# Post PARTNER US TAVI Registry

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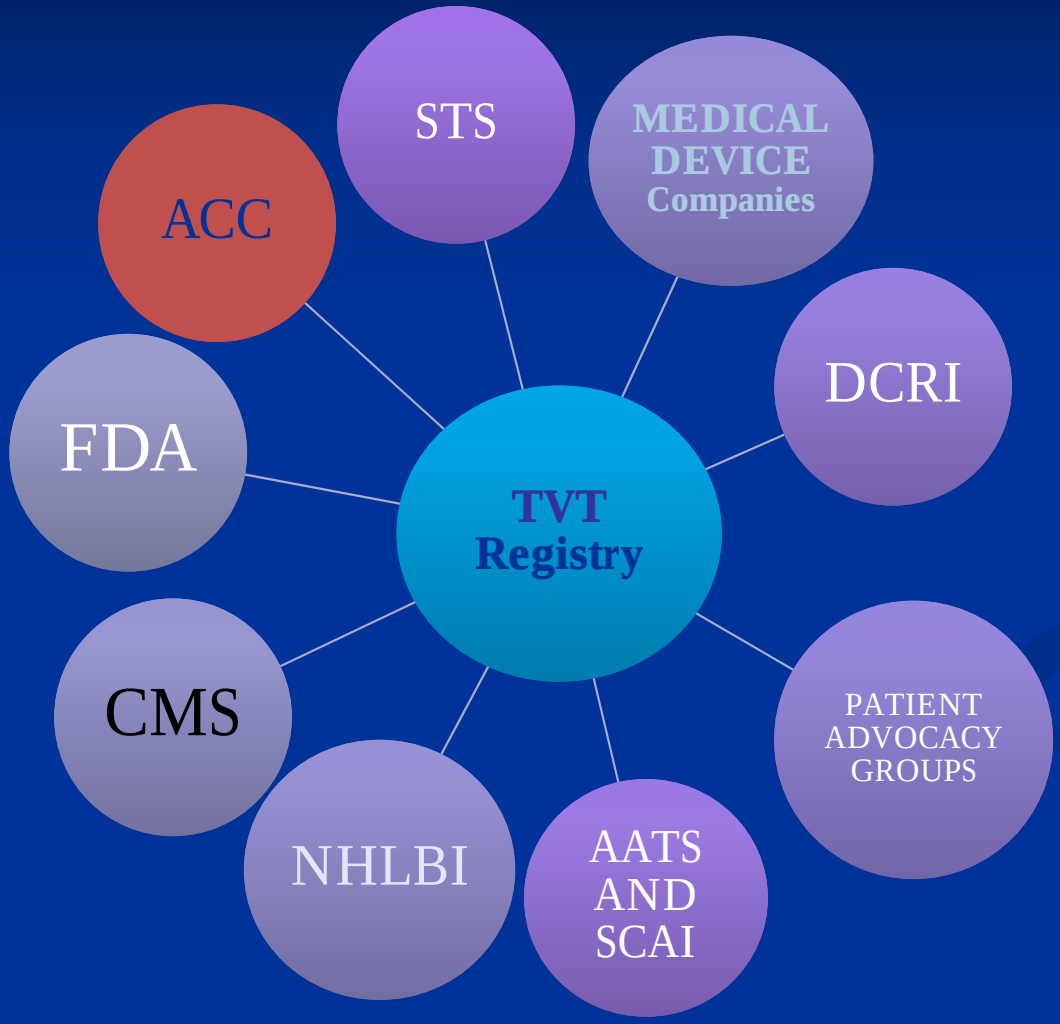
# Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial Interest /arrangement or affiliation with the organization(s) listed below

| Affiliation/Financial Relationship | Company |
| --- | --- |
| **Grant/ Research Support:** | |
| **Consulting Fees/Honoraria:** | **Edwards Lifesciences (consultant & proctor)** |
| **Major Stock Shareholder/Equity Interest:** | |
| **Royalty Income:** | |
| **Ownership/Founder:** | |
| **Salary:** | |
| **Intellectual Property Rights:** | |
| **Other Financial Benefit:** | |

# The Collaborative Partnership




Prospective registry of TAVR in US set up in response to the CMS National Coverage Determination requirement for national registry participation of all TAVR centers

Original Investigation

# Outcomes Following Transcatheter Aortic Valve Replacement in the United States

Michael J. Mack, MD; J. Matthew Brennan, MD, MPH; Ralph Brindis, MD, MPH; John Carroll, MD; Fred Edwards, MD; Fred Grover, MD; David Shahian, MD; E. Murat Tuzcu, MD; Eric D. Peterson, MD, MPH; John S. Rumsfeld, MD, PhD; Kathleen Hewitt, MSN; Cynthia Shewan, PhD; Joan Michaels, RN; Barb Christensen, RN; Alexander Christian; Sean O'Brien, PhD; David Holmes, MD; for the STS/ACC TVT Registry

Editorial page 2045

Author Video Interview at jama.com

Supplemental content at jama.com

**IMPORTANCE** Transcatheter aortic valve replacement (TAVR) was approved by the US Food and Drug Administration for the treatment of severe, symptomatic aortic stenosis and inoperable status (in 2011) and high-risk but operable status (starting in 2012). A national registry (the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy [STS/ACC TVT] Registry) was initiated to meet a condition for Medicare coverage and also facilitates outcome assessment and comparison with other trials and international registries.

**OBJECTIVE** To report the initial US commercial experience with TAVR.

**DESIGN, SETTING, AND PARTICIPANTS** We obtained results from all eligible US TAVR cases (n=7710) from 224 participating registry hospitals following the Edwards Sapien device commercialization (November 2011–May 2013).

**MAIN OUTCOMES AND MEASURES** Primary outcomes included all-cause in-hospital mortality and stroke following TAVR. Secondary analyses included procedural complications and outcomes by clinical indication and access site. Device implantation success was defined as successful vascular access, deployment of a single device in the proper anatomic position, appropriate valve function without either moderate or severe AR, and successful retrieval of the delivery system. Thirty-day outcomes are presented for a representative 3133 cases (40.6%) at 114 centers with at least 80% complete follow-up reporting.

**RESULTS** The 7710 patients who underwent TAVR included 1559 (20%) cases that were inoperable and 6151 (80%) cases that were high-risk but operable. The median age was 84 years (interquartile range [IQR], 78-88 years); 3783 patients (49%) were women and the median STS predicted risk of mortality was 7% (IQR, 5%-11%). At baseline, 2076 patients (75%) were either not at all satisfied (1297 patients [45%]) or mostly dissatisfied (879 patients [30%]) with their symptom status; 2198 (72%) had a 5-m walk time longer than 6 seconds (slow gait speed). The most common vascular access approach was transfemoral (4972 patients [64%]), followed by transapical (2197 patients [29%]) and other alternative approaches (536 patients [7%]); successful device implantation occurred in 7069 patients (92%; 95% CI, 91%-92%). The observed incidence of in-hospital mortality was 5.5% (95% CI, 5.0%-6.1%). Other major complications included stroke (2.0%; 95% CI, 1.7%-2.4%), dialysis-dependent renal failure (1.9%; 95% CI, 1.6%-2.2%), and major vascular injury (6.4%; 95% CI, 5.8%-6.9%). Median hospital stay was 6 days (IQR, 4-10 days), with 4613 (63%) discharged home. Among patients with available follow-up at 30 days (n=3133), the incidence of mortality was 7.6% (95% CI, 6.7%-8.6%) (noncardiovascular cause, 52%); a stroke had occurred in 2.8% (95% CI, 2.3%-3.5%), new dialysis in 2.5% (95% CI, 2.0%-3.1%), and reintervention in 0.5% (95% CI, 0.3%-0.8%).

**CONCLUSIONS AND RELEVANCE** Among patients undergoing TAVR at US centers in the STS/ACC TVT Registry, device implantation success was achieved in 92% of cases, the overall in-hospital mortality rate was 5.5%, and the stroke rate was 2.0%. Although these postmarket US approval findings are comparable with prior published trial data and international experience, long-term follow-up is essential to assess continued efficacy and safety.

**TRIAL REGISTRATION** clinicaltrials.gov Identifier: NCT01073528

JAMA. 2013;310(19):2069-2077. doi:10.1001/jama.2013.281043

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# STS/ACC TVT Registry™
## National Summary Report

## *"Real-World" TAVR in the US*

Michael Mack, M.D.

