

Transcatheter

Aortic

Valve

Implantation /Replacement

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# Aortastenosis

## (förträngning av aortaklaff)

- vanligaste klaffelet
- förekomsten varierar mellan 0,2% i åldern mellan 50-59 och 9,8% i åldern mellan 80-89.
- symptom: andfåddhet, yrsel (svimmning), bröstsmärta (kärlkramp), hjärtsvikt.
- standardbehandling: operation

# Indikationer

- Patienter med tät aortastenos som inte kan opereras pga för hög risk och som kan förväntas att uppleva en förbättring av symptom samt har en förväntad överlevnad > 1år
- TAVI kan övervägas för högriskpatienter som skulle kunna opereras, men "hjärtteamet" tycker att TAVI kan vara bättre med hänsyn till individuella åkomma.

# Högriskpatient

- Euroscore > 20% (European System for Cardiac Operative Risk Evaluation): uppskattar 30 dagars mortalitet.

Är TAVI bra?

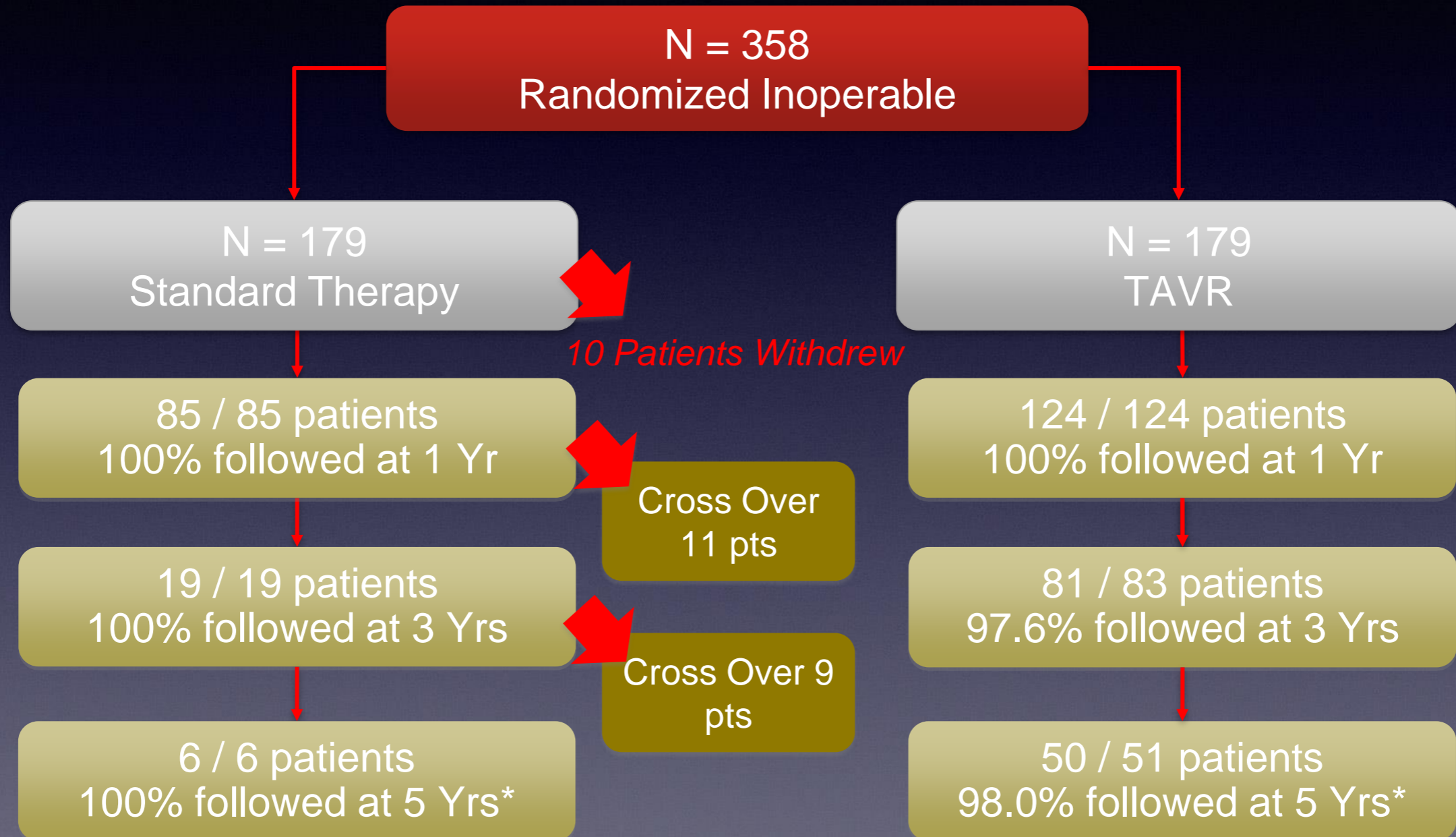
# **PARTNER Trial Cohort B – 5-year Outcomes**

