# Transapical and Transaortic Transcatheter Aortic Valve Replacement in the United States

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**ABSTRACT**

**Background:**

When transcatheter aortic valve replacement (TAVR) cannot be carried out via transfemoral access, alternative access TAVR is indicated. The purpose of this study was to explore in-hospital and one-year outcomes of patients undergoing alternative access TAVR via the transapical (TA) or transaortic (TAo) techniques in the U.S.

**Methods:**

Clinical records of 4,953 patients undergoing TA (n=4,085) or TAo (n=868) TAVR from 2011 to 2014 in the STS/ACC Transcatheter Valve Therapies Registry were linked to Centers for Medicare and Medicaid Services hospital claims. In-hospital and one-year clinical outcomes were stratified by operative risk and the risk-adjusted association between access route and mortality, stroke, and heart failure repeat hospitalization was explored.

**Results:**

Mean age for all patients was 82.8±6.8 years. The median STS PROM was significantly higher in those undergoing TAo (8.8 vs 7.4, $p<0.0001$). TAo, when compared to TA, was associated with an increased risk of unadjusted 30-day (10.3% vs. 8.8%) and 1-year (30.3% vs. 25.6%, $p=0.006$) mortality. There were no significant differences between TAo and TA for in-hospital stroke rate (2.2%), major vascular complications (0.3%), and 1-year heart failure re-hospitalizations (15.7%). Examination of high-risk and inoperable subgroups showed that 1-year mortality was significantly higher for TAo patients classified inoperable ($p=0.012$).

**Conclusions:**

Patients undergoing TAo TAVR are older, more female, and have significantly higher STS PROM scores than patients operated with TA access. There were no risk-adjusted differences in mortality, stroke or re-admission rates up to 1 year post TAVR between the TA and TAo access.

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## Introduction

Within the last decade, there has been a transformation of the surgical management of high- and extreme-risk patients with symptomatic, severe aortic stenosis (AS). The PARTNER (Placement of AoRTic TraNscathetER Valve) trial demonstrated superiority of transcatheter aortic valve replacement (TAVR) over medical therapy in extreme risk surgical patients and confirming the non-inferiority of TAVR to surgical aortic valve replacement (SAVR) in high risk surgical candidates[1-4]. The initial access route of choice has commonly been the transfemoral TAVR (TF-TAVR); however, in those with severe peripheral arterial disease, alternative access routes such as the transapical (TA), transaortic (TAo), transcarotid (TC), or subclavian (SC) approaches have be utilized[5].

While individual institution have reported outcomes of alternative access (AA) TAVR[6], a larger, "real world" analysis since FDA-approval for the balloon expandable valve in the US has not been reported. In this retrospective study, we report the outcomes of patients operated with the two most common alternative access TAVR routes (TA and TAo) as captured in the Society of Thoracic Surgeons (STS) / American College of Cardiology (ACC) Transcatheter Valve Therapy (TVT) Registry.

## Material and Methods

*STS/ACC Transcatheter Valve Therapy Registry*

The TVT registry and its properties have been previously described[7]. Registry activities have been approved by a central institutional review board and the Duke University Institutional Review Board granted a waiver of informed consent and authorization for this study. While not audited by a third party, data quality checks for the TVT registry were implemented both at the National Cardiovascular Data Registry data warehouse and the Duke Clinical Research Institute Analysis Center, including data quality feedback reports as well as data range and consistency

checks. For details of the organization and structure of the registry, the reader is referred to the previous report from TVTR[7].

In an analysis of the TVT registry from November 2011 to June 2014, 18,100 TAVR procedures were performed. During this period, alternative access TAVR was performed in 7,384 (40.8%) patients. For purposes of reporting one-year outcomes, the TVT registry was linked to Centers for Medicare and Medicaid Services (CMS) claims data (67% linkage rate) using direct patient identifiers to evaluate longitudinal patient outcomes, including re-hospitalizations and survival. Only patients of the TVT Registry who had these confirmed follow-up data (n=4,953; TA: n=4,085 and TAo: n=868) were included in the present study. The main reason for missing CMS-linked follow-up data was that the TVTR patient was not covered by Medicare during their TAVR hospital admission.

*Data Element Definitions – TVT Registry*

Data elements were collected using standardized definitions harmonized with the STS National Database wherever possible. The clinical indication for TAVR (inoperable or high-risk status) was based on determination by 2 experienced local cardiac surgeons and was classified by the local heart team. Patients were considered inoperable if combined risk of death and irreversible severe morbidity was prohibitive for SAVR or if technical issues precluded surgery. Furthermore, for the purposes of this analyses patients were classified according to their STS PROM score into three categories: 1) STS PROM <8%, 2) STS PROM 8-15%, or 3) STS PROM >15%.