On Behalf of the STS/ACC TVT Registry Steering Committee

June 6, 2014

Vancouver, BC

NCDR

STS National Database

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# One Year Outcomes from the STS/ACC Transcatheter Valve Therapy (TVT) Registry

David R. Holmes, Jr., J. Matthew Brennan, John S. Rumsfeld, David Dai, Fred Edwards, John Carroll, David Shahian, Fred Grover, E. Murat Tuzcu, Eric Peterson, Ralph Brindis, Michael J. Mack

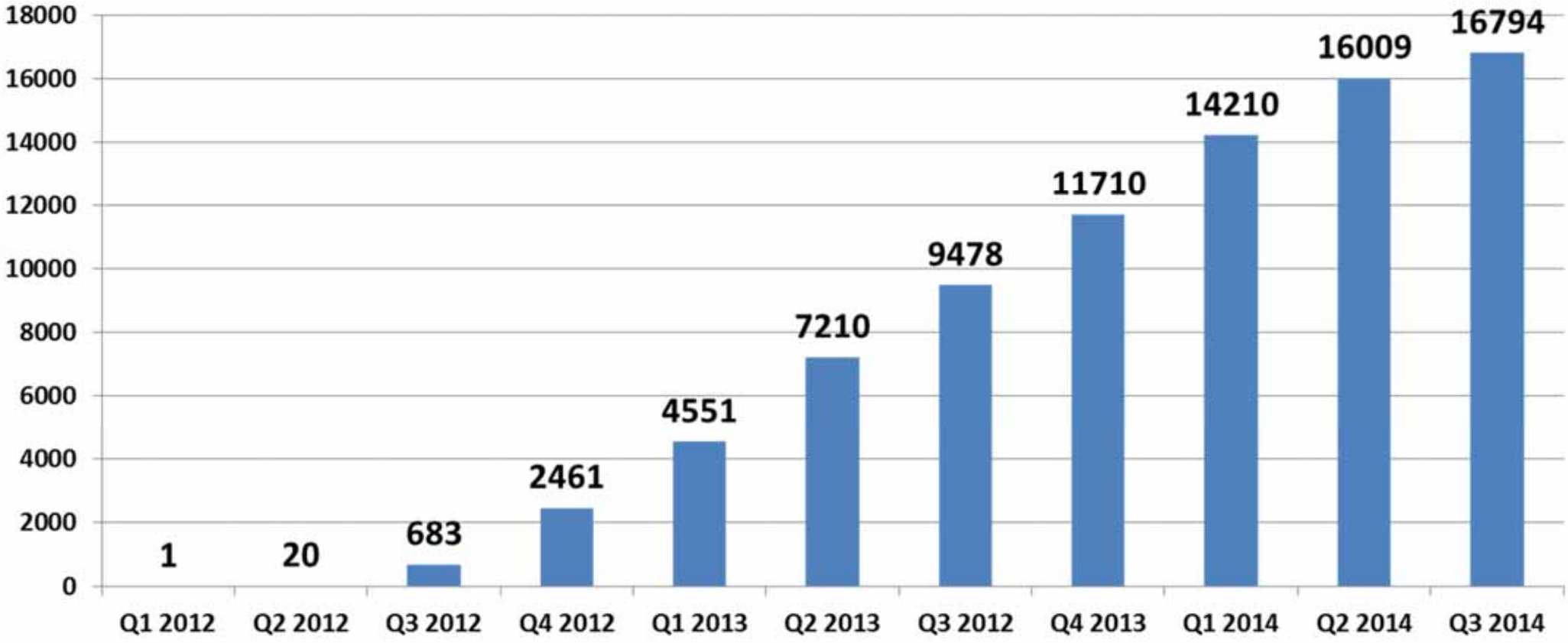
March 2014

On behalf of the TVT Registry

ACC 2014

Washington, D.C.

# Cumulative TVT Records Entered in TVT Registry Jan 2012-June 2014




**All 16,794 Cases are Commercial TAVR**

- 313 Sites Entering Data
- 5 Sites > 200 Cases; 40 Sites > 100 Cases

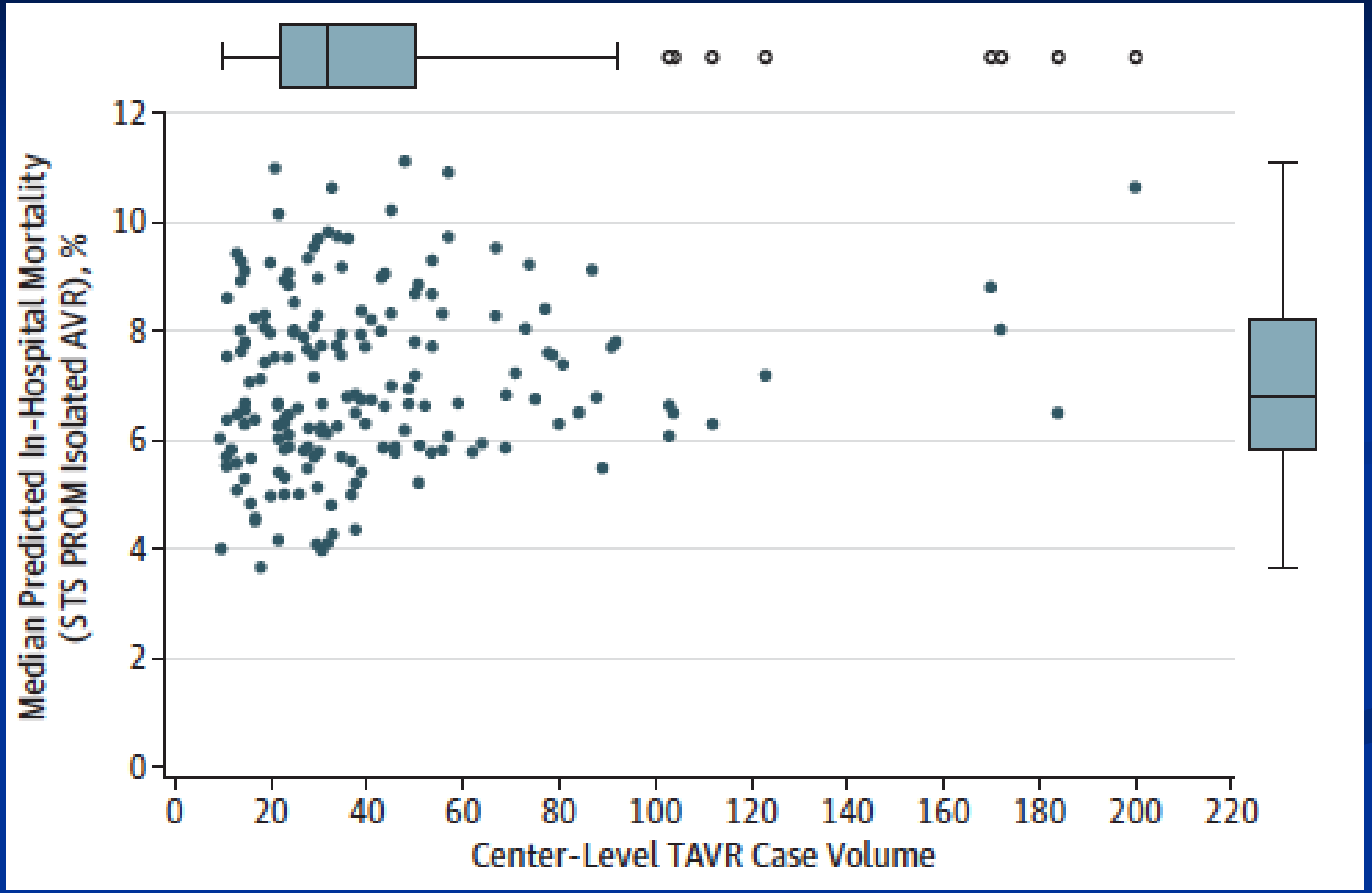
STS/ACC TVT Registry™ Sites by State


No TAVR sites in Alaska and Wyoming (currently patients served by Seattle and Colorado sites)

**Florida 23**
**Penn 22**
**California 19**
**NY 17**
**Texas 14**

# BASELINE DEMOGRAPHICS

| Characteristics | Overall (n = 7710) | High Risk (n = 6151) | | Inoperable (n = 1559) | |
|---|---|---|---|---|---|
| | | Trans-femoral (n = 3833) | Nontrans-femoral (n = 2318) | Trans-femoral (n = 1139) | Nontrans-femoral (n = 420) |
| Age, median (IQR), y | 84 (78-88) | 85 (79-89) | 83 (78-88) | 83 (77-88) | 82 (77-87) |
| Male | 3862 (50) | 2053 (54) | 992 (43) | 616 (54) | 201 (48) |
| STS PROM score, median (IQR), % | 7 (5-11) | 7 (5-11) | 8 (5-12) | 7 (4-10) | 7 (4-11) |
| NYHA class III/IV heart failure | 6272 (81) | 3104 (81) | 1884 (81) | 962 (84) | 322 (77) |

