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Outcomes After Transfemoral Transcatheter Aortic Valve Replacement

A Comparison of the Randomized PARTNER (Placement of AoRTic TraNscathetER Valves) Trial With the NRCA (Nonrandomized Continued Access) Registry

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ABSTRACT

OBJECTIVES This study sought to determine whether outcomes for transfemoral (TF) transcatheter aortic valve replacement (TAVR) differ between the randomized controlled trial (RCT) and the subsequent NRCA (Nonrandomized Continued Access) registry of the PARTNER (Placement of AoRTic TraNscathetER Valves) trial.

BACKGROUND The PARTNER RCT demonstrated that TAVR with the Edwards Sapien valve (Edwards Lifesciences, Irvine, California) is noninferior to surgery in high-risk patients and superior to standard therapy for inoperable patients.

METHODS The inclusion and exclusion criteria, data collection, monitoring, and core laboratories were the same for the RCT and NRCA registry. Baseline characteristics, procedural results, and 1-year outcomes were compared between patients undergoing TF-TAVR as part of the RCT and as part of the NRCA registry.

RESULTS In the RCT, 415 patients underwent TF-TAVR, whereas in the NRCA, 1,023 patients did. At 30 days, death, cardiac death, stroke, and transient ischemic attacks were not different in the NRCA registry than in the RCT. Major vascular complications (8.0% vs. 15.7%, $p < 0.0001$) and major bleeding (6.8% vs. 15.3%, $p < 0.0001$) were significantly lower in the NRCA registry. At 1 year, death rates were significantly lower in the NRCA cohort (19.0% vs. 25.3%, $p = 0.009$) and cardiac death tended to be lower (8.4% vs. 11.1%, $p = 0.12$). Stroke or transient ischemic attack (6.2% vs. 8.7%, $p = 0.10$) and stroke alone (5.0% vs. 7.1%, $p = 0.13$) also tended to be lower.

CONCLUSIONS The large NRCA registry demonstrates further improvement in procedural and longer-term outcomes after TF-TAVR when compared with the favorable results from the PARTNER RCT. (THE PARTNER TRIAL: Placement of AoRTic TraNscathetER Valve Trial; NCT00530894) (J Am Coll Cardiol Intv 2014;7:1245–51) © 2014 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

RCT = randomized control trial

STS = Society of Thoracic Surgery

TAVR = transcatheter aortic valve replacement

TF = transfemoral

The PARTNER (Placement of AoRTic TraNscathetER Valves) randomized controlled trial (RCT) demonstrated that transcatheter aortic valve replacement (TAVR) is superior to medical therapy in inoperable patients with severe, symptomatic aortic stenosis (PARTNER 1B) and noninferior to surgical aortic valve replacement in patients who are at high risk for complications with traditional surgery (PARTNER 1A) (1-4). The PARTNER trial represented the first experience with TAVR for most of the participating investigators, primarily using an early generation delivery system from the transfemoral (TF) approach. Following completion of the randomized portions of the PARTNER trial, the U.S. Food and Drug Administration allowed the creation of the NRCA (Nonrandomized

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Continued Access) registry, which includes >1,000 patients with a newer generation TF delivery system and with greater availability to a transapical approach. The objective of this study is to determine whether outcomes differ between the RCT and the subsequent NRCA registry in patients who underwent TF-TAVR.

METHODS

PATIENT POPULATION. Patients included in the RCT and NRCA registry were those with severe, symptomatic aortic stenosis who were either high-risk candidates for surgical aortic valve replacement or inoperable. The inclusion and exclusion criteria have been reported previously (1,2). Briefly, patients had to have severe aortic stenosis, defined as an aortic valve area <0.8 cm^2, plus either a mean gradient across the aortic valve ≥40 mm Hg or a peak velocity across the valve of ≥4 m/s on the basis of echocardiographic evaluation, and with symptoms consistent with New York Heart Association Functional classification ≥II. The definition of high risk was on the basis of a Society of Thoracic Surgery (STS) predicted operative mortality ≥8% and/or an estimated risk of death >15% at 30 days as assessed by the participating site's cardiac surgeons (5,6). Inoperability was on the basis of a >50% predicted risk of death or serious irreversible condition at 30 days after surgery as assessed by the participating site's cardiac surgeons. Every case was presented on a web-based conference call in order to receive approval by the executive committee of the study. Major exclusion criteria were a bicuspid aortic valve, coronary disease requiring revascularization, percutaneous coronary intervention within the past month, left ventricular ejection fraction <20%, or severe mitral regurgitation.

STUDY DEVICE AND PROCEDURE. The TF-TAVR procedure has been previously described (7). In the randomized trial and the NRCA registry, a 22-F sheath was inserted for a 23-mm Edwards Sapien valve (Edwards Lifesciences, Irvine, California) and a 24-F sheath for a 26-mm valve. In the majority (>85%) of patients in the randomized trial, the valve was delivered with the RetroFlex 1 or 2 delivery systems (Edwards Lifesciences), whereas in the NRCA registry, the RetroFlex 3 delivery system was used for all patients (8,9). The RetroFlex 3 system allowed for easier crossing of the native valve due to changes in the nose cone of the delivery system and for more predictable deployment, with less movement of the valve during balloon inflation. Patients received aspirin indefinitely and clopidogrel for 6 months following the procedure.