Both in-hospital, 30-day, 6-month and 1-year outcomes were site-reported to the TVT Registry using standardized definitions, including harmonization with Valve Academic Research Consortium (VARC) and VARC-2 definitions for stroke, transient ischemic attack (TIA), aortic valve re-intervention, major bleeding, and major vascular complications[8,9]. All site-reported stroke, TIA, and valve re-intervention events were adjudicated by a board-certified cardiologist using a combination of site-reported clinical information and targeted chart reviews.

*Centers for Medicare and Medicaid Services*

The primary endpoint was all-cause mortality and was identified with the Medicare denominator file. Secondary endpoints were identified with primary hospital diagnosis International Classification of Diseases, Ninth Revision, Clinical Modification codes and included re-hospitalization for cerebrovascular accident (433.x1, 434.x1, 997.02, 436, 437.1, 437.9, 430, 431, 432.x), heart failure hospitalization (398.x, 402.x1, 404.x1, 404.x3, 428.x), and aortic valve re-intervention (35.11, 35.21, 35.22, 35.01, 35.05, 35.06, 35.09).

*Procedural details*

The patients in this cohort were operated with the first generation balloon expandable SAPIEN valve (Edwards Lifesciences, Irvine, CA), which at the time of study enrollment was the only commercially available transcatheter valve.

*Statistical Analysis*

Patients in the CMS-linked cohort (n=4,953) were stratified based on surgical risk (high risk or inoperable/prohibitive risk). Baseline characteristics and hospital outcomes were compared. Continuous variables were compared using the Wilcoxon rank-sum test, while categorical variables were compared using the Pearson Chi-square test. Cox proportional hazards regression modeling was performed in order to determine the association of technique with 1-year mortality. Variables included in the Cox model were selected based on clinical merit, including age, sex, renal failure, ejection fraction, prior aortic valve procedure, primary procedure indication, valve morphology, and atrial fibrillation/flutter. Overall missingness of these covariates was very low (<1% for most variables) and imputation to the most common category was used in these cases. Missingness of ejection fraction was 2.7% and missing data were imputed to median value of the population. Patients were classified into different risk groups according to their STS predicted risk of mortality (<8%, 8-15%, >=15%). The interaction between the access site and risk groups is also taken into account in the Cox models.

All analyses were performed using SAS version 9.3 (SAS Institute, Inc., Cary, NC 2010). A p-value of 0.05 was used to determine statistical significance.

## Results

*Preoperative characteristics*

Preoperative demographics of the study cohort are displayed in Table 1. The TAo cohort was slightly older, had higher STS PROM scores, included more females and a higher proportion of patients with chronic obstructive pulmonary disease (COPD) and a low left ventricular ejection fraction (LVEF<30%). The prevalence of concomitant preoperative moderate or severe mitral regurgitation (MR) was also higher in the TAo cohort. Parameters of subjective functional status such as the 12-question Kansas City Cardiomyopathy Questionnaire short form (KCCQ-12) score, as well as variables associated with frailty such hemoglobin and albumin levels were marginally lower in the TAo group. The TA group included more patients who had previously undergone coronary artery bypass grafting, while the incidence of previous aortic valve surgery was similar in both groups.

*Operative characteristics*

Operative characteristics are summarized in Table 2. Briefly, the TAo group had more urgent procedures, marginally longer procedure and fluoroscopy times, more conversions to an open procedure, and slightly more blood transfusions. The TA patients experienced more frequent need for unplanned cardiopulmonary bypass (CPB) and marginally greater volume of contrast agent.

*In-Hospital Outcomes*

The rate of observed in-hospital mortality was 7.0% in the entire study cohort and was similar between groups (Table 3). There were no differences between the access groups in terms of stroke, vascular complications, or renal failure. Transaortic patients had slightly longer hospital stays and were more likely to need a rehabilitative setting after discharge as opposed to TA patients who were mostly discharged directly to home.

Discharge TTE was available for 2,081 patients (42%). At discharge, 5.8% of the entire cohort had moderate/severe paravalvular aortic insufficiency with no difference between TA and TAo.