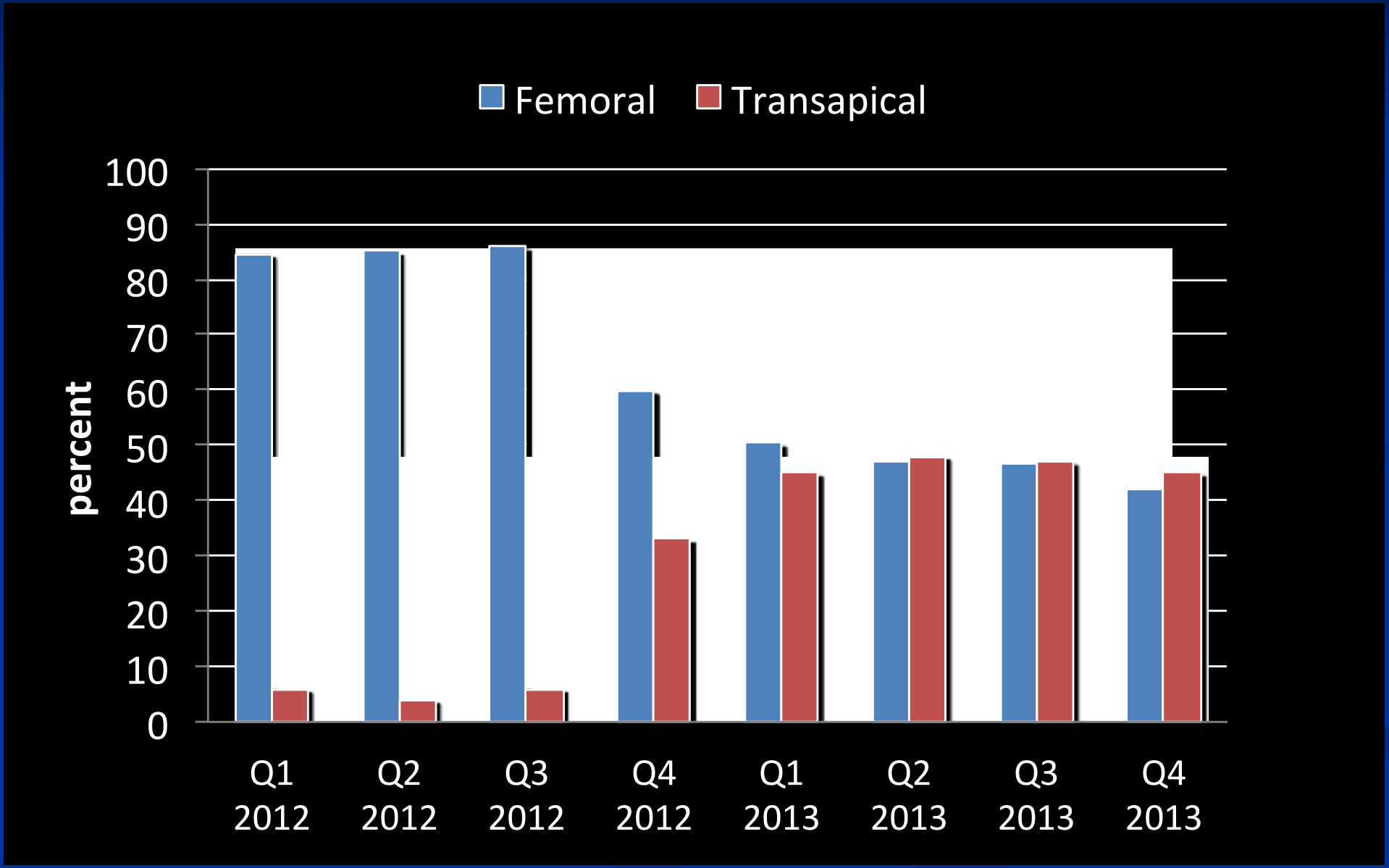

Median Predicted In-Hospital Mortality (STS PROM Isolated AVR), %
0
2
4
6
8
10
12
0
20
40
60
80
100
120
140
160
180
200
220
Center-Level TAVR Case Volume

| Characteristics | Overall (n = 7710) | High Risk (n = 6151) | | Inoperable (n = 1559) | |
|---|---|---|---|---|---|
| | | Trans-femoral (n = 3833) | Nontrans-femoral (n = 2318) | Trans-femoral (n = 1139) | Nontrans-femoral (n = 420) |
| Coronary artery disease | 5316 (69) | 2506 (66) | 1706 (74) | 793 (70) | 311 (74) |
| No. of prior cardiac surgeries | | | | | |
| 1 | 2045 (27) | 905 (24) | 700 (30) | 309 (27) | 133 (32) |
| ≥2 | 400 (5) | 164 (5) | 140 (6) | 71 (6) | 25 (6) |
| Prior aortic valve intervention | | | | | |
| Balloon aortic valvuloplasty | 1197 (16) | 516 (13) | 432 (19) | 177 (16) | 72 (17) |
| Surgical AVR | 123 (2) | 58 (2) | 32 (1) | 25 (2) | 8 (2) |
| TAVR | 14 (0.2) | 7 (0.2) | 4 (0.2) | 2 (0.2) | 1 (0.2) |
| Previous stroke | 1004 (13) | 503 (13) | 321 (14) | 130 (11) | 50 (12) |
| Peripheral arterial disease | 2416 (31) | 898 (23) | 1067 (46) | 274 (24) | 177 (42) |
| COPD | | | | | |
| Moderate | 1081 (14) | 511 (13) | 358 (15) | 154 (14) | 58 (14) |
| Severe | 1064 (14) | 536 (14) | 336 (15) | 138 (12) | 54 (13) |
| Oxygen-dependent lung disease | 1135 (15) | 569 (15) | 347 (15) | 161 (14) | 58 (14) |
| Renal failure | | | | | |
| Dialysis-dependent | 350 (5) | 190 (5) | 95 (4) | 47 (4) | 18 (4) |
| Serum creatinine level ≥3.0 mg/dL | 361 (5) | 194 (5) | 103 (4) | 47 (4) | 17 (4) |

| Characteristics | Overall (n = 7710) | High Risk (n = 6151) | | Inoperable (n = 1559) | |
|---|---|---|---|---|---|
| | | Trans-femoral (n = 3833) | Nontrans-femoral (n = 2318) | Trans-femoral (n = 1139) | Nontrans-femoral (n = 420) |
| 5-m walk time >6 s | 2198 (72) | 1008 (73) | 784 (73) | 304 (70) | 102 (57) |
| Atrial fibrillation | 3148 (41) | 1627 (42) | 919 (40) | 445 (39) | 157 (37) |
| Permanent pacemaker/ICD | 1500 (19) | 774 (20) | 433 (19) | 215 (19) | 78 (19) |
| Hostile chest | 742 (10) | 272 (7) | 167 (7) | 222 (19) | 81 (19) |
| Porcelain aorta | 587 (8) | 174 (5) | 215 (9) | 113 (10) | 85 (20) |
| Left ventricular ejection fraction <30% | 540 (7) | 276 (7) | 141(6) | 87 (8) | 36 (9) |
| Bicuspid aortic valve | 122 (2) | 66 (2) | 35 (2) | 16 (1) | 5 (1) |
| Pre-TAVR mitral insufficiency | | | | | |
| Moderate | 2037 (26) | 1028 (27) | 619 (27) | 290 (25) | 100 (24) |
| Severe | 347 (5) | 179 (5) | 104 (4) | 49 (4) | 15 (4) |

