Baseline LDL = 83 mg/dL. Last visit LDL = 65 mg/dL.

Medication Use Over Time



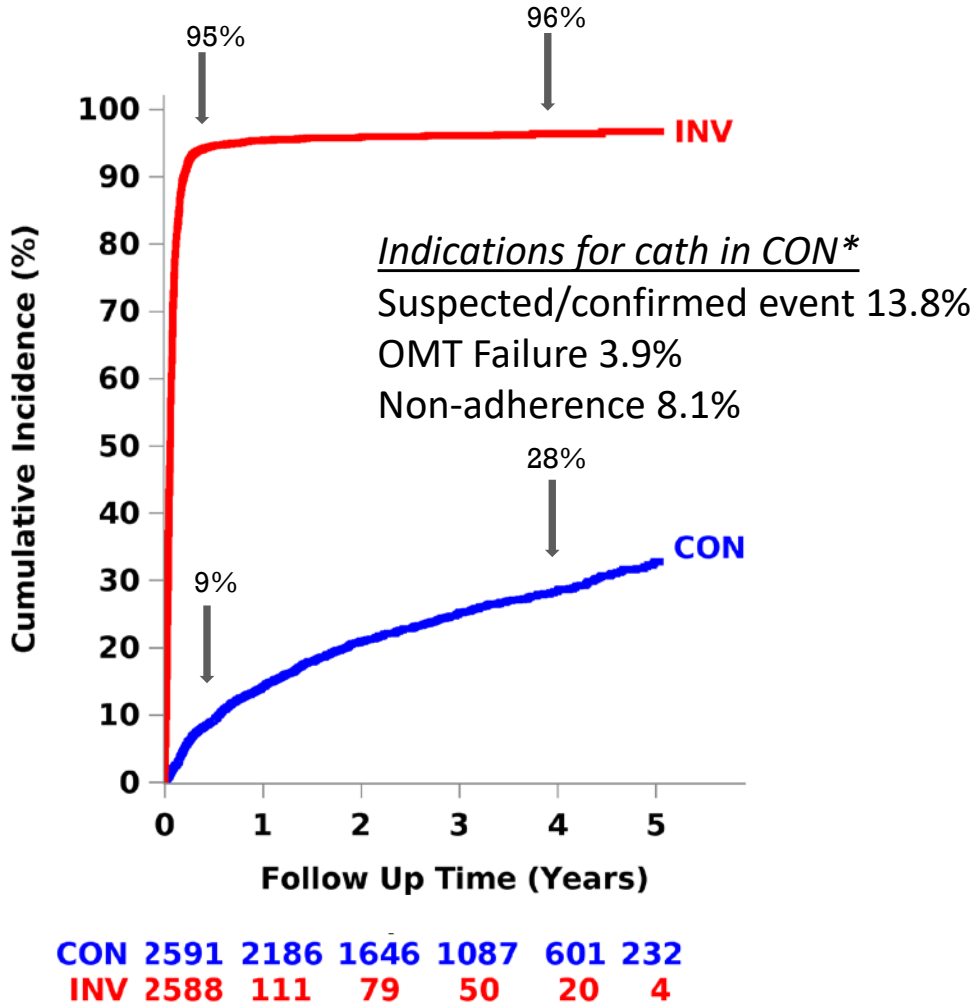






Cardiac Catheterization and Revascularization

Cardiac Catheterization



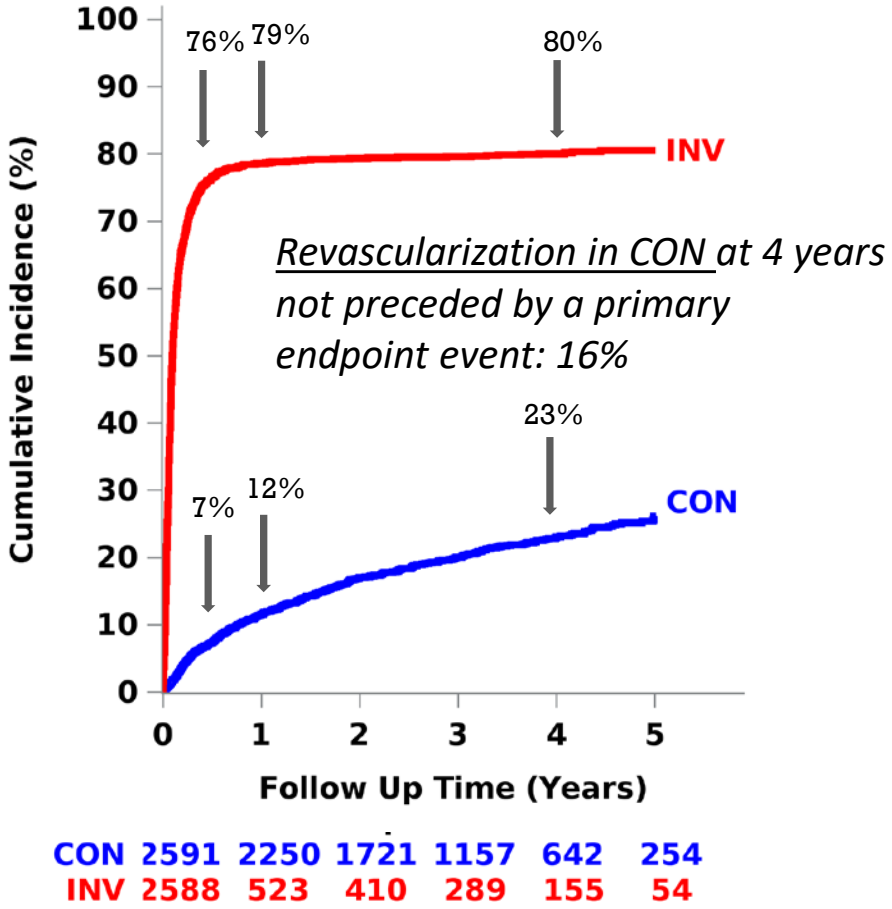
*Indications for cath in CON**

Suspected/confirmed event 13.8%

OMT Failure 3.9%

Non-adherence 8.1%

Revascularization



Revascularization in CON at 4 years not preceded by a primary endpoint event: 16%

*Indications for Cath are percentages of CON patients whereas cumulative event rate shown at 4 years reflects censoring and the rate at that time point.