*Thirty-Day and One-Year Outcomes*

The TAo approach was associated with an increased 30-day (10.3% vs. 8.8%), 6-month (22.8% vs 19.7%) and 1-year (30.3% vs. 25.6%) mortality compared to the TA approach (p=0.006) in unadjusted analyses (Figure 1). There were no differences between the access groups in terms of the unadjusted incidences of re-hospitalization for either stroke or re-hospitalization for heart failure (Figure 1). The overall stroke rate was 2.4% at 30 days (TA: 2.4% and TAo: 2.6%), 3.4% at 6 months (TA: 3.4% and TAo: 4.0%) and 3.9% at 1 year (3.9% for both TA and TAo, p=0.825). The rate of re-hospitalization for heart failure was 5.4% at 30 days (TA: 5.4% and TAo: 5.5%), 12.9% at 6 months (TA: 13.4% and TAo: 10.4%) and 14.7% at 1 year (TA: 16.1% and TAo: 14.0%, p=0.141).

The adjusted analysis of 1-year death, stroke, and heart-failure re-hospitalization is displayed in Table 4. The higher mortality in the TAo cohort remained significant in inoperable patients in adjusted analysis (p=0.012), no other differences were seen between the two access groups.

A further adjusted analysis was performed comparing TA versus TAo categorizing patients into three groups as defined by the STS PROM (Figures 2A, 2B, and 2C). While there was no mortality difference between TAo and TA in the first two categories (STS PROM >8 and STS PROM 8-15%) up to one year, there was a trend towards higher unadjusted mortality in TAo patients with STS PROM >15% at 30 days (20.3% vs 13.5%), 6 months (38.7% vs. 34.1%), and 1 year (47.2% vs. 42.3%, p=0.08). There was no difference in stroke between groups in any STS PROM category. TA patients in only the category STS PROM <8% were more frequently re-hospitalized for heart failure than their TAo counterparts (4.2% vs. 2.6% at 30 days, 10.2% vs. 5.6% at 6 months and 12.7% vs. 8.5% at 1 year, p=0.013).

*Analyses based on operative risk classification*

In the study cohort, 992 (20.0%) patients were classified as high-risk, 3,762 (76.0%) inoperable, and 199 (4%) were missing a classification. The analysis of in-hospital outcomes stratified by high risk versus inoperable classification for the CMS linked study cohort is found

in Appendix 1, Tables A1.1-A1.3. Although there was no difference in short term mortality between TA and TAo in the high-risk group, there was a significantly higher unadjusted mortality in TAo inoperable patients compared to TA (8.9% vs. 6.3%, p=0.019).

Furthermore, the preoperative characteristics and in-hospital outcomes of the full TVT registry cohort, with or without CMS linkage (overall 7,384 patients; 6,108 TA and 1,276 TAo) are summarized in Appendix 2, Tables A2.1-A2.3.

## Comment

Our data show that TA and TAo TAVR were performed with good results in the United States after FDA approval of the balloon-expandable transcatheter valve system. Mortality rate of this 4,953-patient alternative access TAVR cohort was 9.1% at 30 days and 26.3% at 1 year. Vascular complications occurred in 0.3% of patients, stroke affected 2.4% of the cohort and acute kidney injury complicated the postoperative course in 39% of patients. The TAo cohort was inherently of higher risk and in unadjusted analyses demonstrated increased rates of mortality throughout the first postoperative year compared to the TA group. In adjusted analysis only the subgroup of patients deemed inoperable for SAVR or those at an extreme operative risk had significantly higher mortality in the TAo group when compared to TA access.

### *Mortality*

Traditionally AA-TAVR has had higher mortality than TF-TAVR and most clinicians agree that alternative access patients tend to be a higher risk population. In the previous report from the TVT registry, 30 day mortality for inoperable patients was 6.7% in the TF group and 12.6% if AA-TAVR was undertaken; the same figures for the high-risk patients were 5.0% (TF-TAVR) vs 10.8% (AA-TAVR)[7]. Modern all cause 30-day mortality rates for TF-TAVR have been reported to be 1.7-17.5%[10], whereas the same range is reported to be 5.7% - 17.5% for TA-TAVR[11-13] and 7.4% - 14% for TAo TAVR[14-16]. Outcomes between patients operated with the TA or TAo have been comparable in previous series[14,16]; however, a recent report suggested a

survival advantage in TAo compared to TA at 1 year (mortality 18% vs. 34%) in a propensity matched analysis[17].

Our findings are well in line with previous reports of mortality associated with alternative access. The higher mortality observed in the TAo cohort was mostly related to the higher risk profile of patients in this group, although an effect of a learning curve with this technique, which is newer than the TA approach, cannot be ruled out.

*Stroke*

Some studies suggest that AA-TAVR could have a lower neurologic risk profile due to its avoidance of the often heavily calcified aortic arch [18-20], but this has not been validated in larger prospective series [21-23]. Small series have been reported no postoperative strokes associated with TA or TAo[14,24]. The stroke rate reported in this study (2.3%) reflects that of the landmark PARTNER trial (3.8-5.0%) and previously published data from the TVT registry (1.9-2.2% for TF and 1.6-3.3% for AA TAVR)[1,2,7]. No apparent differences were observed between TA and TAo in terms of strokes.