# PROCEDURAL / ACUTE OUTCOMES

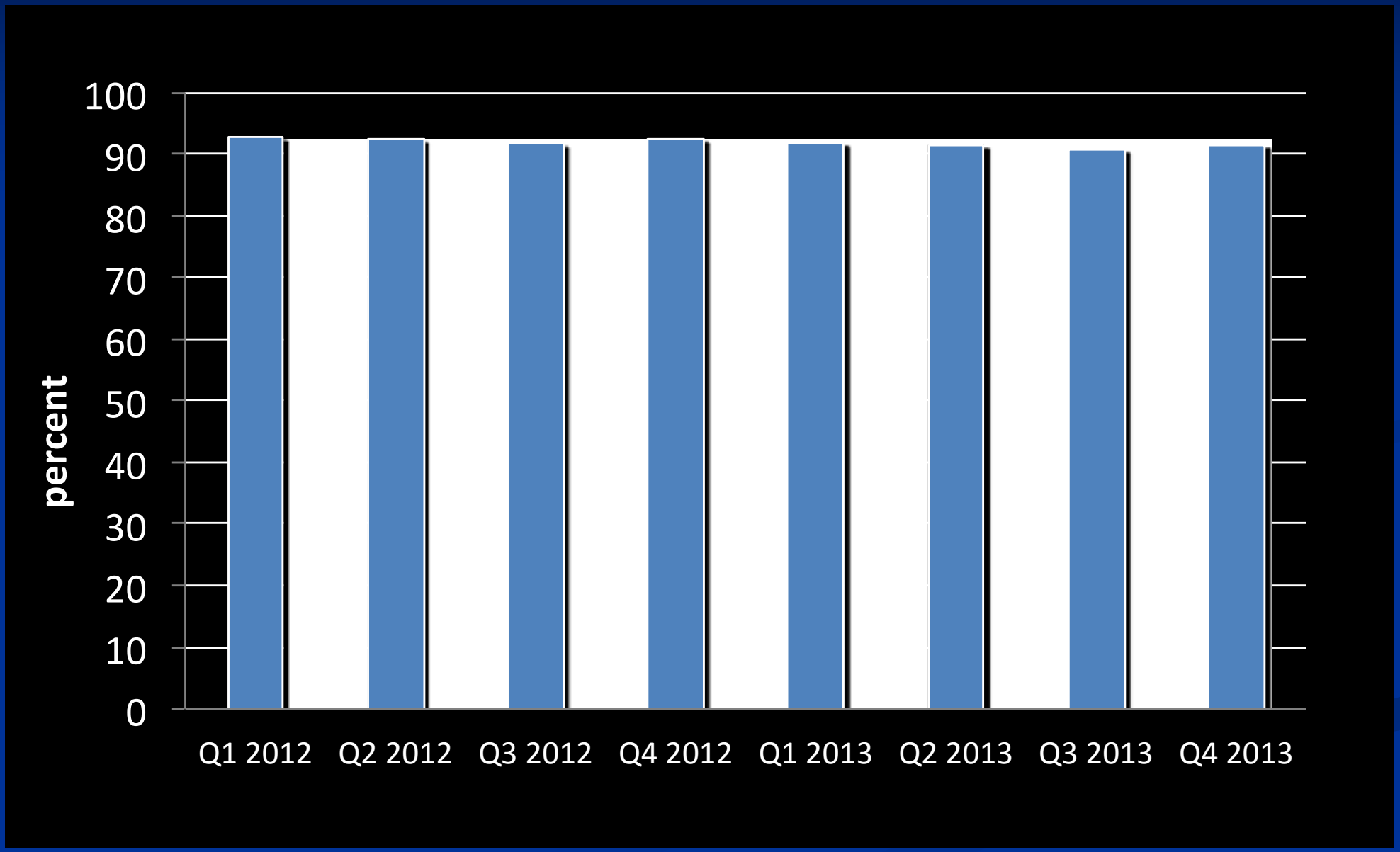
# % Patients by Access Site




Source: STS/ACC TVT Registry n=12,563

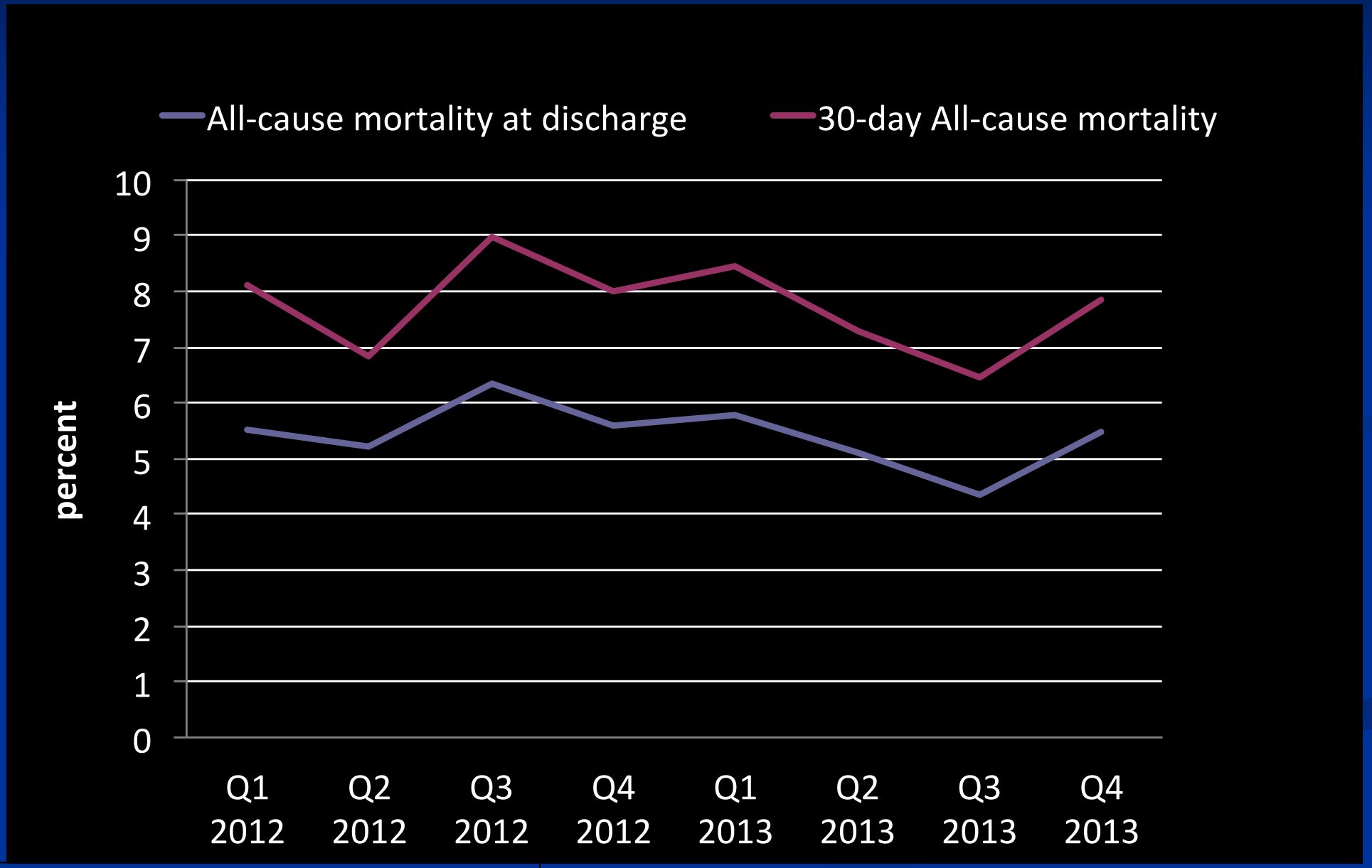
# % Patients with Device Success

## *VARC 2*



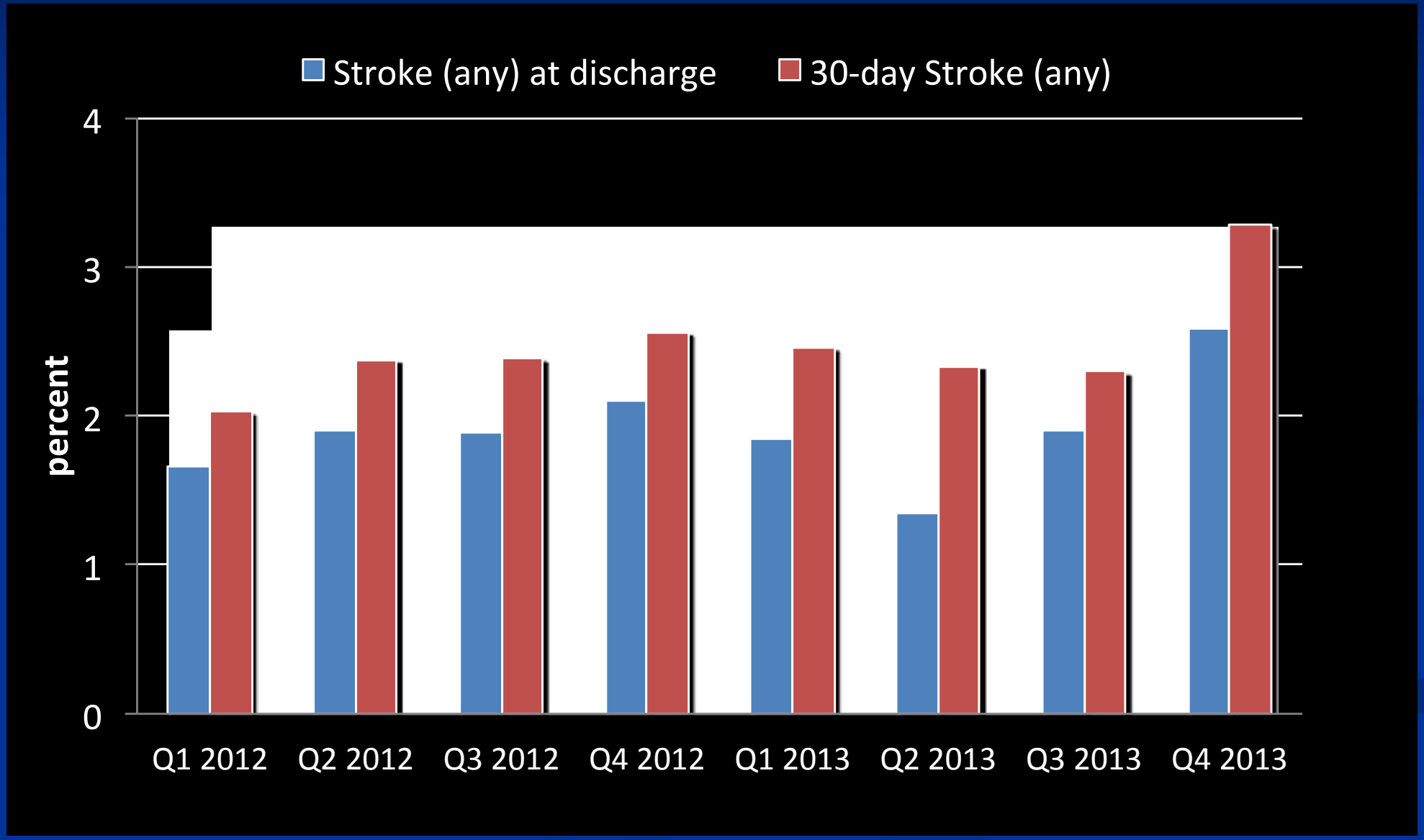

Source: STS/ACC TVT Registry n=12,563

# % All Cause Mortality at Discharge and 30-day



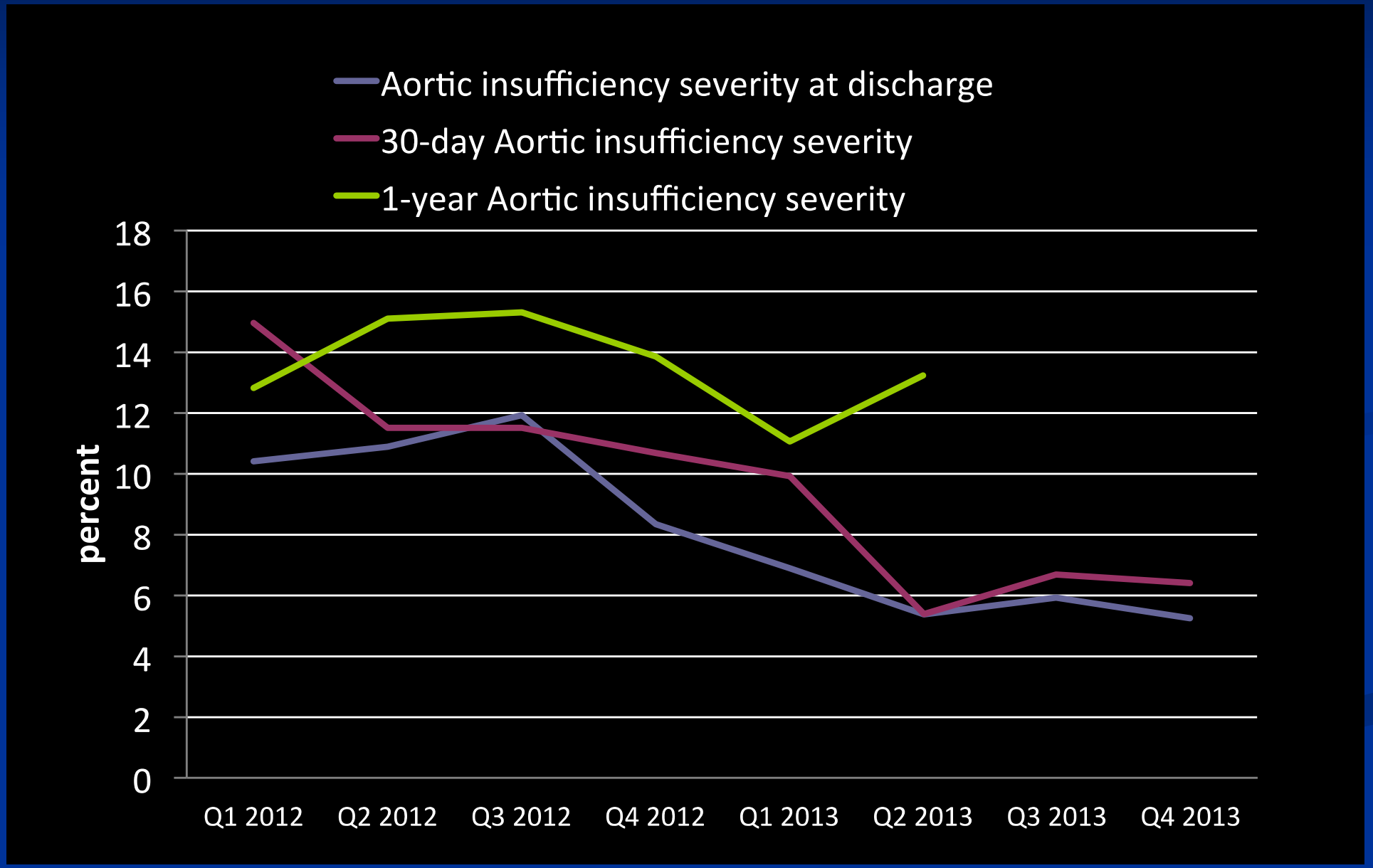