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Mode of Revascularization

First Procedure for Those Revascularized in Invasive Group (80% of INV)

Of the 20% with no revascularization
~2/3 had insignificant disease on coronary angiogram
~1/3 had extensive disease unsuitable for any mode of revascularization

First Procedure	Total
PCI	74%
• Successful, stent able to be placed	93%
• Of stents placed, drug eluting	98%

First Procedure	Total
CABG	26%
• Arterial Grafts	93%
• IMA	92%

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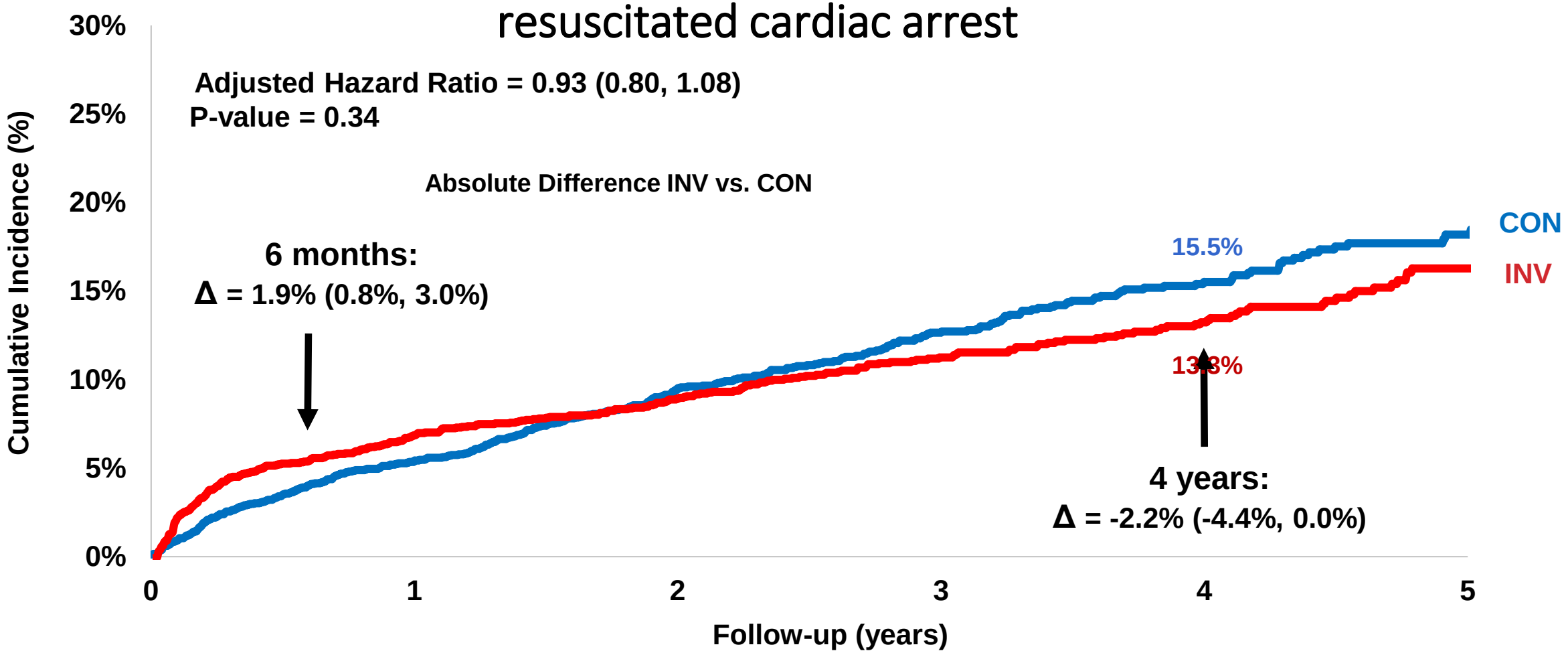
Primary Outcome: CV Death, MI, hospitalization for UA, HF or resuscitated cardiac arrest



Subjects at Risk

CON	2591	2431	1907	1300	733	293
INV	2588	2364	1908	1291	730	271

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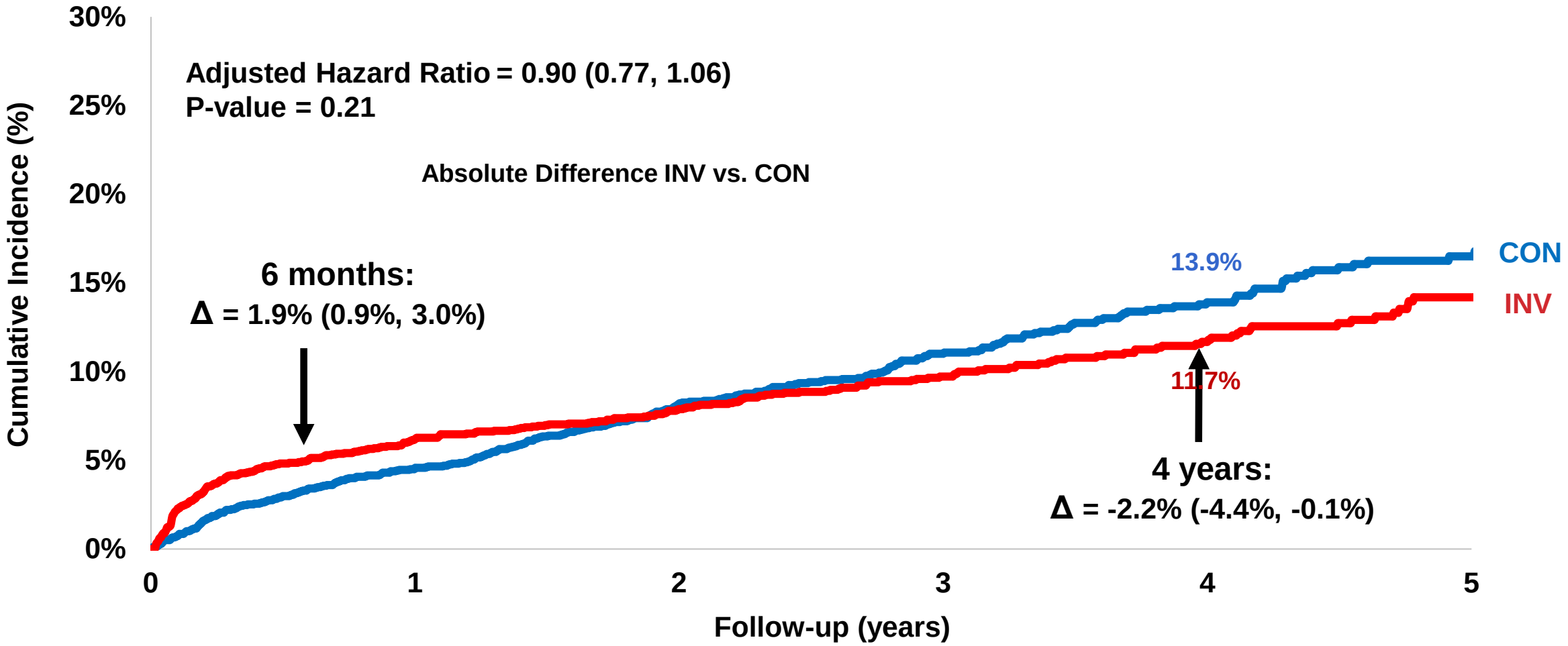
Major Secondary: CV Death or MI