*Paravalvular leaks*

Paravalvular leak (PVL) may be an independent predictor of mortality, with increased morbidity and mortality in patients with greater than mild PVL[4, 25, 26]. In the PARTNER trial, moderate or severe paravalvular aortic regurgitation was apparent in 11.8% of inoperative patients and 12.2% of high-risk patients[1,2]. These results are all consistent with a recent review where PVL rate was reported at 3-21% [26]. Thus far published evidence does not indicate that non-TF approaches have rates of PVL significantly different from the TF approach [27, 28]. Current study cohort demonstrated greater than mild site reported paravalvular leak rate of 5.8% at discharge without apparent differences between access routes, results that are similar if not favorable compared to previously published data.

*Limitations*

This retrospective study was not designed or powered to compare AA-TAVR to TF-TAVR, rather to describe the outcomes in the AA-TAVR cohort. The study is limited by

potential selection bias and a lack of randomization. Whilst data completeness was good overall, certain parameters such as discharge echocardiography had a high level of missing values (up to 60%). The 30-day and 1-year outcomes are limited to a subset of centers and patients for whom CMS-linked data was available. There has been limited capture of patient functional status follow-up data in the TVT Registry, which has precluded the postoperative analysis of quality-of-life and frailty parameters. Furthermore, institutional protocols may vary depending on operator and team preferences and heterogeneity in this study cohort based on institutional variation is inevitable.

While the outcomes in the TVT registry were adjudicated, stroke and heart failure from the CMS follow-up data were not. However, numerous studies have examined the sensitivity, specificity, positive and negative predictive values of CMS-based claims for stroke with reassuring outcomes[29,30], and some studies have even indicated that CMS claims compared favorably to neurologist adjudicated events[31].

*Conclusion*

The current series provides outcomes data for the largest study to date on alternative access TAVR, which represents approximately 40% of all TAVR procedures since United States FDA approval. Patients undergoing TAo TAVR are older, more female, and have significantly higher STS PROM scores than patients operated with TA access. Conversion to open surgery and blood transfusion rates are higher in TAo patients. There were no risk-adjusted differences in mortality, stroke, or re-admission rates up to 1 year post TAVR between the TA and TAo access. In subgroup analysis, 1-year risk-adjusted mortality was higher in TAo patients who were considered inoperable for SAVR due to technical issues or prohibitive risk. Further prospective studies are required to better tailor the most appropriate AA algorithm for non-TF TAVR candidates.

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**Table 1. Preoperative characteristics**