Source: STS/ACC TVT Registry n=12,563

# % Patients with Stroke at Discharge and 30-days



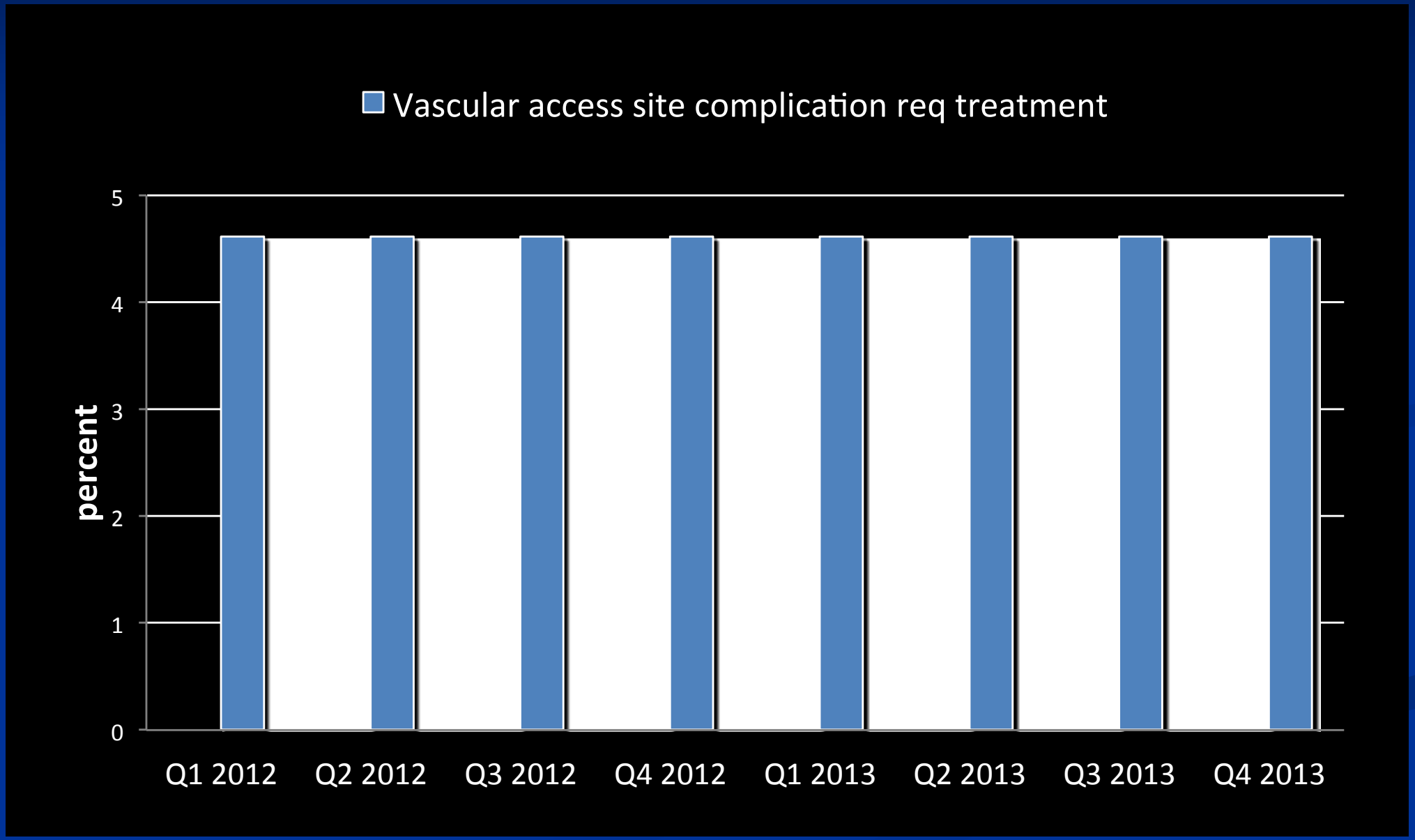

Source: STS/ACC TVT Registry n=12,563

# % Mod/sev Aortic Insufficiency at Discharge, 30-day and 1-year




Source: STS/ACC TVT Registry n=12,563

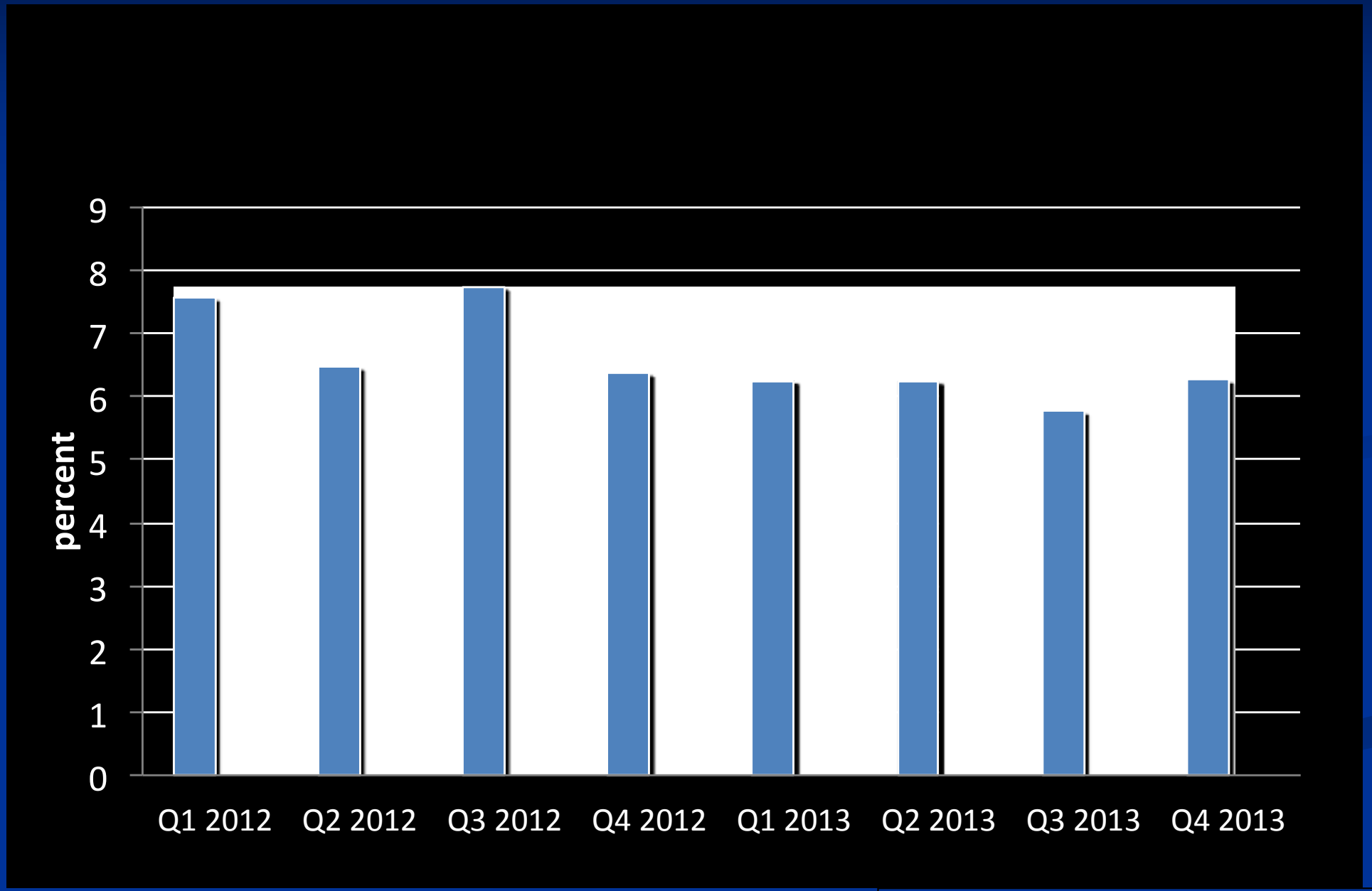
# % Patients with Major Vascular Complications
## *VARC 2*