Five-Year Outcomes of Transcatheter  
Aortic Valve Replacement (TAVR) in  
“Inoperable” Patients With Severe Aortic  
Stenosis:

**The PARTNER Trial**

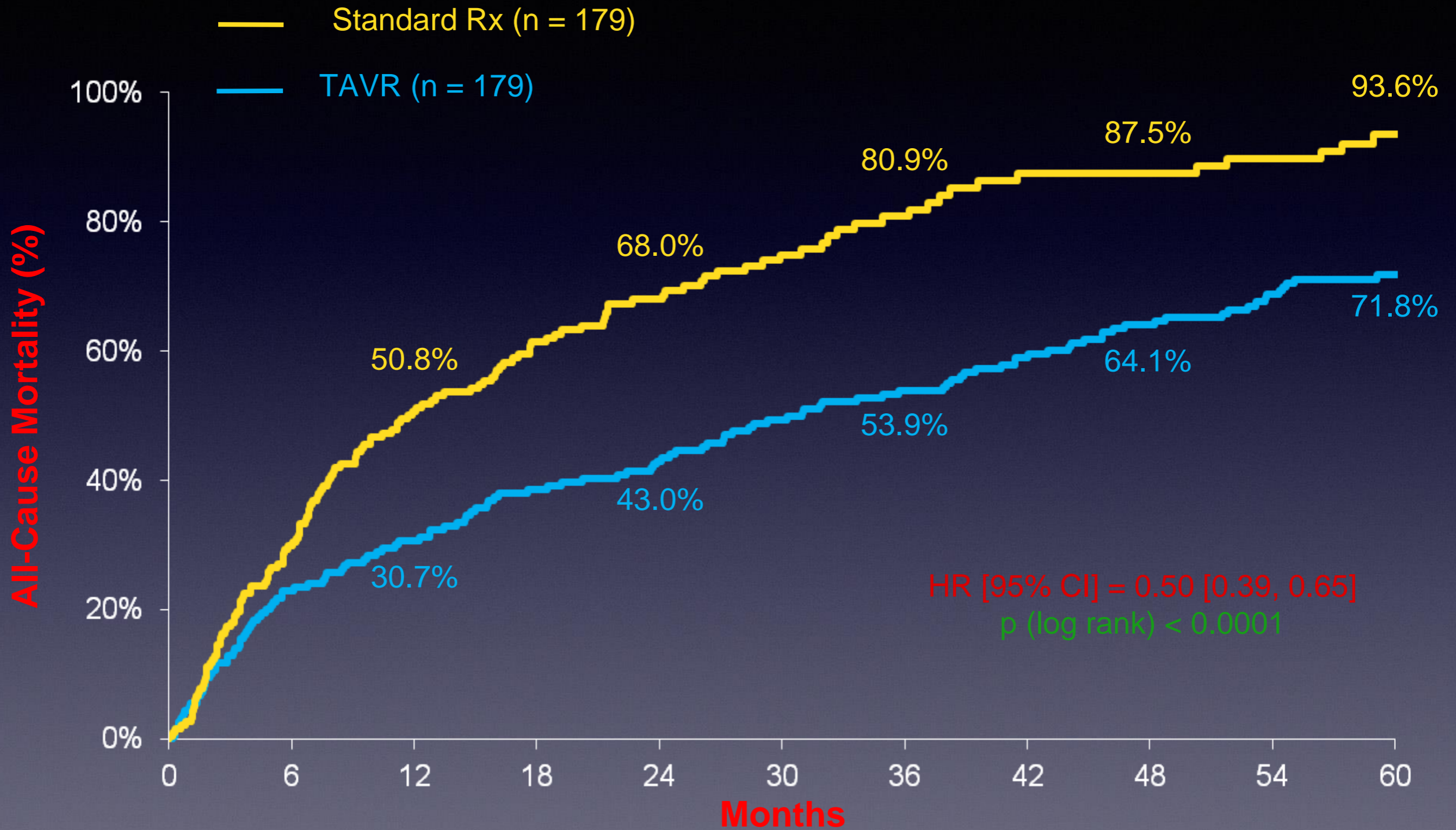
# Study Flow

## Inoperable Cohort



\* ± 2 months follow-up window

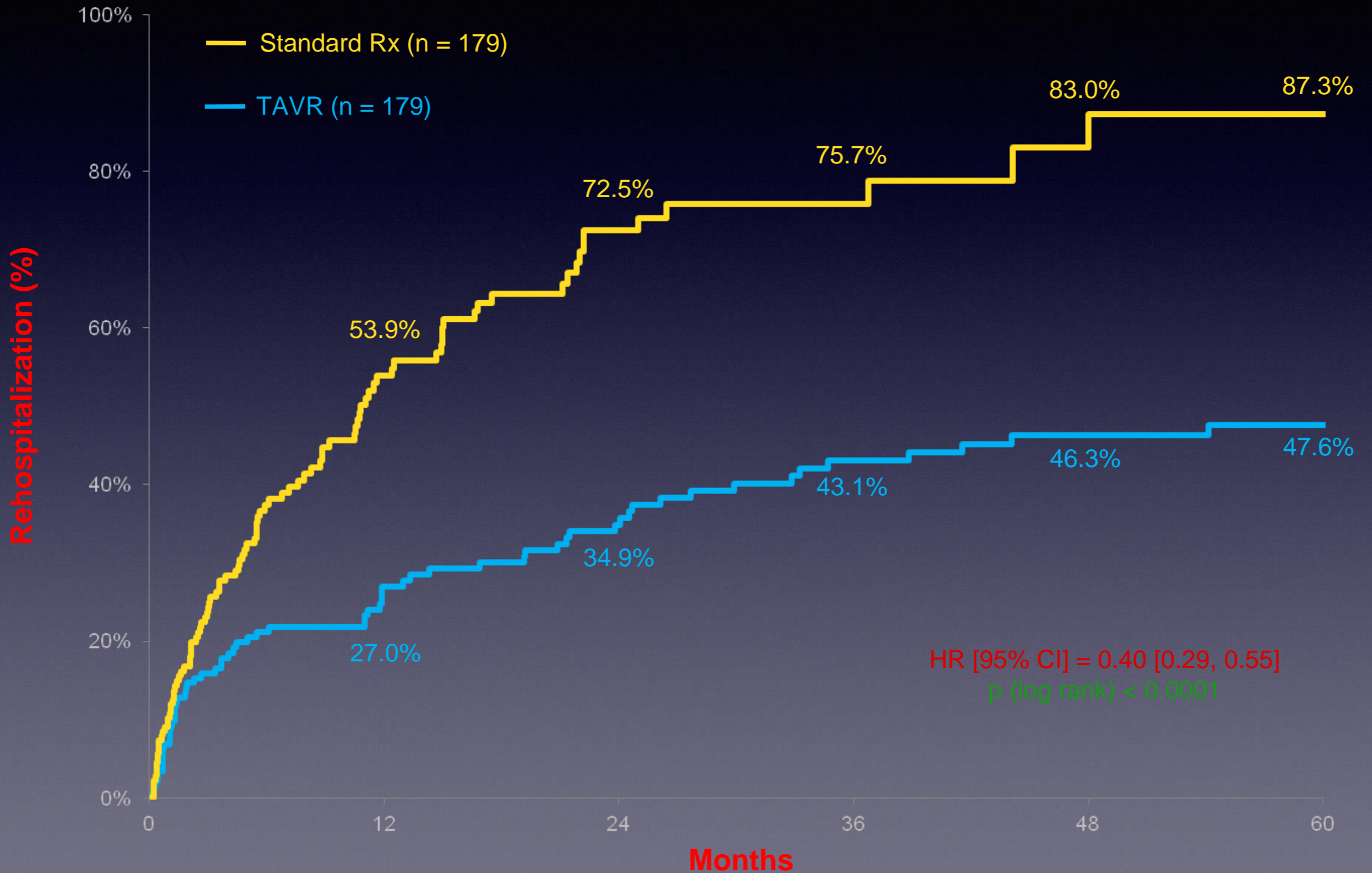