| Patient Characteristics | All (N=4,953) | Transapical (N=4,085) | Transaortic (N=868) | P value |
|---|---|---|---|---|
| Age, mean ± SD | 82.8 ± 6.8 | 82.6 ± 6.8 | 83.6 ± 6.8 | <.001 |
| Female, n (%) | 2,895 (58.5) | 2,301 (56.4) | 594 (68.4) | <.001 |
| STS Prom Score (Median, IQR) | 7.6 (5.1,11.5) | 7.4 (5.0,11.1) | 8.8 (5.8,13.0) | <.001 |
| Body surface area [Mean±SD] | 1.8 ± 0.2 | 1.8 ± 0.2 | 1.7 ± 0.2 | <.001 |
| Hemoglobin (g/L) [Mean±SD] | 11.7 ± 2.0 | 11.7 ± 2.1 | 11.5 ± 1.7 | 0.002 |
| Albumin (g/dL) [Mean±SD] | 3.7 ± 0.5 | 3.7 ± 0.5 | 3.6 ± 0.5 | 0.082 |
| **History of:** | | | | |
| Coronary artery disease [n (%)] | 1,434 (29.0) | 1,206 (29.5) | 228 (26.3) | 0.055 |
| Prior MI [n (%)] | 1,429 (28.9) | 1,202 (29.4) | 227 (26.2) | 0.053 |
| Prior PCI [n (%)] | 1,898 (38.3) | 1,588 (38.9) | 310 (35.7) | 0.082 |
| Prior CABG [n (%)] | 1,765 (35.6) | 1,588 (38.9) | 177 (20.4) | <.001 |
| Previous aortic valve surgery [n (%)] | 789 (15.9) | 650 (15.9) | 139 (16.0) | 0.941 |
| Chronic lung disease, mod/severe [n (%)] | 1,430 (28.9) | 1,117 (27.3) | 313 (36.1) | <.001 |
| Prior stroke [n (%)] | 635 (12.8) | 534 (13.1) | 101 (11.6) | 0.250 |
| Renal Dialysis, n (%) | 185 (3.7) | 153 (3.8) | 32 (3.7) | 0.518 |
| Peripheral artery disease [n (%)] | 2,224 (44.9) | 1,851 (45.3) | 373 (43.0) | 0.208 |
| Permanent pacemaker [n (%)] | 839 (16.9) | 695 (17.0) | 144 (16.6) | 0.763 |
| Diabetes [n (%)] | 1,701 (34.3) | 1,410 (34.5) | 291 (33.5) | 0.577 |
| LVEF <30% [n (%)] | 301 (6.2) | 228 (5.7) | 73 (8.6) | 0.002 |
| KCCQ –SCORE | | | | |
| Performed | 3,604 (72.8) | 2,950 (72.2) | 654 (75.3) | 0.060 |
| [Mean±SD] | 40.8 ± 23.0 | 41.2 ± 22.9 | 38.8 ± 23.6 | 0.016 |
| [Median (IQR)] | 37.5 (22.9,56.9) | 38.0 (24.0,57.3) | 35.4 (20.3,55.2) | 0.016 |
| LV Ejection fraction [Mean+SD] | 54.1 ± 13.4 | 54.2 ± 13.3 | 53.6 ± 14.1 | 0.670 |
| AV Peak Velocity (m/s) [Mean+SD] | 4.16 ± 0.75 | 4.16 ± 0.74 | 4.19 ± 0.77 | 0.142 |
| AV Mean Gradient (mmHg) [Mean+SD] | 44.9 ± 15.2 | 44.7 ± 15.1 | 45.4 ± 15.3 | 0.125 |
| AV Regurgitation mod / severe [n (%)] | 1,017 (20.5) | 847 (20.7) | 170 (19.6) | 0.447 |
| MR moderate / severe [n (%)] | 1,531 (30.9) | 1,236 (30.3) | 295 (34.0) | 0.031 |
| TR moderate / severe [n (%)] | 1,224 (24.7) | 989 (24.2) | 235 (27.1) | 0.076 |

## Table 2. Operative characteristics

| Patient Characteristics | All (N=4,953) | Transapical (N=4,085) | Transaortic (N=868) | p Value |
|---|---|---|---|---|
| Procedure status | | | | <.001 |
| Salvage [n (%)] | 1 (0.0) | 1 (0.0) | 0 (0) | |
| Emergent [n (%)] | 3 (0.1) | 1 (0.0) | 2 (0.2) | |
| Urgent [n (%)] | 522 (10.5) | 402 (9.8) | 120 (13.8) | |
| Elective [n (%)] | 4,422 (89.3) | 3,677 (90.0) | 745 (85.8) | |
| Total procedure time [hour, mean±SD] | 2.4 ± 1.2 | 2.4 ± 1.2 | 2.5 ± 1.2 | <.001 |
| Death during procedure [n (%)] | 48 (0.97) | 40 (0.98) | 8 (0.92) | 0.515 |
| Procedure aborted [n (%)] | 30 (0.6) | 25 (0.6) | 5 (0.6) | 0.901 |
| CPB used [n (%)] | 314 (6.3) | 273 (6.7) | 41 (4.7) | 0.031 |
| Conversion to open heart surgery [n (%)] | 74 (1.5) | 50 (1.2) | 24 (2.8) | <.001 |
| PRBC use [n (%)] | 2,584 (52.2) | 2,073 (50.7) | 511 (58.9) | <.001 |
| PRBC units transfused [Mean±SD] | 0.5 ± 0.5 | 0.5 ± 0.5 | 0.6 ± 0.5 | <.001 |
| Fluoroscopy time[Mean±SD] | 14.2 ± 9.7 | 13.5 ± 9.2 | 17.2 ± 11.3 | <.001 |
| Contrast volume[Mean±SD] | 104.5 ± 70.7 | 105.3 ± 70.2 | 100.6 ± 73.2 | 0.010 |