Source: STS/ACC TVT Registry n=12,563

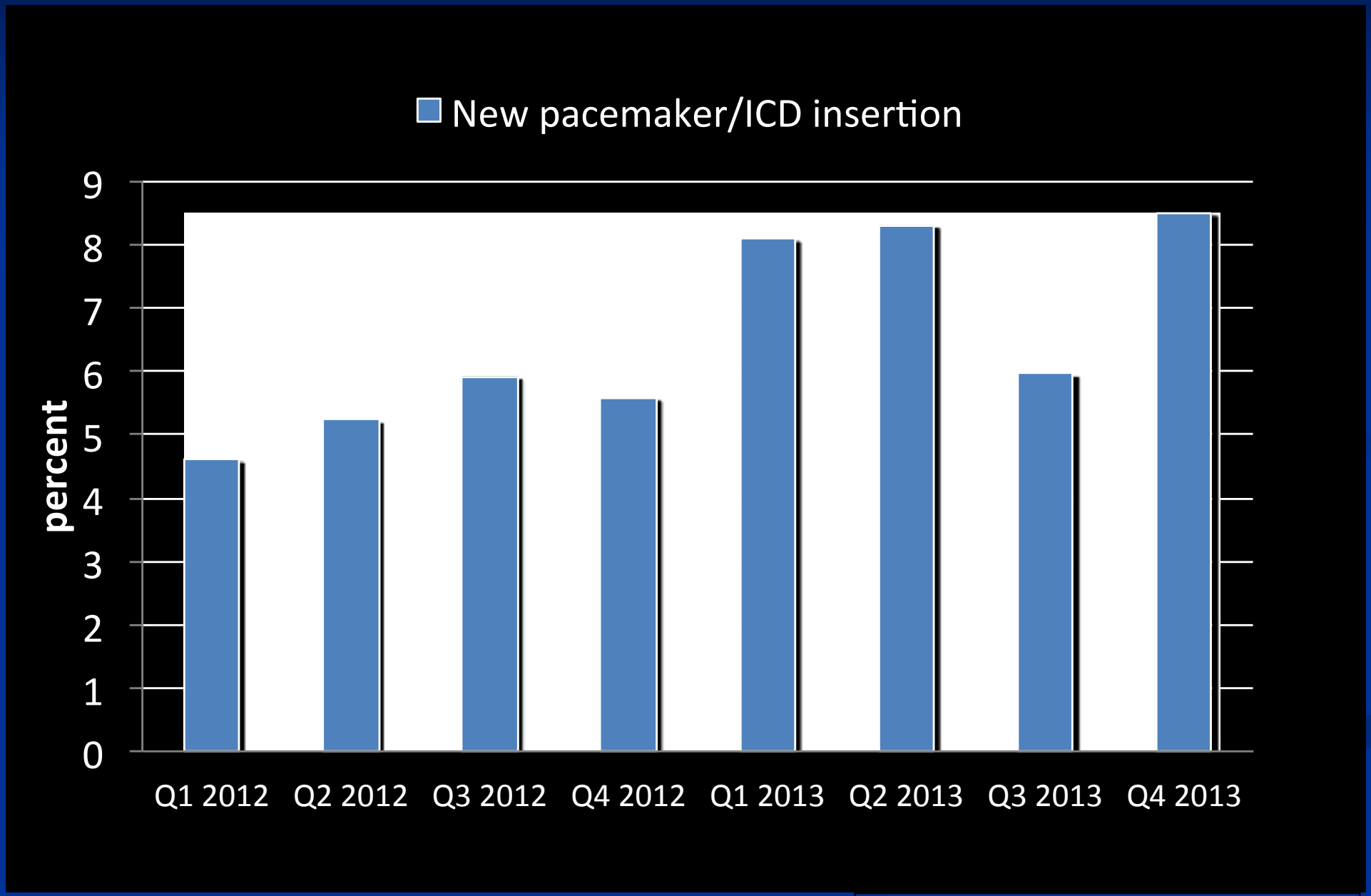
# % Patients with Major Bleeding

## *VARC 2*



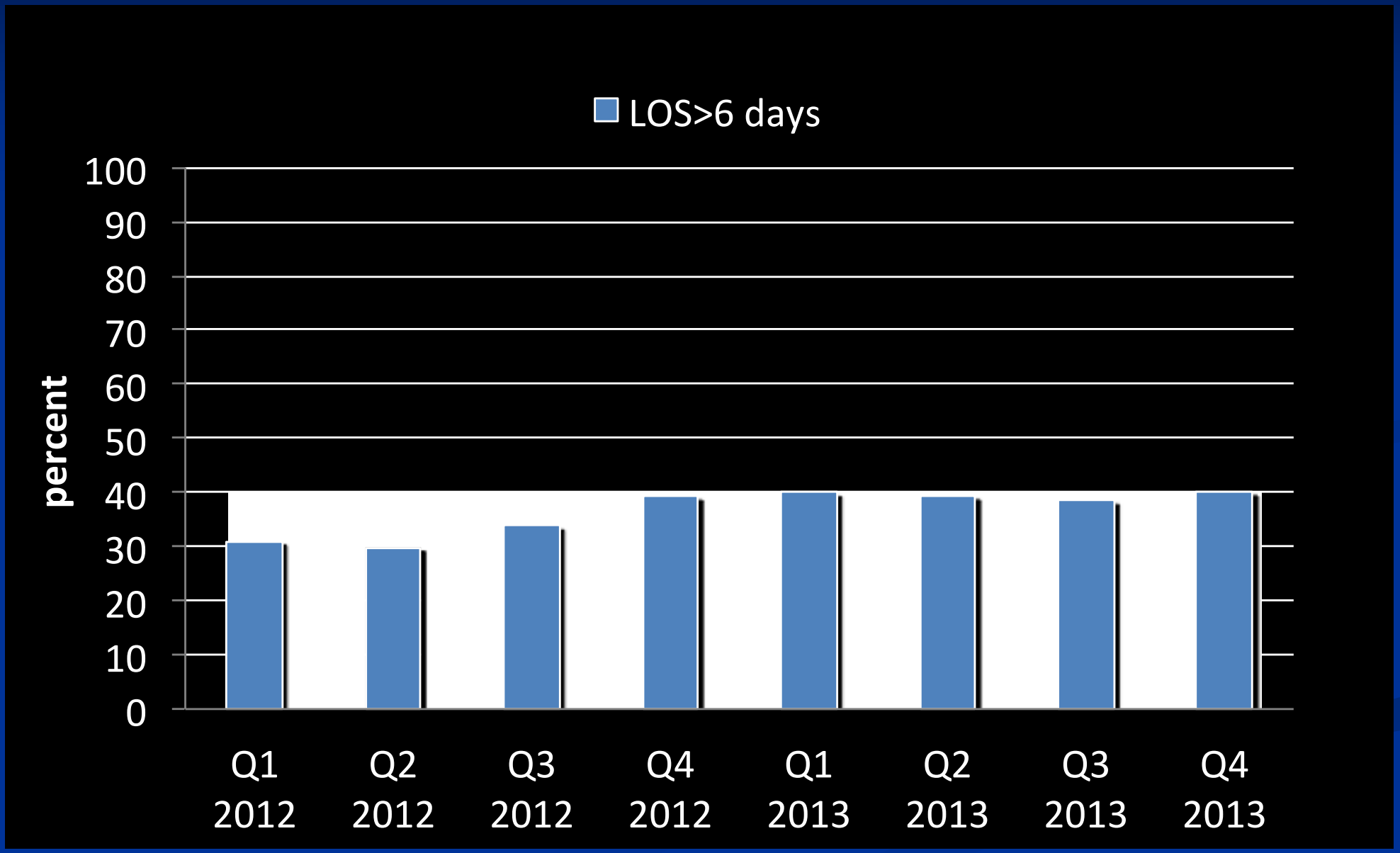

Source: STS/ACC TVT Registry n=12,563

# % Patients with New Pacemaker/ICD Insertion



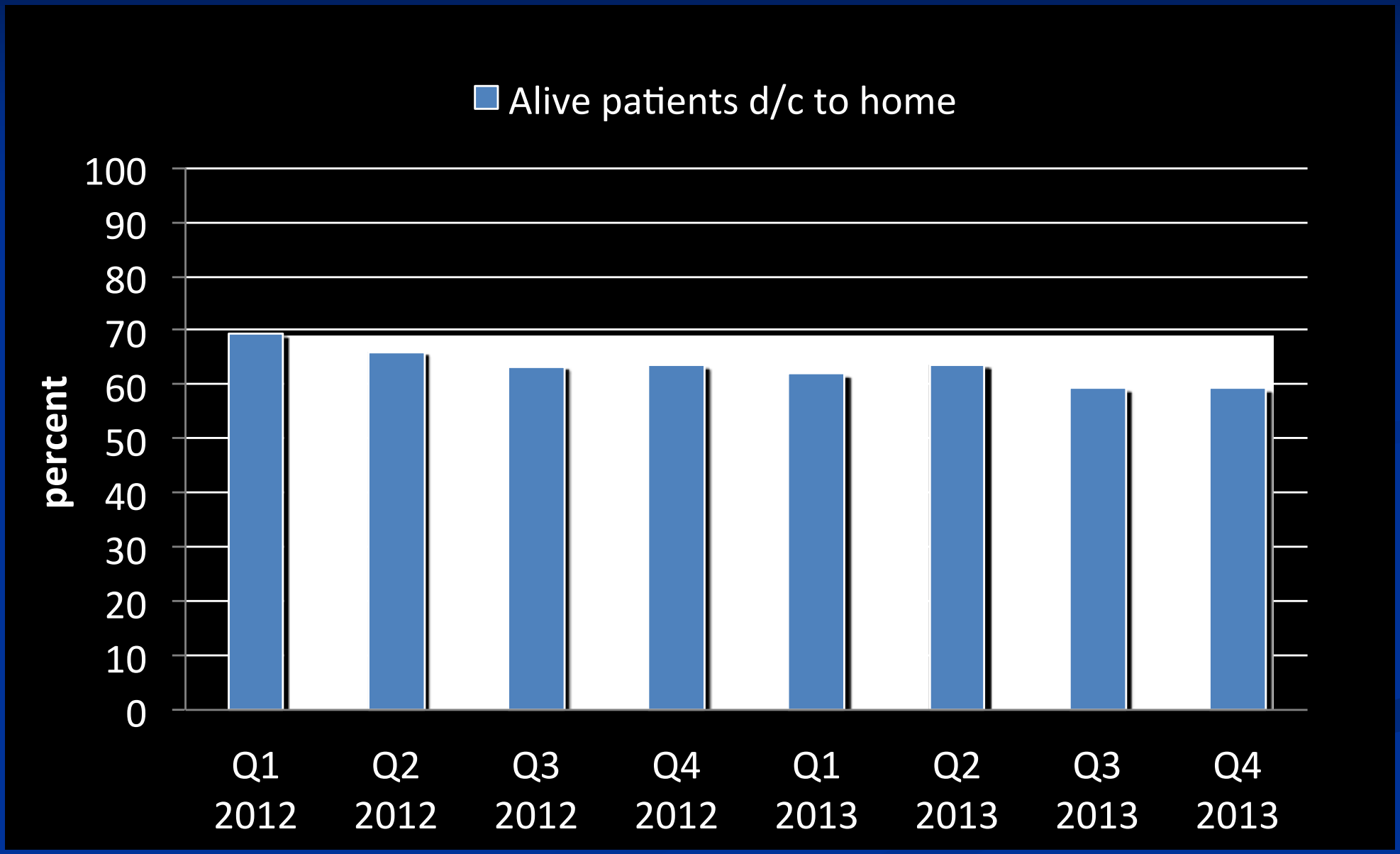

Source: STS/ACC TVT Registry n=12,563

# % Patients with LOS > 6 Days



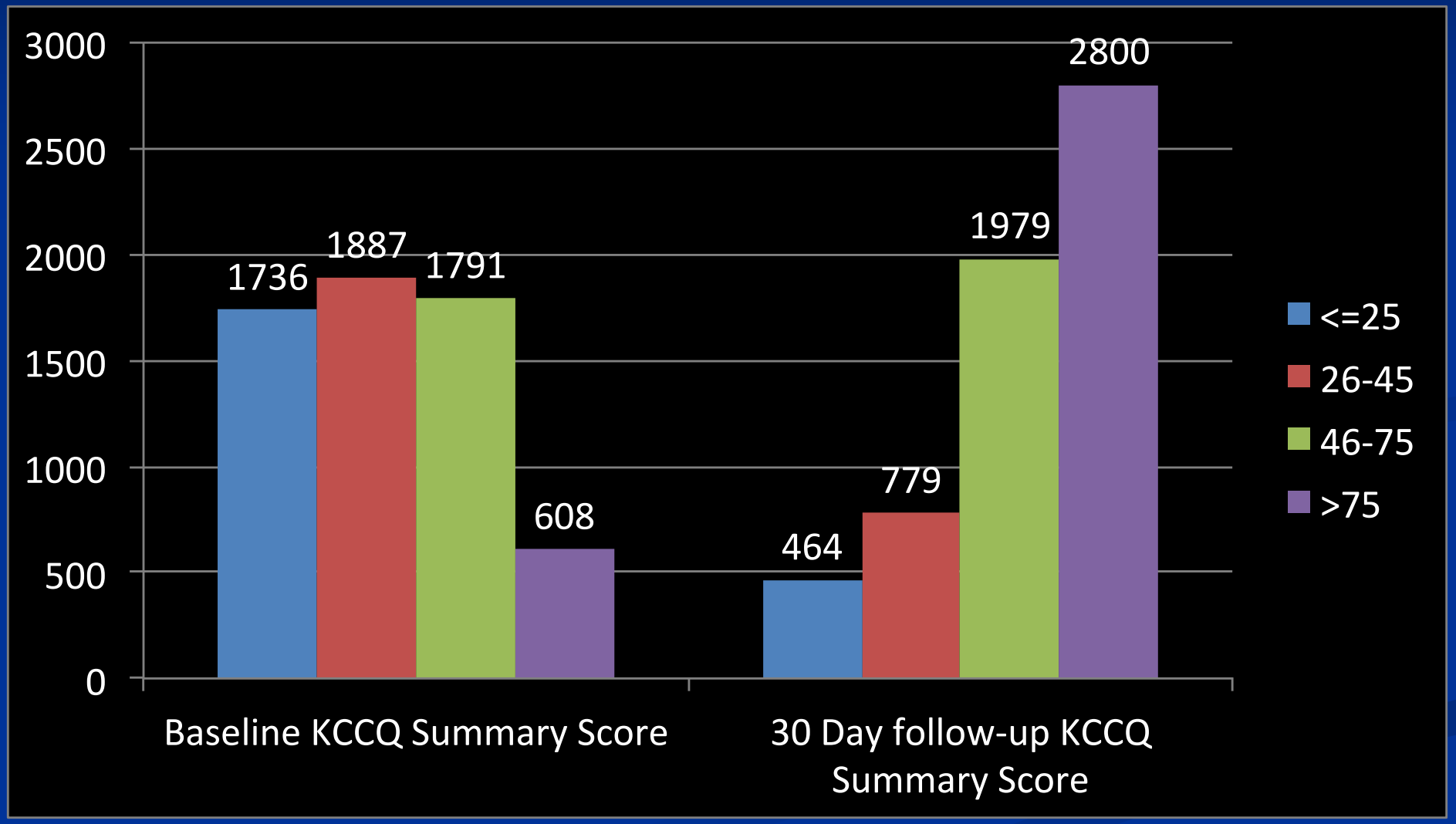

Source: STS/ACC TVT Registry n=12,563

# % Patients Discharged to Home




Source: STS/ACC TVT Registry n=12,563

# Baseline and 30 Day Follow-up KCCQ Summary Scores




*Source: 6021 patients with pre and post KCCQ summary scores between 2012-April 2014 in the STS/ACC TVT Registry data warehouse*