Subjects at Risk

CON	2591	2453	1933	1325	746	298
INV	2588	2383	1933	1314	752	282

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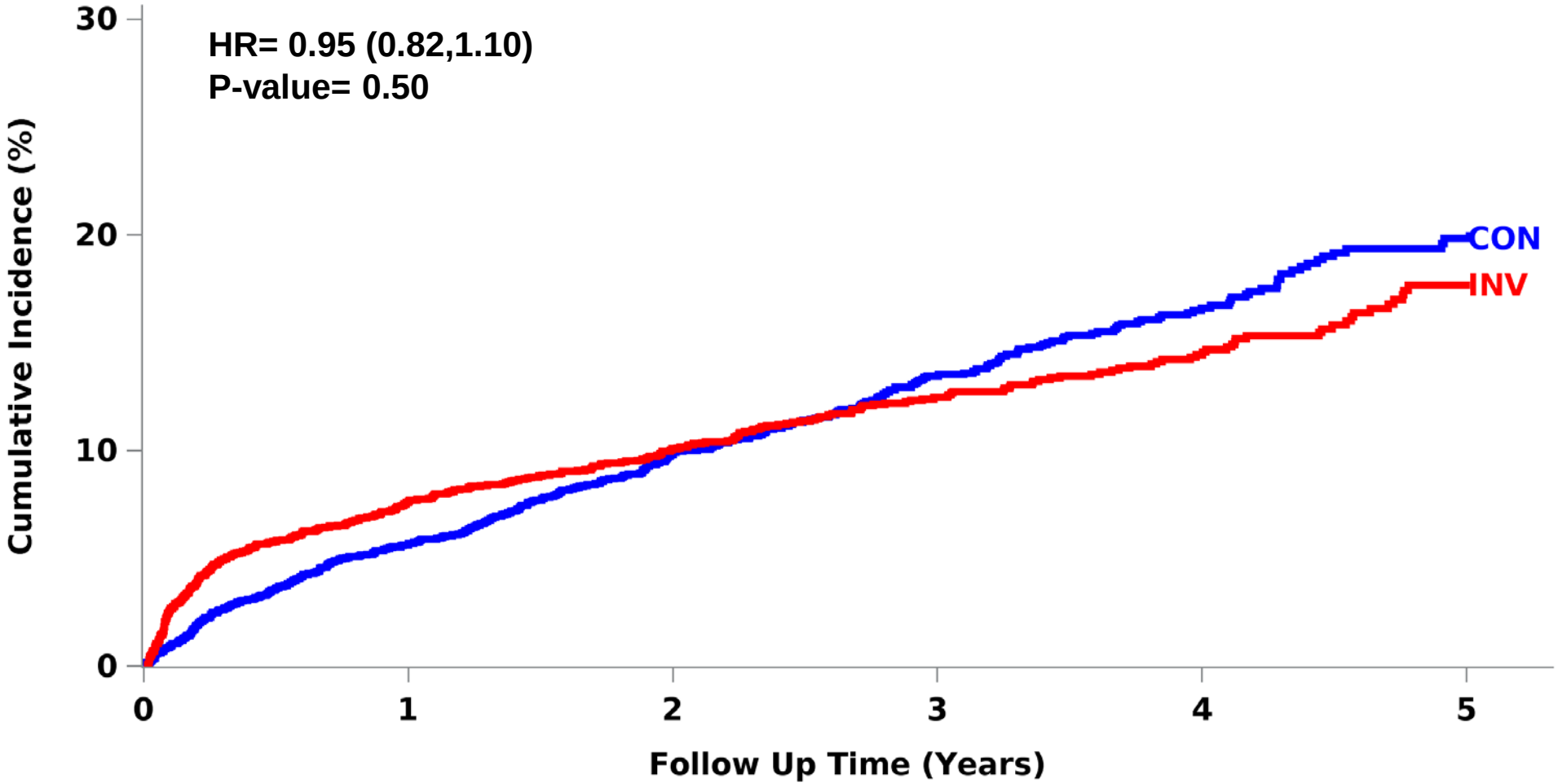
Net Clinical Benefit: CV Death, MI, UA, HF, RCA, Stroke



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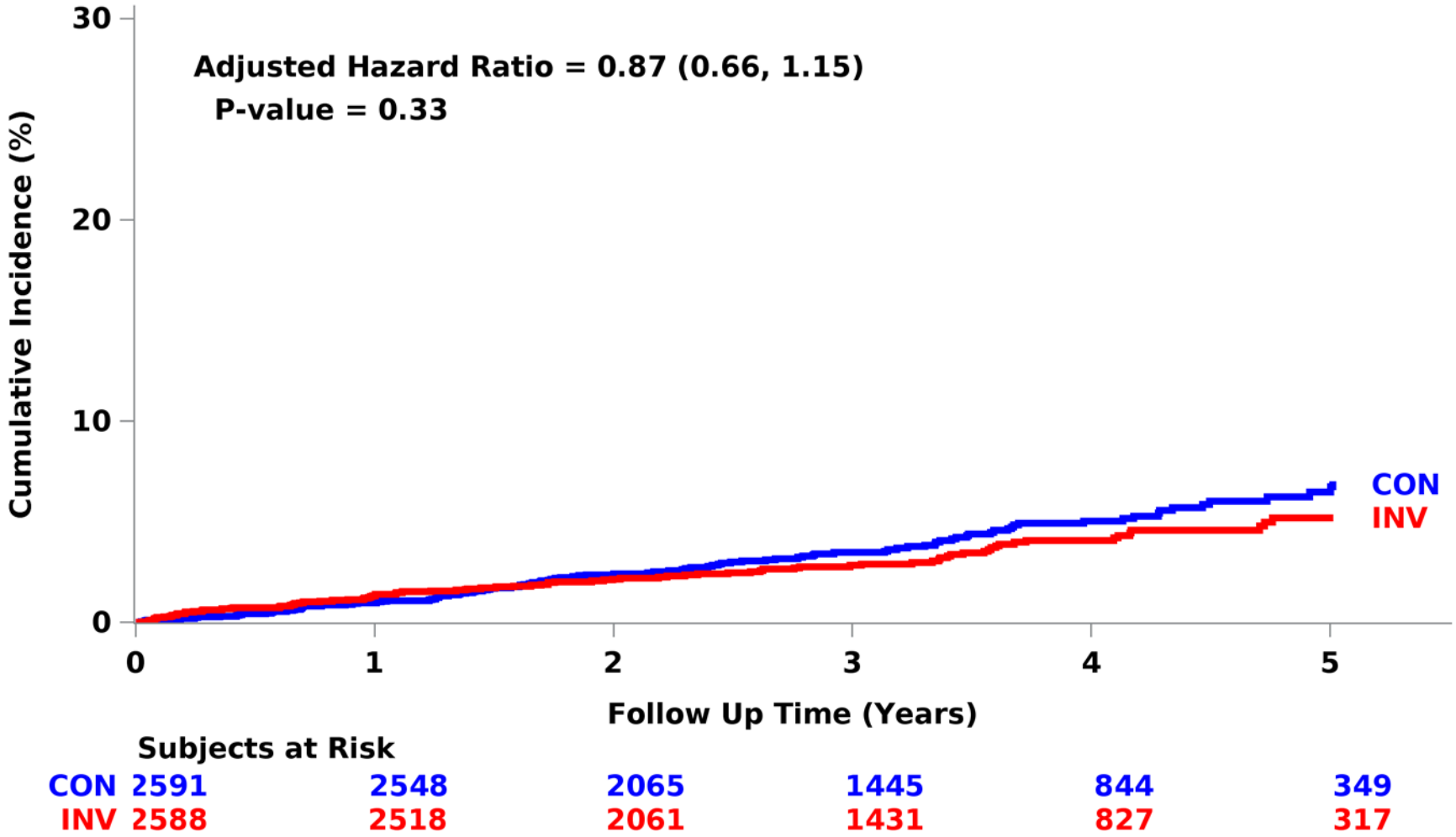
Cardiovascular Death