**Table 3. In-hospital outcomes**

| | Overall | | | |
|---|---|---|---|---|
| **Patient Characteristics** | **All (N=4,953)** | **Transapical (N=4,085)** | **Transaortic (N=868)** | **p Value** |
| In-hospital mortality [n (%)] | 347 (7.0) | 277 (6.8) | 70 (8.1) | 0.178 |
| MI [n (%)] | 40 (0.8) | 37 (0.9) | 3 (0.3) | 0.094 |
| Stroke [n (%)] | 108 (2.2) | 86 (2.1) | 22 (2.5) | 0.433 |
| Ischemic Stroke | 95 (1.9) | 75 (1.8) | 20 (2.3) | 0.362 |
| Hemorrhagic Stroke | 3 (0.1) | 3 (0.1) | | 0.424 |
| Undetermined Stroke | 10 (0.2) | 8 (0.2) | 2 (0.2) | 0.837 |
| MACCE (death/stroke/MI) [n (%)] | 455 (9.2) | 364 (8.9) | 91 (10.5) | 0.145 |
| Minor vascular complication [n (%)] | 16 (0.3) | 14 (0.3) | 2 (0.2) | 0.596 |
| Major vascular complication [n (%)] | 17 (0.3) | 14 (0.3) | 3 (0.3) | 0.990 |
| Multiple transcatheter valves used [n (%)] | 372 (7.5) | 299 (7.3) | 73 (8.4) | 0.268 |
| Acute renal failure [n (%)] | 1,931 (39.0) | 1,587 (38.8) | 344 (39.6) | 0.668 |
| New Dialysis [n (%)] | 124 (2.5) | 100 (2.5) | 24 (2.8) | 0.588 |
| Postop ICU stay (days), mean ± SD | 98.5 ± 140.8 | 98.1 ± 142.4 | 100.6 ± 133.3 | 0.555 |
| Postop LOS (days), mean ± SD | 8.5 ± 6.6 | 8.5 ± 6.6 | 8.9 ± 6.4 | <.001 |
| O/E mortality ratio | 0.759 | 0.756 | 0.771 | 0.177 |
| Where discharged (among survivors) | | | | |
| Home [n (%)] | 2,292 (49.8) | 1,943 (51.0) | 349 (43.7) | <.001 |
| Other acute care hospital [n (%)] | 44 (1.0) | 33 (0.9) | 11 (1.4) | 0.177 |
| Moderate/severe paravalvular leak [n (%)] | 121 (5.8) | 93 (5.6) | 28 (6.7) | 0.364 |

**Table 4. One-year outcomes, unadjusted and adjusted analysis**

| | | *Unadjusted* | | | | *Adjusted* | | | |
|---|---|---|---|---|---|---|---|---|---|
| *Outcome* | *Comparing* | *H.R.* | *95% Lower Limit* | *95% Upper Limit* | *P Value* | *H.R.* | *95% Lower Limit* | *95% Upper Limit* | *P Value* |
| Death in 1 year | Interaction | | | | 0.032 | | | | 0.065 |
| | TA vs. TAo at Operable with Risk<8% | 0.877 | 0.666 | 1.154 | 0.347 | 0.882 | 0.669 | 1.164 | 0.376 |
| | TA vs. TAo at Operable with Risk>=8% and <15% | 1.097 | 0.856 | 1.406 | 0.466 | 1.139 | 0.883 | 1.471 | 0.317 |
| | TA vs. TAo at Operable with Risk>=15% | 0.895 | 0.662 | 1.209 | 0.469 | 0.914 | 0.673 | 1.243 | 0.567 |
| | TA vs. TAo at Inoperable | 0.537 | 0.360 | 0.802 | 0.002 | 0.594 | 0.395 | 0.893 | 0.012 |
| HF in 1 year | Interaction | | | | 0.792 | | | | 0.899 |
| | TA vs. TAo at Operable with Risk<8% | 1.428 | 0.952 | 2.141 | 0.085 | 1.406 | 0.936 | 2.112 | 0.100 |
| | TA vs. TAo at Operable with Risk>=8% and <15% | 1.311 | 0.939 | 1.830 | 0.112 | 1.380 | 0.979 | 1.943 | 0.066 |
| | TA vs. TAo at Operable with Risk>=15% | 1.120 | 0.729 | 1.721 | 0.605 | 1.157 | 0.752 | 1.780 | 0.507 |
| | TA vs. TAo at Inoperable | 1.058 | 0.584 | 1.918 | 0.852 | 1.210 | 0.653 | 2.242 | 0.545 |
| Stroke in 1 year | Interaction | | | | 0.821 | | | | 0.804 |
| | TA vs. TAo at Operable with Risk<8% | 1.168 | 0.603 | 2.262 | 0.646 | 1.248 | 0.644 | 2.421 | 0.511 |
| | TA vs. TAo at Operable with Risk>=8% and <15% | 1.038 | 0.554 | 1.945 | 0.906 | 1.157 | 0.616 | 2.173 | 0.650 |
| | TA vs. TAo at Operable with Risk>=15% | 0.730 | 0.260 | 2.048 | 0.550 | 0.782 | 0.278 | 2.197 | 0.641 |
| | TA vs. TAo at Inoperable | 0.741 | 0.273 | 2.009 | 0.556 | 0.785 | 0.289 | 2.135 | 0.636 |