# ONE YEAR OUTCOMES

# Patient Characteristics

| Characteristic | Study Cohort N= 5,980 |
|---|---|
| Age (yr) Median (25th, 75th) | 85 (79, 88) |
| 75-84, n (%) | 2,244 (37.5) |
| 85-94, n (%) | 2,869 (48.0) |
| Female, n (%) | 3,006 (50.4) |
| STS PROM Score (25th, 75th) | 7.1 (4.7, 10.9) |
| <8% n, (%) | 3,405 (57.0) |
| 8-15% | 1,844 (30.8) |
| >15% | 729 (12.2) |
| NYHA Class III/IV Heart Failure, n (%) | 4,876 (83.6) |
| CAD, n (%) | 3,564 (61.7) |

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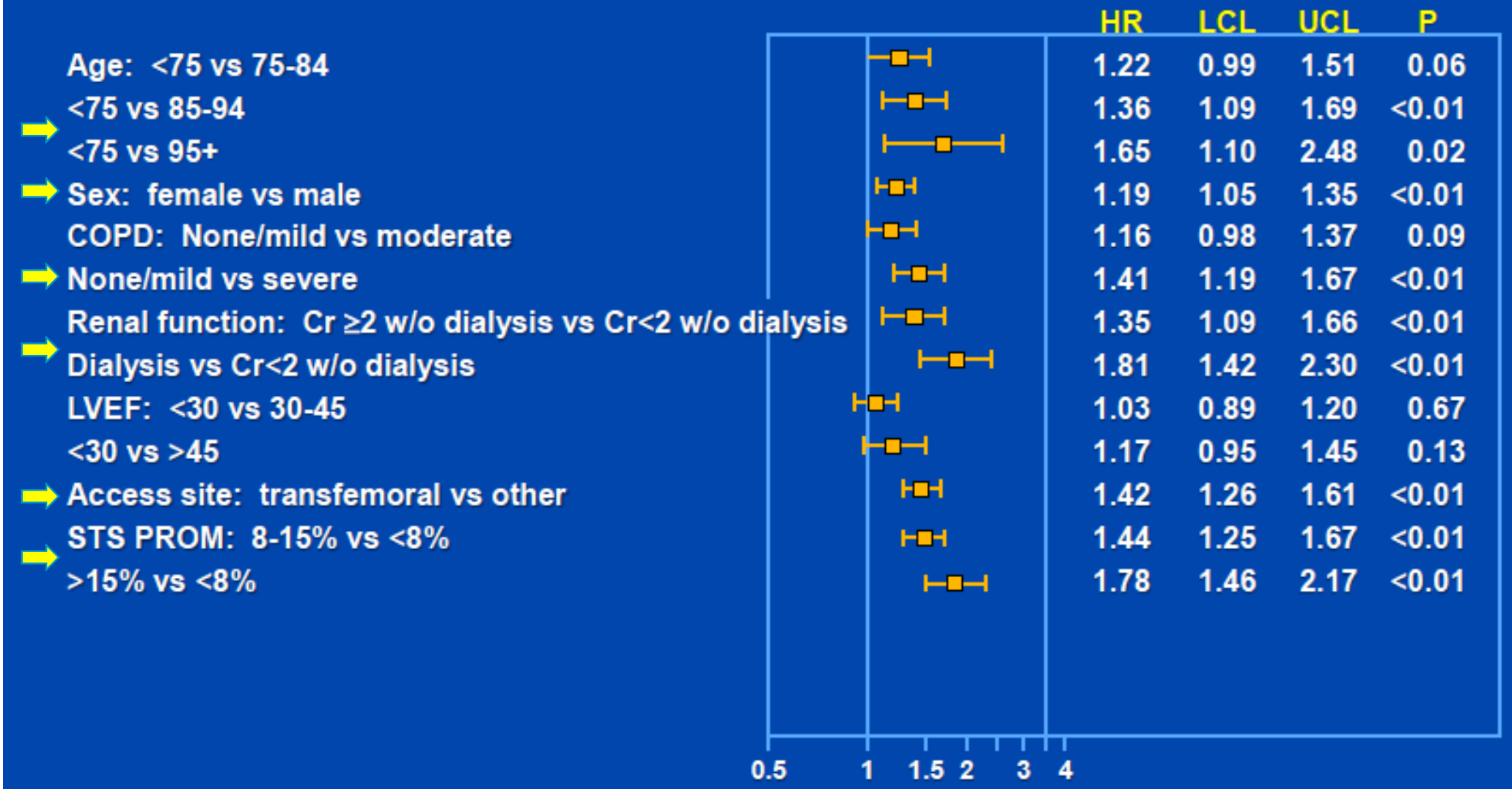
# One Year Outcomes

| | |
|---|---|
| **Mortality** | **26.2% (24.7%, 27.8%)** |
| Stroke | 3.6% (3.1%, 4.2%) |
| Death or stroke | 28.4% (26.9%, 30.0%) |