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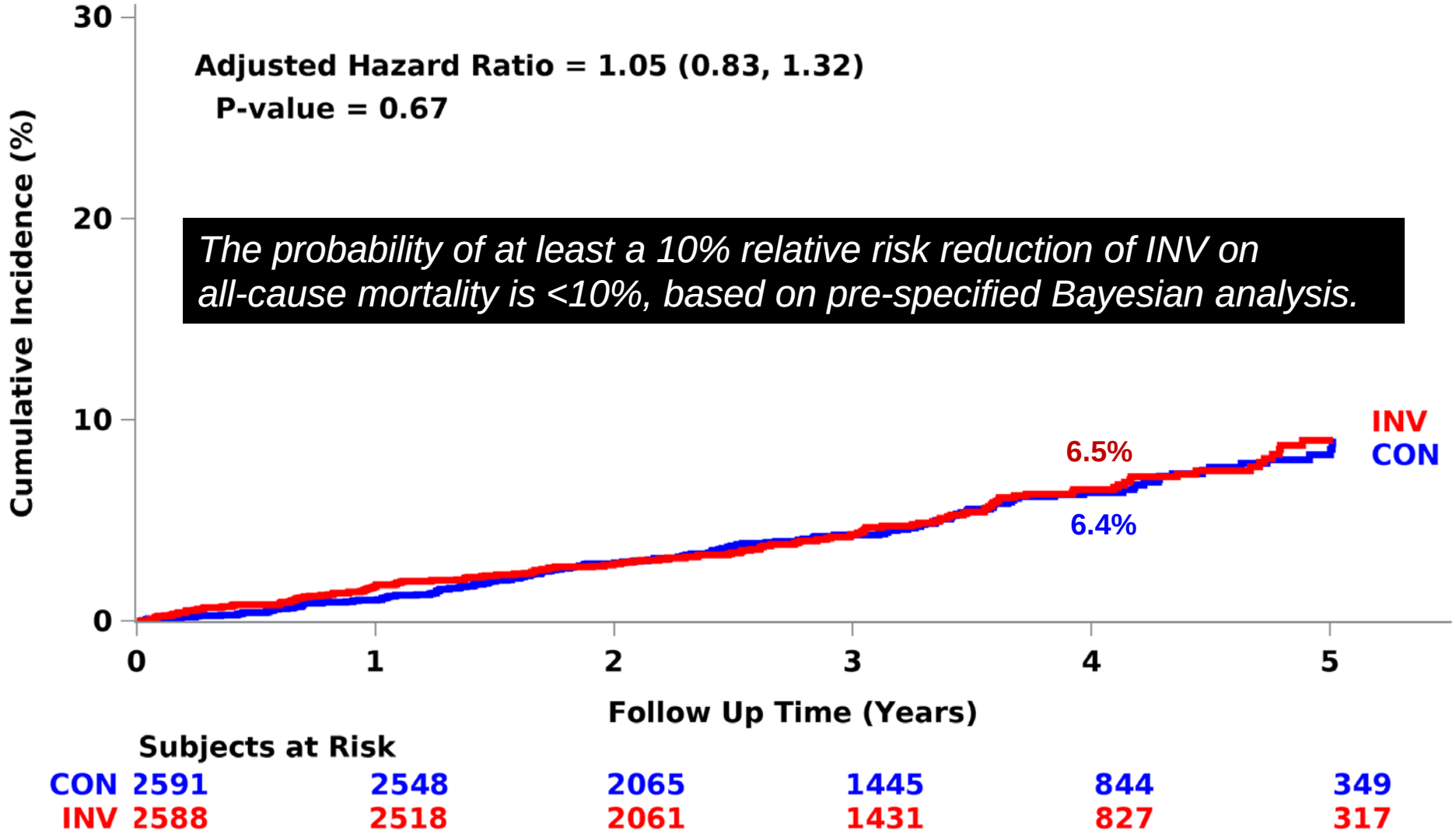
All-Cause Death