# All-Cause Mortality



Numbers at risk

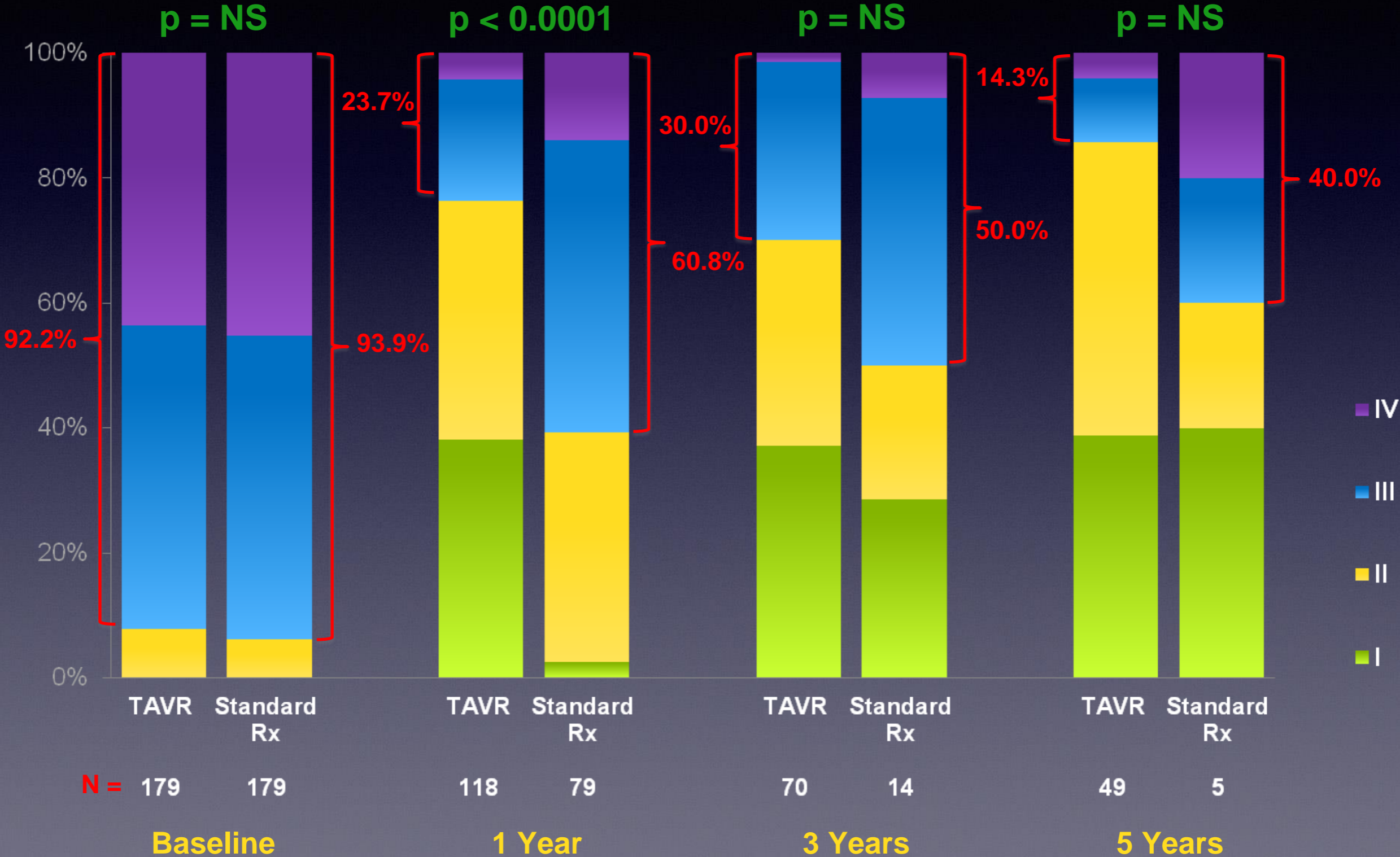
Std Rx	179	121	85	62	46	27	19	11	11	9	3
TAVI	179	138	124	110	101	89	81	72	63	53	35