## FIGURE LEGENDS

Figure 1. Cumulative incidence plot for mortality, stroke and heart failure within the first postoperative year

Figure 2 A. One-year mortality, stroke and heart failure for patients with STS PROM < 8%

Figure 2 B. One-year mortality, stroke and heart failure for patients with STS PROM 8-15%

Figure 2 C. One-year mortality, stroke and heart failure for patients with STS PROM >15%

# Figures

Figure 1

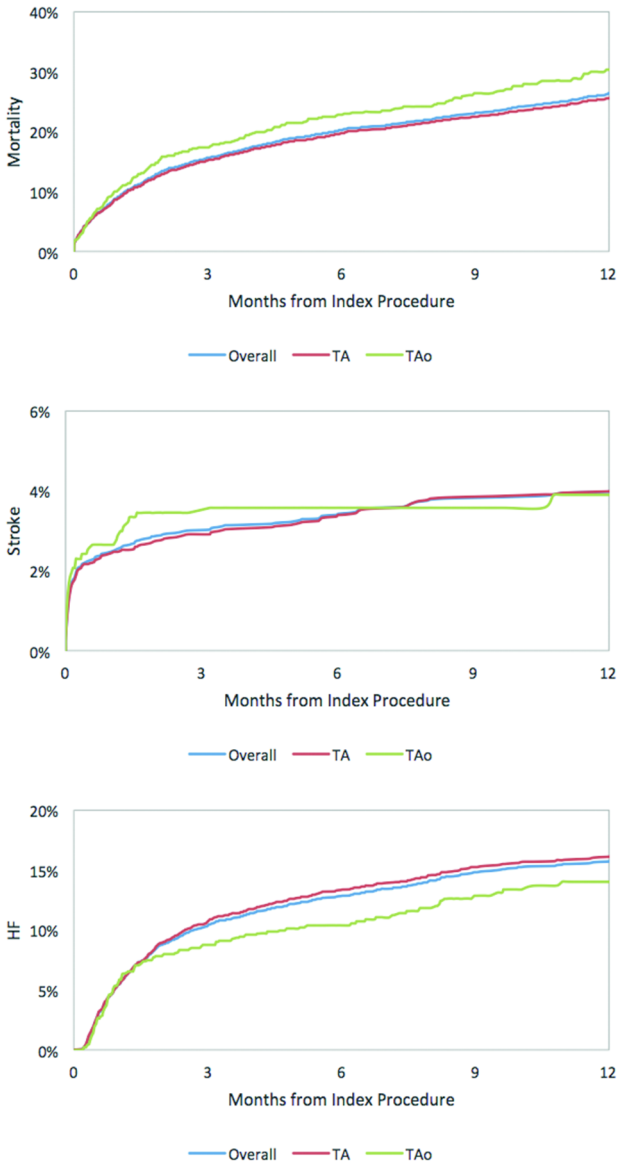


Figure 2A


STSPROM<8%
Mortality
50%
40%
30%
20%
10%
0%
0
3
6
9
12
Months from Index Procedure
Overall
TA
TAo
STSPROM<8%
Stroke
6%
4%
2%
0%
0
3
6
9
12
Months from Index Procedure
Overall
TA
TAo
STSPROM<8%
HF
20%
15%
10%
5%
0%
0
3
6
9
12
Months from Index Procedure
Overall
TA
TAo