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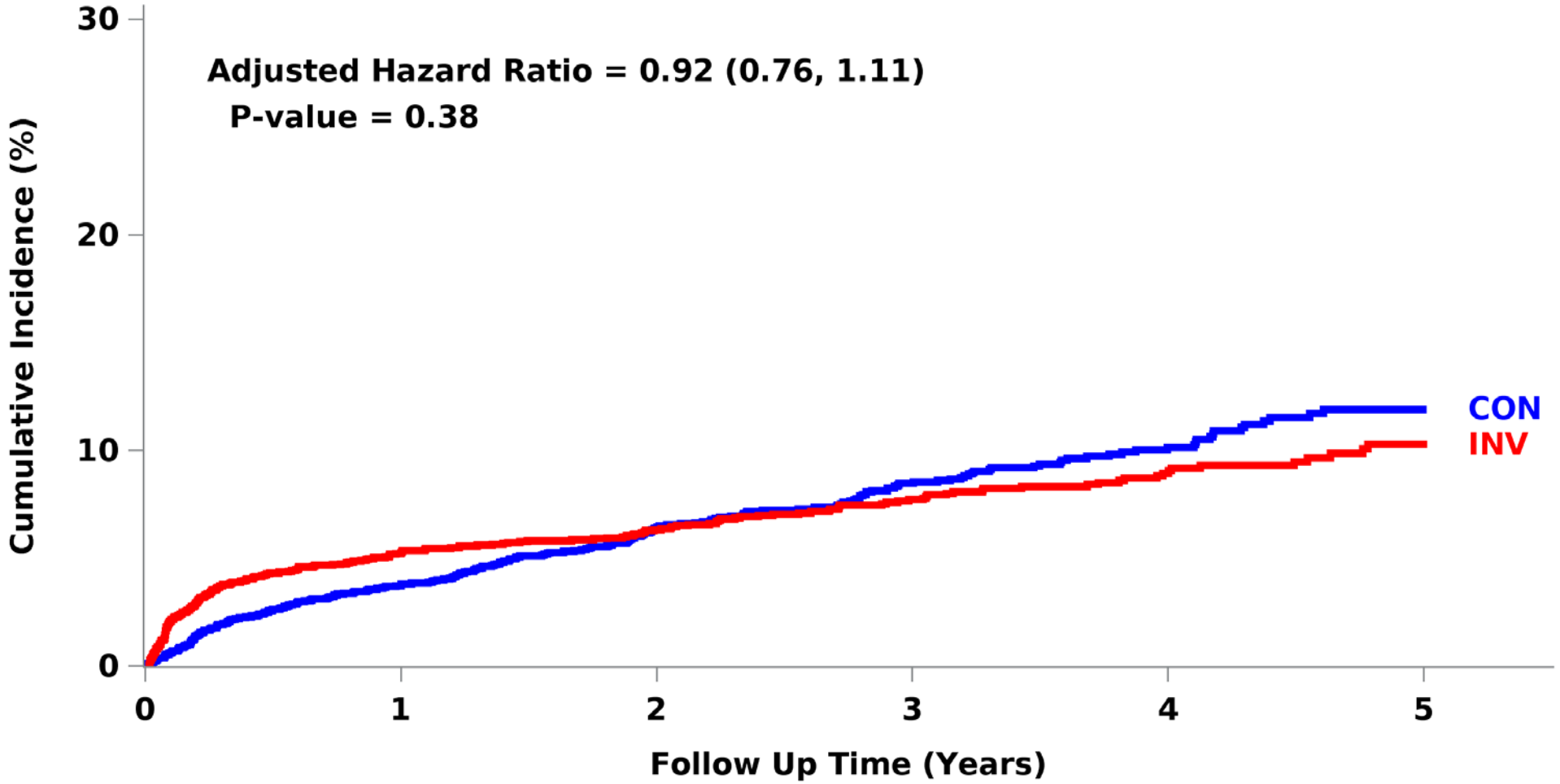
Myocardial Infarction



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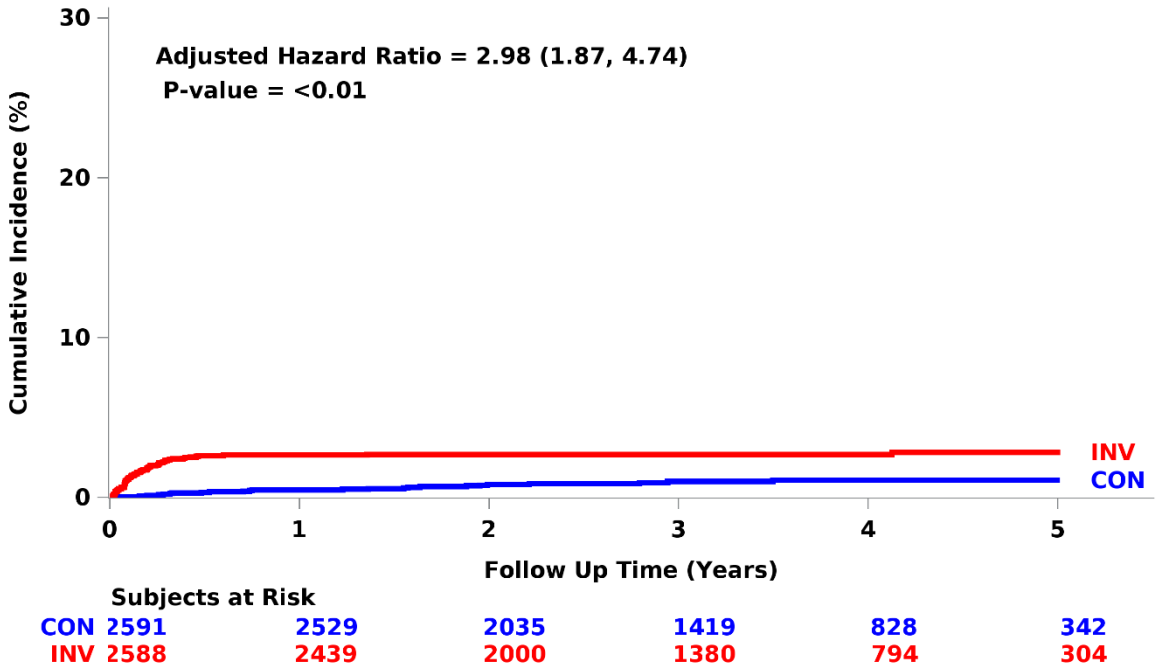
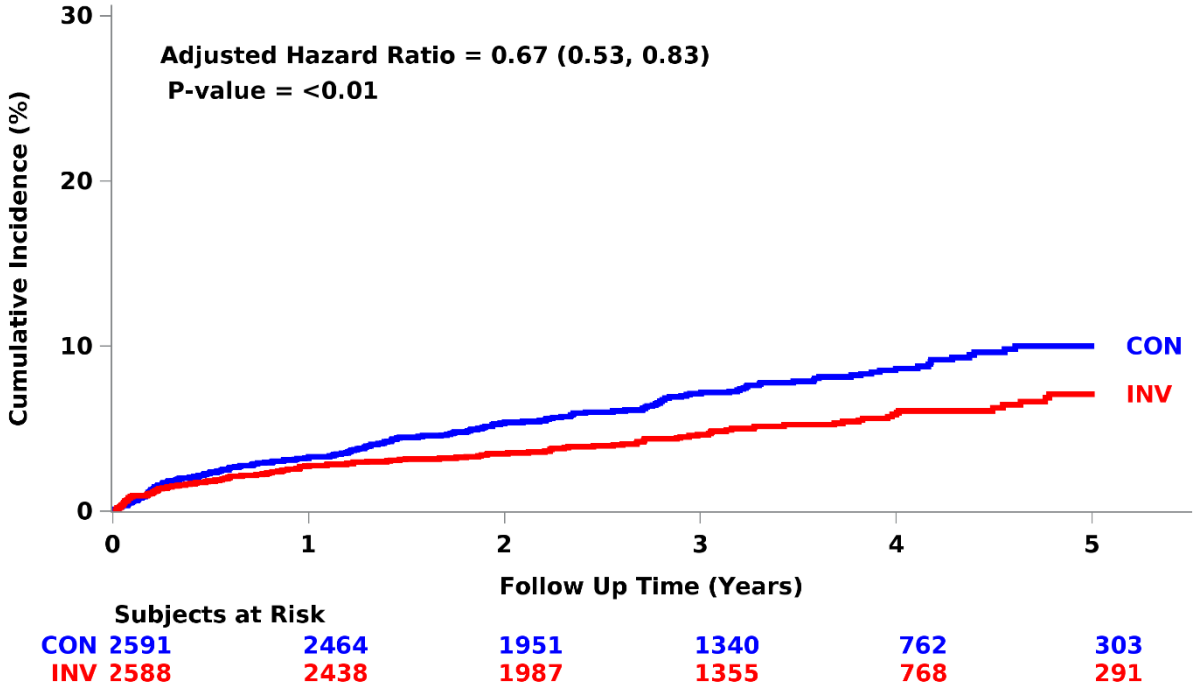
Procedural MI
Type 4a or 5 MI