# Repeat Hospitalization



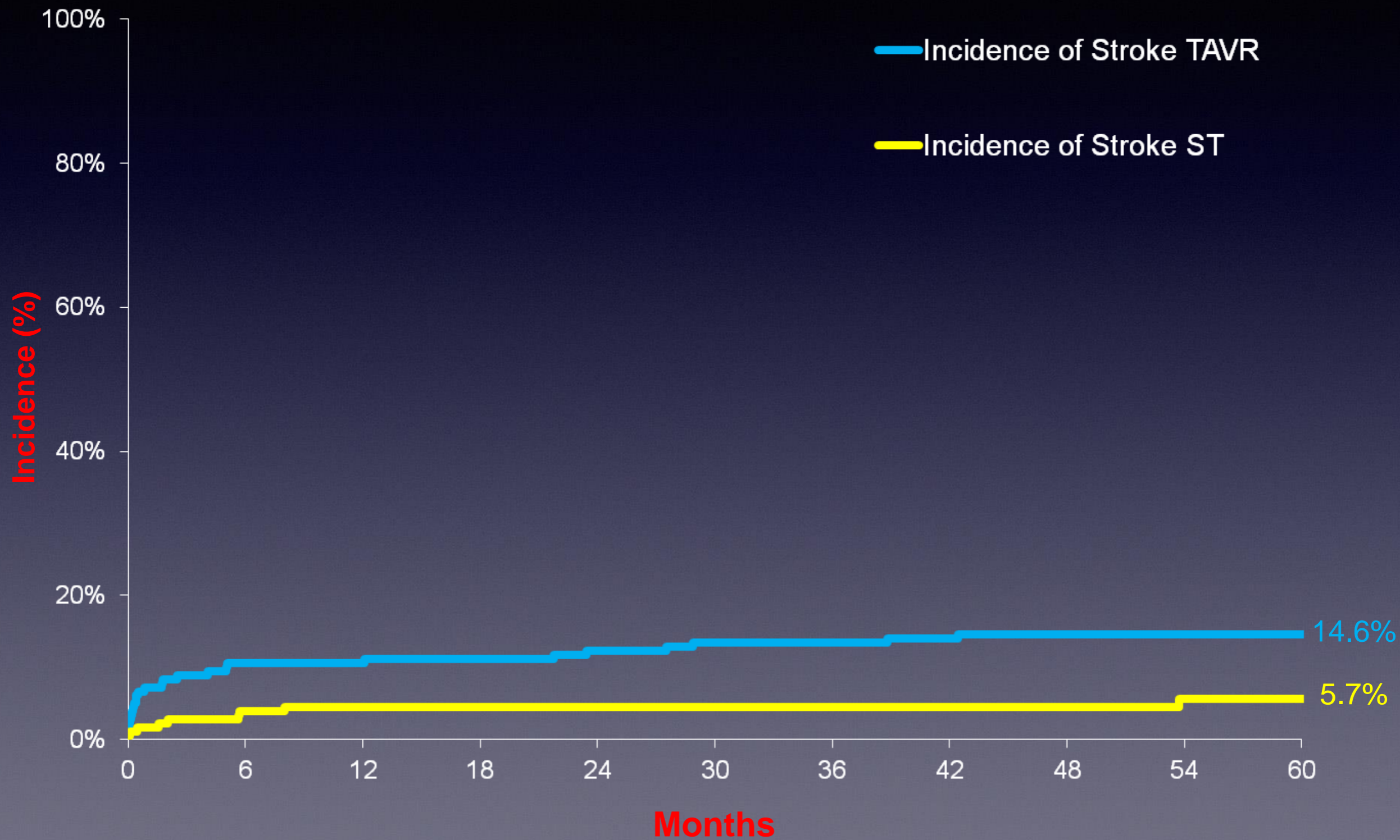
# NYHA Class Over Time

## Survivors

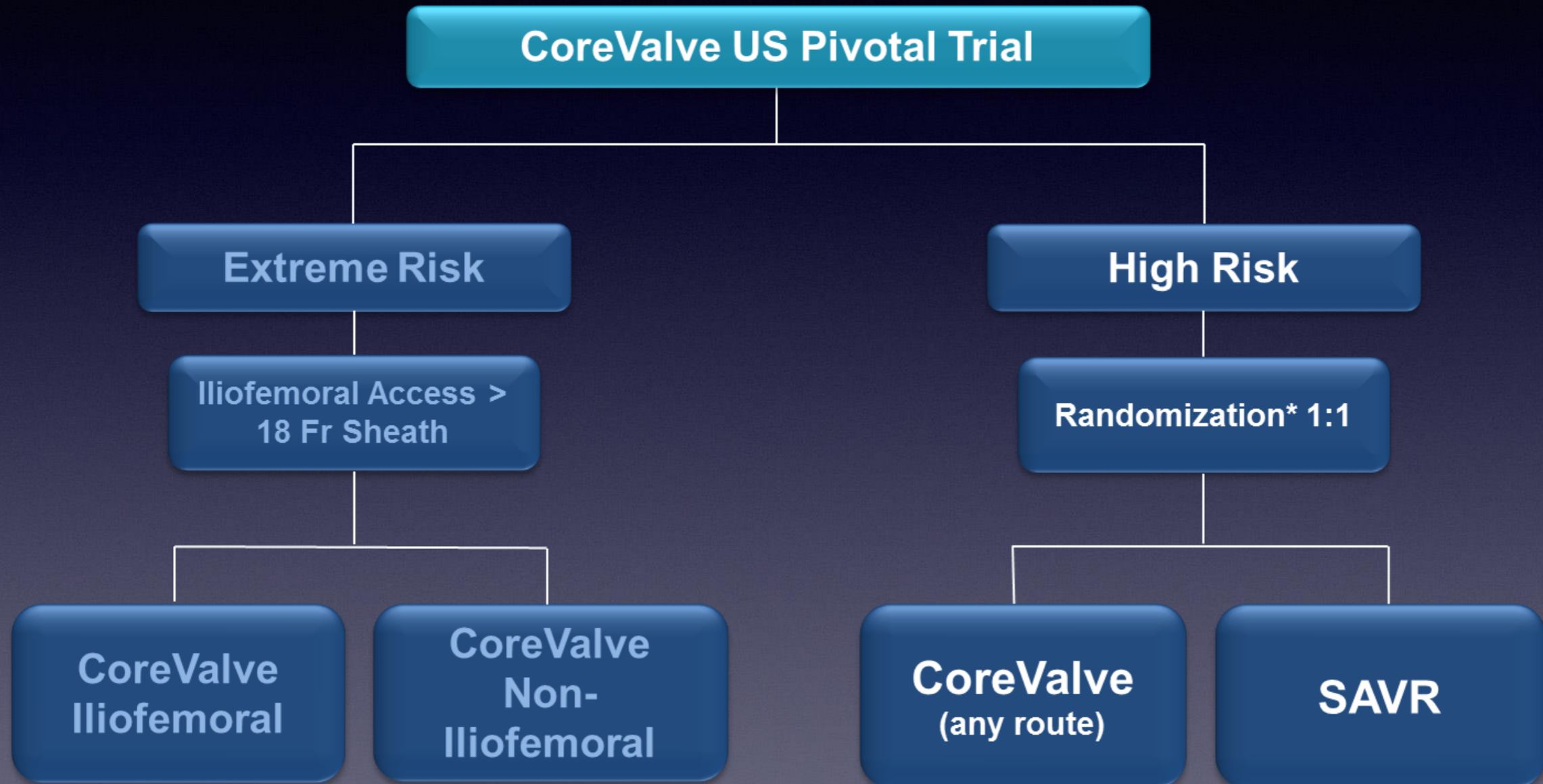


# Competing Risks Analysis

## Stroke



# Pivotal Trial Design