# Multivariable Model of 1-Year Mortality after TAVR

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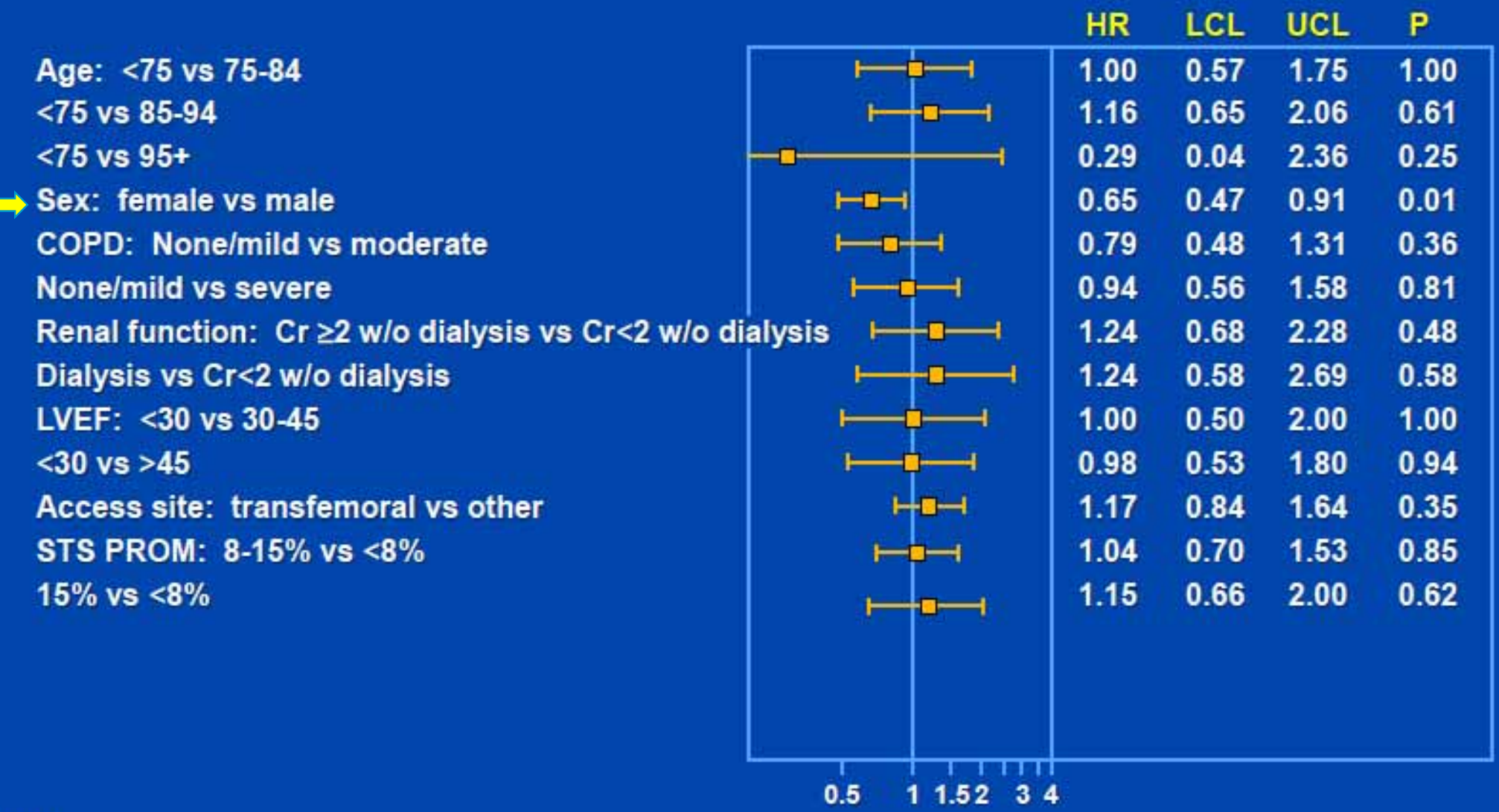
# Multivariable Model of 1-Year Stroke after TAVR

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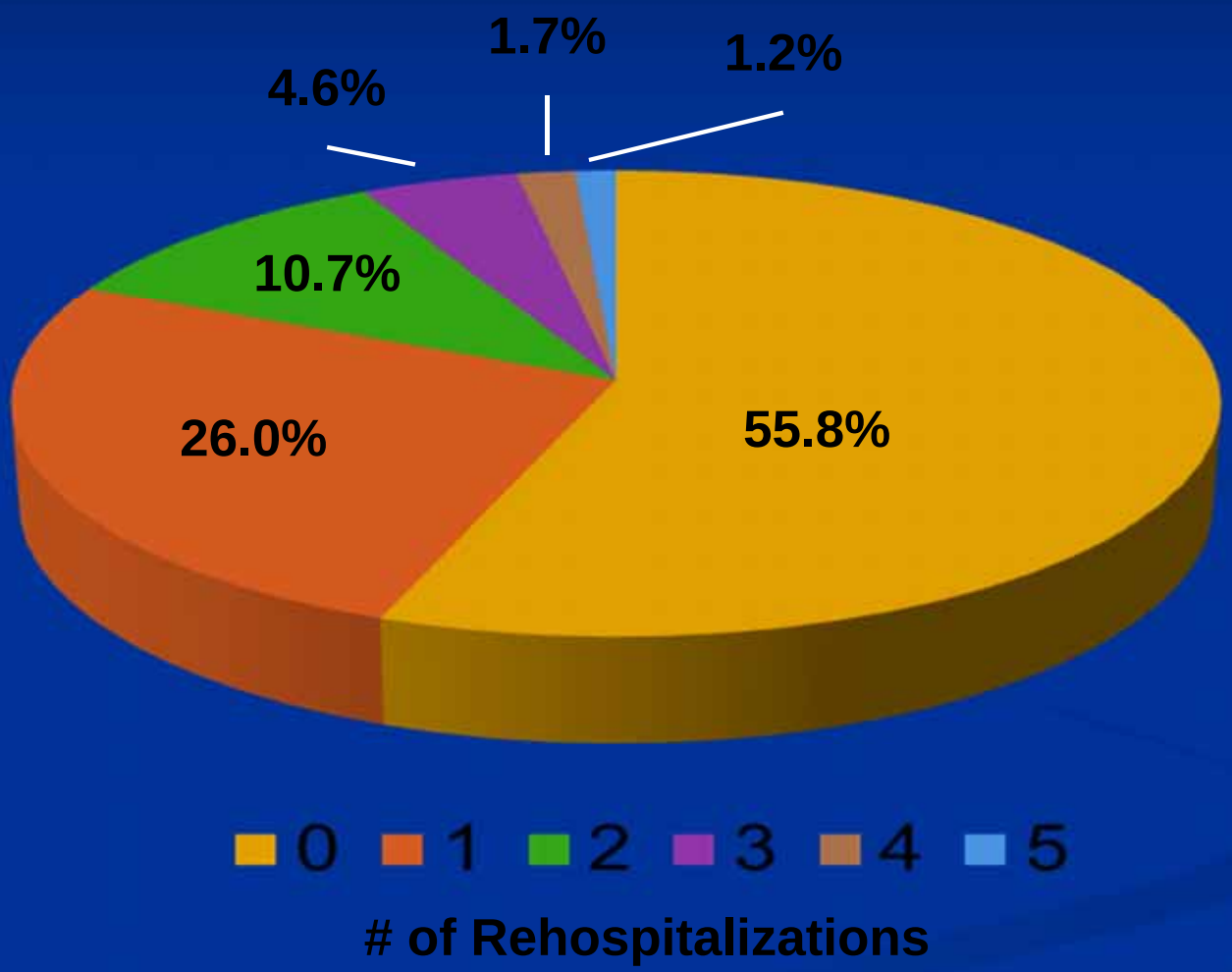
# One Year Rehospitalisation



# TAVR
## 1 Year Outcomes

| | Centers N | Patients N | Death % | Stroke % | Author |
|---|---|---|---|---|---|
| **TVT/CMS** | **230** | **5,980** | **26.2** | **3.6** | **TVT** |
| PARTNER B | 21 | 179 | 30.7 | 11.2 | Leon |
| PARTNER A | 25 | 348 | 24.3 | 8.7 | Smith |
| UK TAVI | 25 | 870 | 21.4 | NR | Moat |
| Canadian TAVI | 6 | 339 | 24.0 | NR | Rodes-Cabau |
| France 2 | 33 | 3,195 | 24.0 | 4.1 | Gilard |
| Belgium | 15 | 328 | 26.0 | NR | Bosmans |
| Pragmatic | 4 | 793 | 14.3 | NR | Chieffo |
| SOURCE Reg | 93 | 2,706 | 21.1 | 7.1 | Treede |

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# Summary

- ~17,000 patients entered
- 313 sites in 48 states
- Half of procedures access= TF ( Sapien only)
- Mortality
  - 30 Day Mortality ~8%
  - 1 year Mortality 26.2%
- Stroke
  - 30 Day Stroke ~3%
  - 1 year stroke 3.6%
- High risk patients for one year mortality & stroke are being identified