Spontaneous MI
Types 1, 2, 4b, or 4c MI



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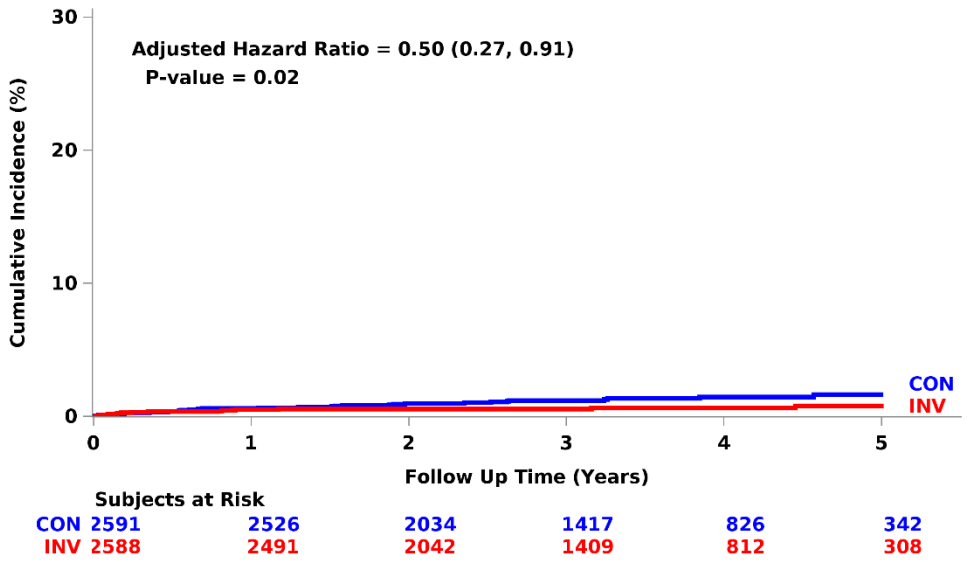
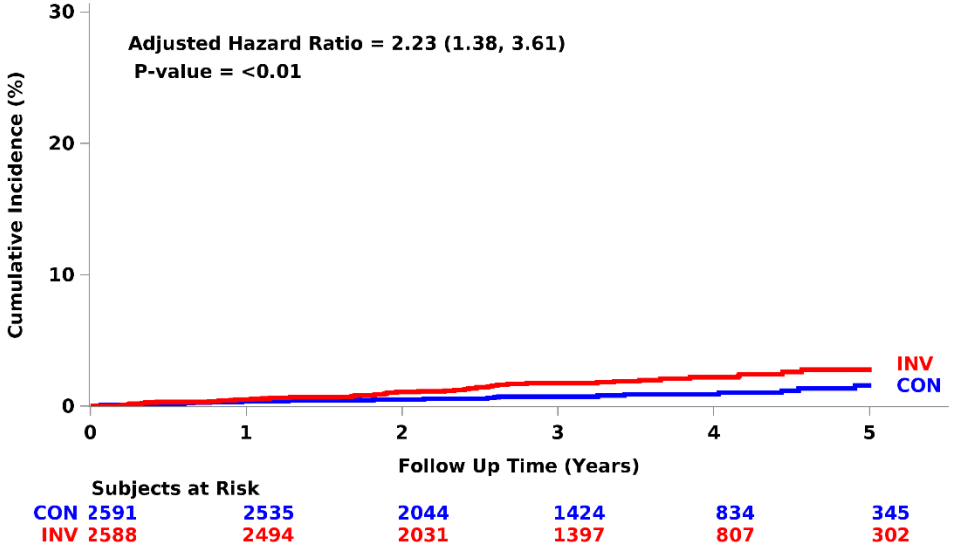
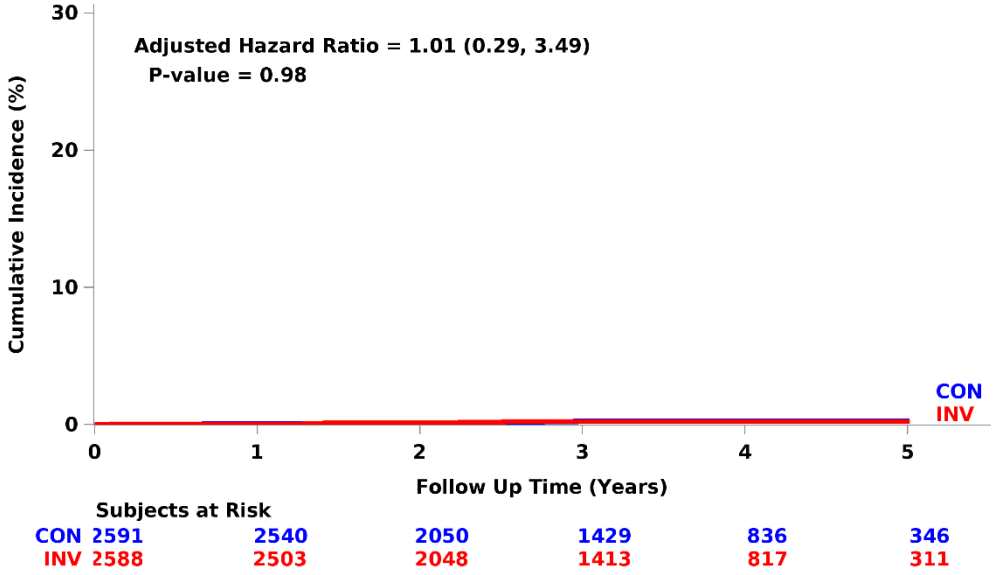
Hospitalization for Unstable Angina