\* Randomization stratified by intended access site

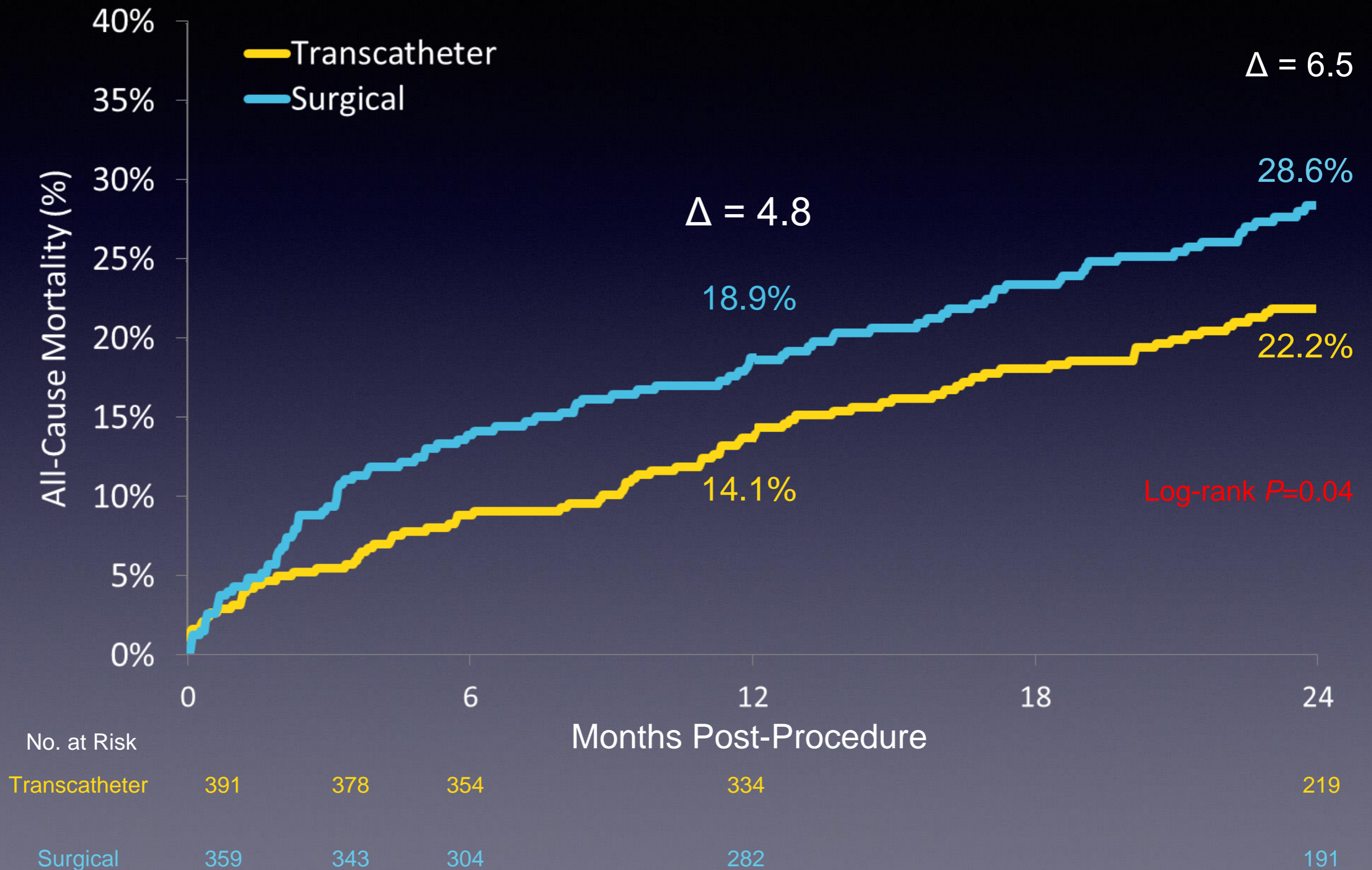
# Primary Endpoint

**Primary Endpoint:** All-cause mortality at 1 year

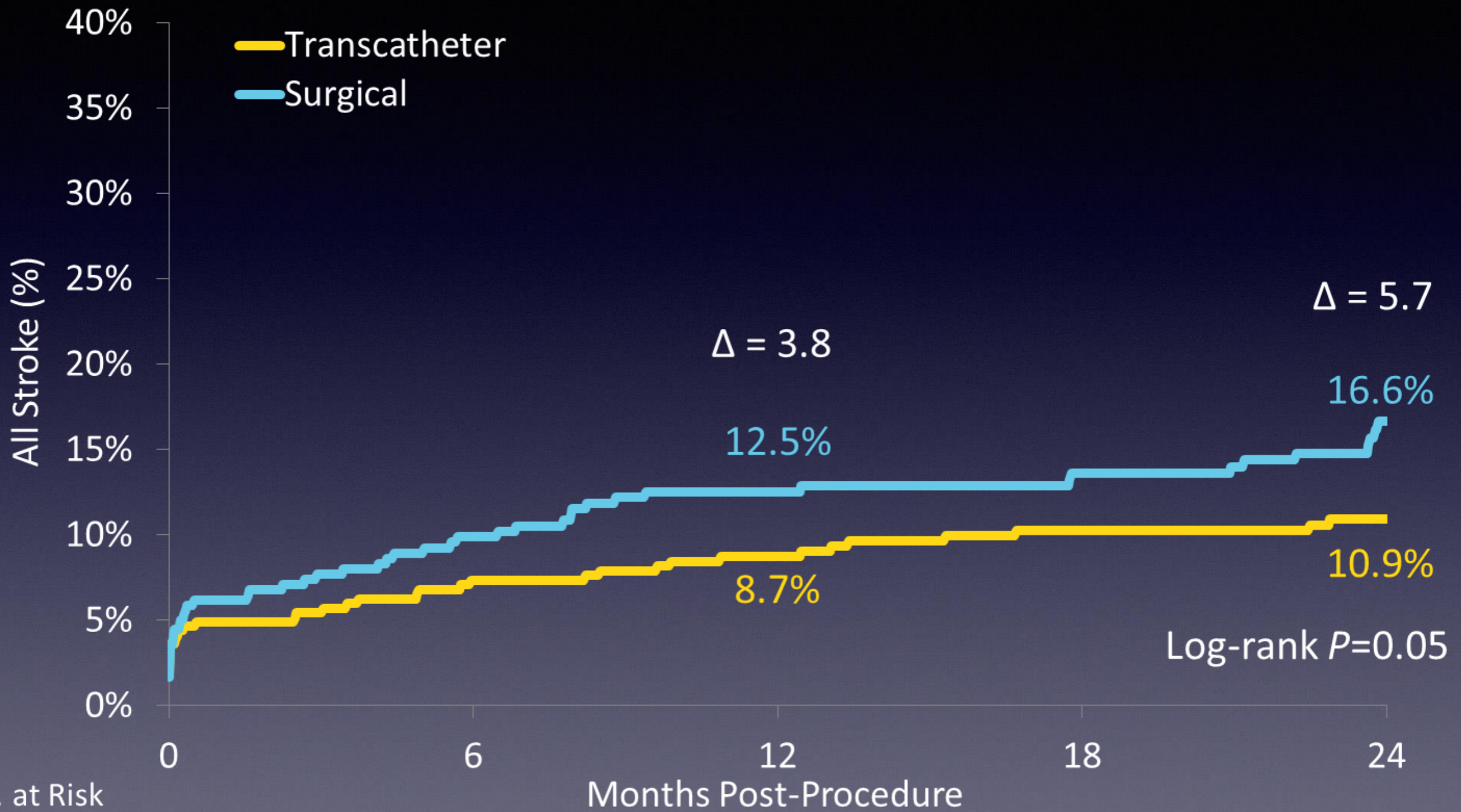
**Non-inferiority Testing:** TAVR with the CoreValve bioprosthesis was non-inferior to SAVR for 1 year all-cause mortality with a 7.5% non-inferiority margin

**Superiority Testing:** If the primary endpoint was met at the 1-sided 0.05 level, a subsequent test for superiority was performed at the 1-sided 0.05 level

# All-Cause Mortality



# All Stroke



No. at Risk

	0	6	12	18	24
Transcatheter	391	364	335	318	205
Surgical	359	324	281	256	169