Figure 2B

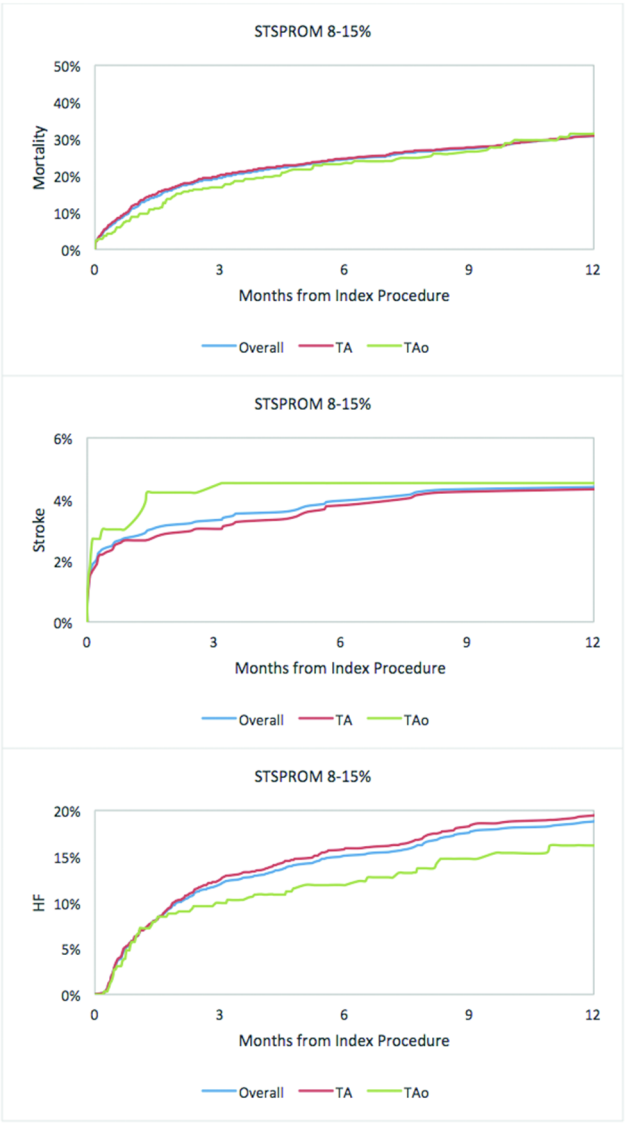
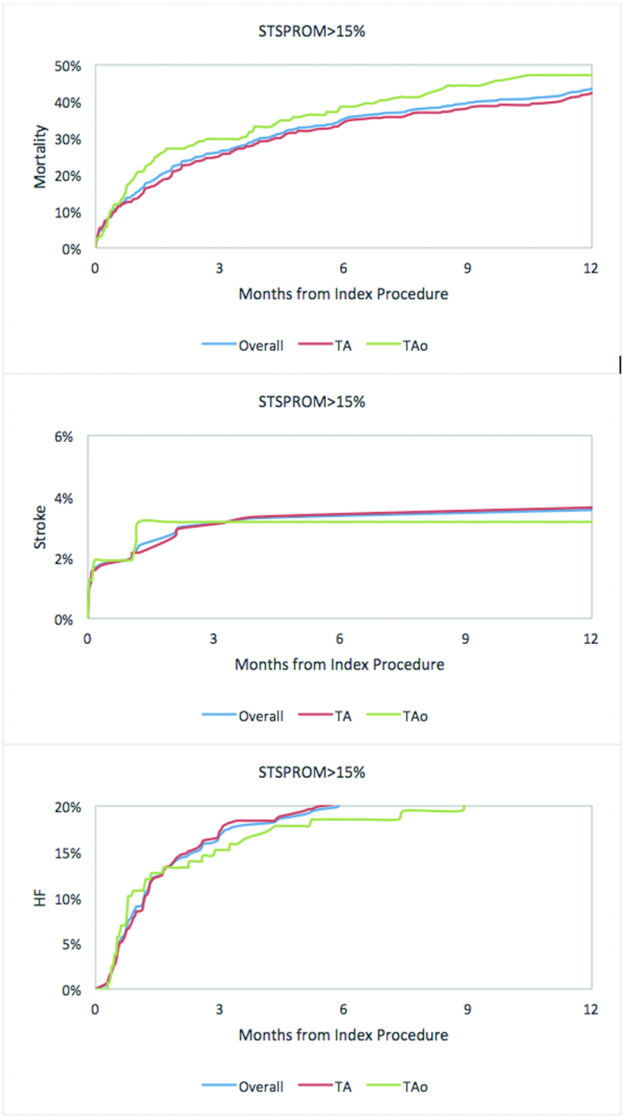

STSPROM 8-15%
Mortality
50%
40%
30%
20%
10%
0%
0
3
6
9
12
Months from Index Procedure
Overall
TA
TAo
STSPROM 8-15%
Stroke
6%
4%
2%
0%
0
3
6
9
12
Months from Index Procedure
Overall
TA
TAo
STSPROM 8-15%
HF
20%
15%
10%
5%
0%
0
3
6
9
12
Months from Index Procedure
Overall
TA
TAo

Figure 2C


STSPROM>15%
Mortality
50%
40%
30%
20%
10%
0%
0
3
6
9
12
Months from Index Procedure
Overall
TA
TAo
STSPROM>15%
Stroke
6%
4%
2%
0%
0
3
6
9
12
Months from Index Procedure
Overall
TA
TAo
STSPROM>15%
HF
20%
15%
10%
5%
0%
0
3
6
9
12
Months from Index Procedure
Overall
TA
TAo