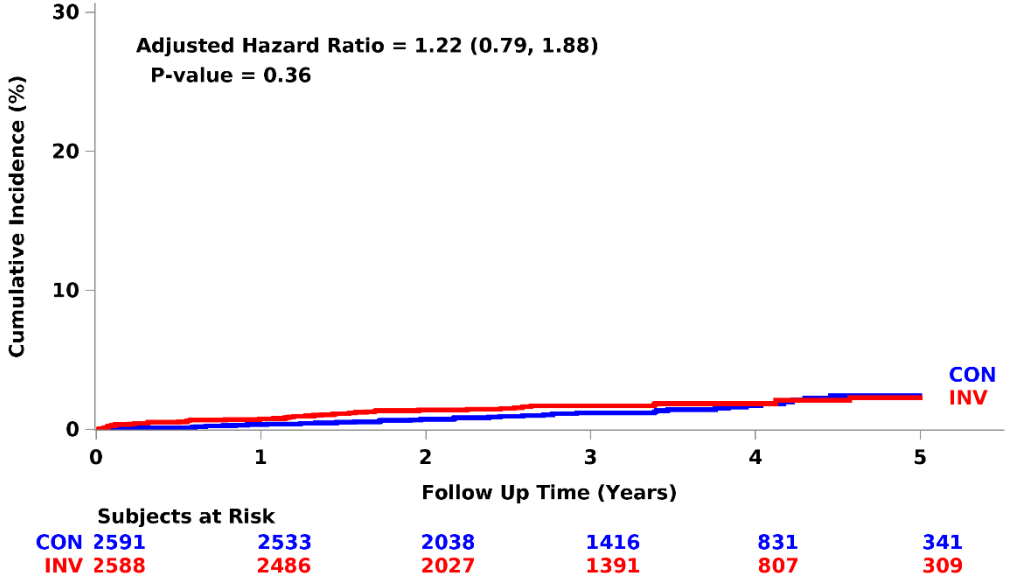
Hospitalization for Heart Failure



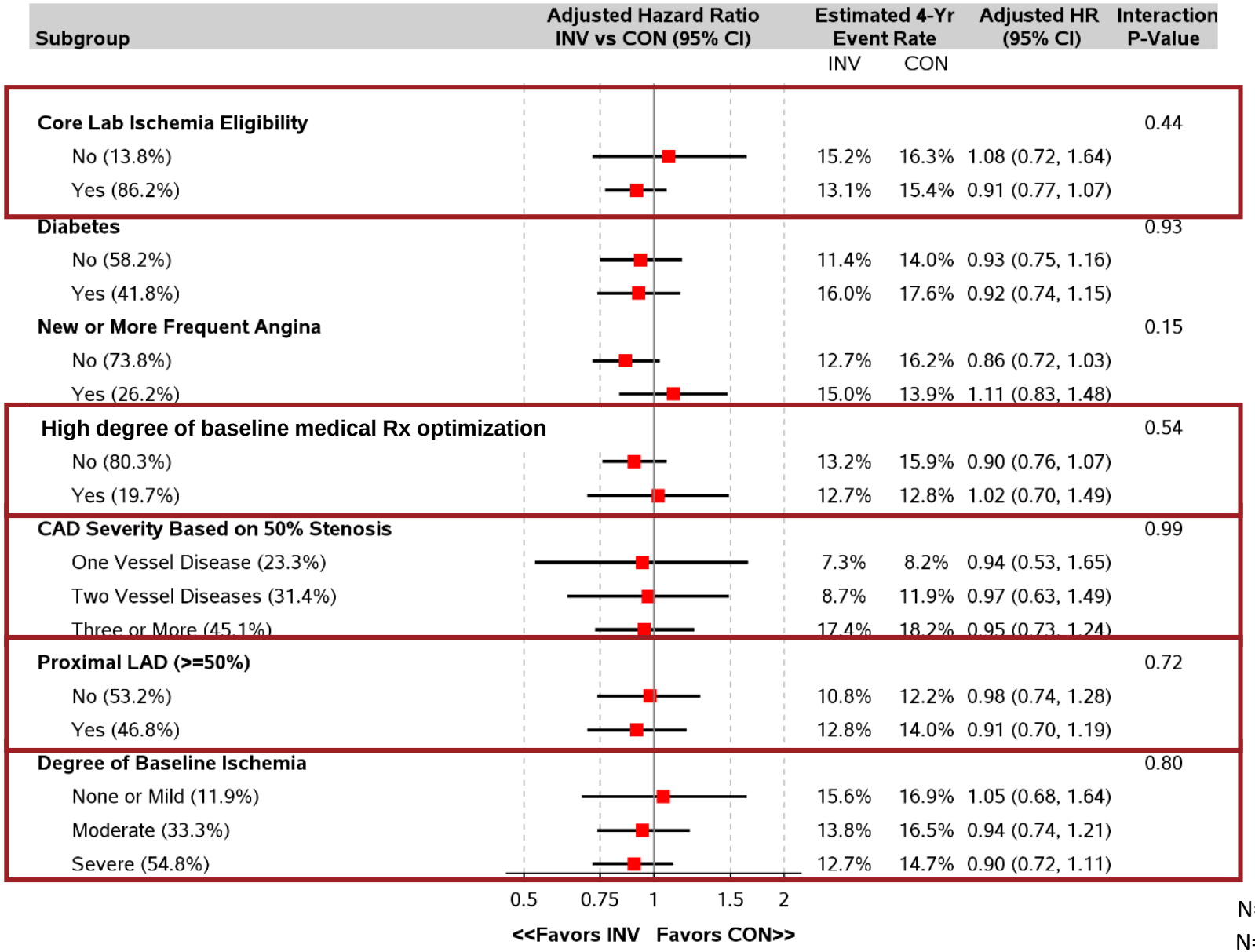
Resuscitated Cardiac Arrest



Stroke



Primary endpoint
Pre-specified Important Subgroups
There was no heterogeneity of treatment effect



Subgroup	Adjusted Hazard Ratio INV vs CON (95% CI)	Estimated 4-Yr Event Rate INV	Estimated 4-Yr Event Rate CON	Adjusted HR (95% CI)	Interaction P-Value
Core Lab Ischemia Eligibility					0.44
No (13.8%)		15.2%	16.3%	1.08 (0.72, 1.64)	
Yes (86.2%)		13.1%	15.4%	0.91 (0.77, 1.07)	
Diabetes					0.93
No (58.2%)		11.4%	14.0%	0.93 (0.75, 1.16)	
Yes (41.8%)		16.0%	17.6%	0.92 (0.74, 1.15)	
New or More Frequent Angina					0.15
No (73.8%)		12.7%	16.2%	0.86 (0.72, 1.03)	
Yes (26.2%)		15.0%	13.9%	1.11 (0.83, 1.48)	
High degree of baseline medical Rx optimization					0.54
No (80.3%)		13.2%	15.9%	0.90 (0.76, 1.07)	
Yes (19.7%)		12.7%	12.8%	1.02 (0.70, 1.49)	
CAD Severity Based on 50% Stenosis					0.99
One Vessel Disease (23.3%)		7.3%	8.2%	0.94 (0.53, 1.65)	
Two Vessel Diseases (31.4%)		8.7%	11.9%	0.97 (0.63, 1.49)	
Three or More (45.1%)		17.4%	18.2%	0.95 (0.73, 1.24)	
Proximal LAD (>=50%)					0.72
No (53.2%)		10.8%	12.2%	0.98 (0.74, 1.28)	
Yes (46.8%)		12.8%	14.0%	0.91 (0.70, 1.19)	
Degree of Baseline Ischemia					0.80
None or Mild (11.9%)		15.6%	16.9%	1.05 (0.68, 1.64)	
Moderate (33.3%)		13.8%	16.5%	0.94 (0.74, 1.21)	
Severe (54.8%)		12.7%	14.7%	0.90 (0.72, 1.11)	

N=3739 for Prox LAD Y/N
N=2982 for # diseased vessels

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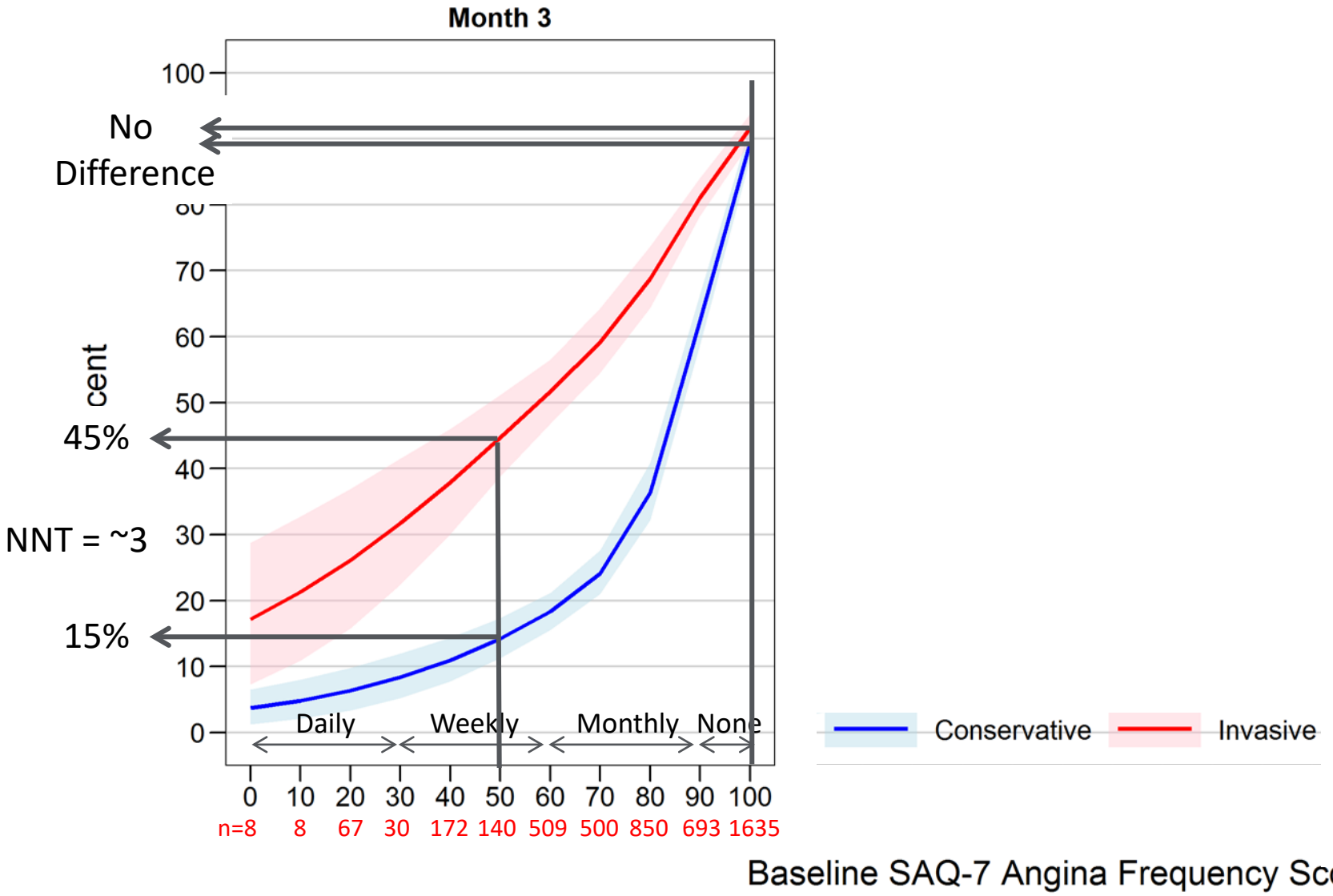
Probability of No Angina by Baseline Angina Frequency



Primary endpoint and major secondary endpoint (CV death or MI)

No heterogeneity of treatment effect based on any characteristic

- Age
- Sex
- Ethnicity
- Race
- Geographic region
- Stress test, imaging vs no imaging
- Stress imaging modality
- Moderate or severe anterior ischemia
- Prior MI
- Prior cardiac cath
- Prior PCI
- Prior CABG
- Ejection Fraction
- eGFR

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Limitations

- Unblinded trial – no sham procedure
- Based on exclusion criteria, the trial results do not apply to patients with:
  - Acute coronary syndromes within 2 months
  - Highly symptomatic patients
  - Left main stenosis
  - LVEF <35%
- Trial findings may not be generalizable to centers with higher procedural complication rates
- Completeness of revascularization has not yet been assessed
- Women were enrolled in the trial but more often excluded from randomization compared to men due to less ischemia and more non-obstructive CAD

Summary

- The curves cross for the primary endpoint and the major secondary endpoint at approximately 2 years from randomization
  - ~2 in 100 *higher* estimated rate with INV at 6 months
  - ~2 in 100 *lower* estimated rate with INV at 4 years
- Procedural MIs were increased with an invasive strategy
- Spontaneous MIs were reduced with an invasive strategy
- Low all-cause mortality in both groups despite high-risk clinical characteristics, high-risk ischemia and extensive CAD
- No heterogeneity of treatment effect, including by type of stress test, severity of ischemia or extent of CAD
- Very low rates of procedure-related stroke and death

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Conclusions

- ISCHEMIA is the largest trial of an invasive vs conservative strategy for patients with SIHD
- Overall, an initial INV strategy as compared with an initial CON strategy did not demonstrate a reduced risk over median 3.3 years for
  - Primary endpoint - CV death, MI, hospitalization for UA, HF, RCA
  - Major Secondary endpoint - CV death or MI
- The probability of at least a 10% benefit of INV on all-cause mortality was <10%, based on pre-specified Bayesian analysis

Conclusions- Quality of Life

- Patients with stable CAD and moderate to severe ischemia had significant, durable improvements in angina control and quality of life with an invasive strategy *if they had angina* (daily/weekly or monthly)

- In patients without angina, an invasive strategy led to minimal symptom or quality of life benefits, as compared with a conservative strategy

- In patients with angina, shared decision-making should occur to align treatment with patients' goals and preferences

Thank You

- To the thousands of investigators and coordinators
- The dedication of thousands of participants
- The NHLBI
- We are extremely grateful for their contribution to advance our understanding of the relative risks and benefits of two commonly used management strategies for stable ischemic heart disease

Slides at ischemiatrial.org

Simultaneous publication precluded by short time from last patient, last visit to database lock to AHA

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*in memoriam

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