STUDY DESIGN. Details regarding the study design have been reported previously (1,2). The PARTNER 1B trial randomized inoperable patients to either TF-TAVR or medical therapy. The PARTNER 1A trial randomized high-risk patients with adequate femoral access to either TF-TAVR or open surgical aortic

Boston Scientific Corporation, Edwards Lifesciences, Medtronic, Siemens, St. Jude Medical, and W. L. Gore and Associates; and is a consultant for Edwards Lifesciences, St. Jude Medical, and Siemens. Dr. Brown has received grants from Edwards Lifesciences, Medtronic, and St. Jude Medical; and owns equity in The Heart Hospital Baylor Plano and TRG Healthcare. Dr. Mack has received travel reimbursements from Edwards Lifesciences related to his activities as an unpaid member of the PARTNER Trial Executive Committee. Dr. Teirstein is a consultant for Abbott Vascular, Boston Scientific Corporation, and Medtronic Cardiovascular; has received research funding from Edwards Lifesciences and Medtronic; has received speaking fees from Edwards Lifesciences and Medtronic; and holds equity in Shepherd Scientific. Dr. Whisenant is a consultant for Edwards Lifesciences, Boston Scientific, and Medtronic; has received speaking fees from Edwards Lifesciences, Boston Scientific, and Medtronic; holds principal/partnership in Coherex Medical; and has received research support from Gore Medical. Dr. Makkar has received grant support from Edwards Lifesciences and St. Jude Medical; is a consultant for Abbott Vascular, Cordis, and Medtronic; and holds equity in Entourage Medical. Dr. Leon has received travel reimbursements from Edwards Lifesciences related to his activities as an unpaid member of the PARTNER Trial Executive Committee. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose. Drs. Fearon and Kodali contributed equally to this study.

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valve replacement. Those without TF access were randomized to transapical TAVR or to open surgical aortic valve replacement. The NRCA registry included patients who were either inoperable or high risk and assigned them to TF-TAVR if their access was adequate. If not, they underwent transapical TAVR. For this study, patients were followed during the index hospitalization and at 30 days, 6 months, and 1 year. All events were adjudicated by a clinical events committee. Independent core laboratories analyzed all electrocardiograms and echocardiograms (10). All patients provided written informed consent and the study was approved by the institutional review board at each participating site.

STATISTICAL ANALYSIS. Patients enrolled in the RCT who underwent TF-TAVR were compared with patients in the NRCA registry who received TF-TAVR. The analyses were performed on an as-treated basis. Continuous variables are presented as a mean ± SD and compared using the Student *t*-test. Categorical variables were compared using chi-square or Fisher exact test. Event rates are reported as Kaplan-Meier estimates and were compared with the use of the log-rank test. A 2-sided alpha level of 0.05 was used for all superiority testing. All statistical analyses were performed with the use of SAS software (version 9.2, SAS Institute, Cary, North Carolina).

RESULTS

Patients were enrolled in the RCT from 27 eligible sites between May 1, 2007, and August 1, 2009, whereas patients were enrolled in the NRCA from 27 eligible sites between September 2009 and January 2012. The study flowchart is displayed in Figure 1. Of the 519 patients undergoing TAVR in the RCT, 415 received TF-TAVR, which represented 80% of all TAVR cases. Of the 2,014 patients included in the NRCA registry, 1,039 were assigned to TF-TAVR, which represented 52% of all TAVR cases. Of the 1,039 patients assigned to TF-TAVR, 1,023 actually underwent the procedure and are included in this analysis; of the other remaining patients, they were immediately converted to a transapical approach, underwent the procedure at a later date, and/or never received a valve. Twenty-seven sites participated in both the RCT and the NRCA registry. During the RCT, the median enrollment was 8 patients per site with a mean of 15 patients per site. During the NRCA, the median enrollment was 34 patients per site with a mean of 38 patients per site.

The baseline characteristics of the 2 groups are displayed in Table 1. The NRCA group was older, but had a lower STS score and logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation). A greater percent had received a

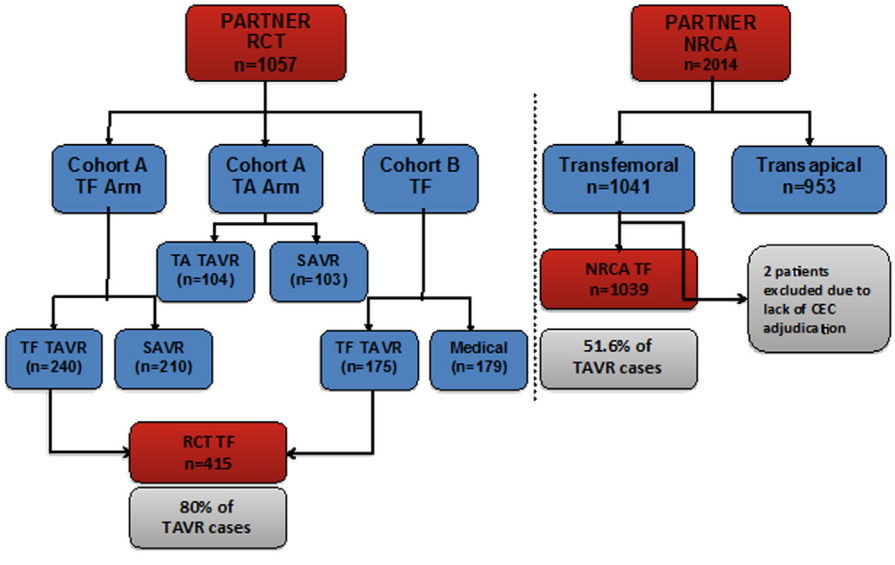

FIGURE 1 Study Flowchart

Flowchart depicting the distribution and numbers of patients in the randomized controlled trial (RCT) and the NRCA (Nonrandomized Continued Access) registry arm. CEC = Clinical Events Committee; PARTNER = Placement of Aortic Transcatheter Valve; TA = transapical; SAVR = surgical aortic valve replacement; TAVR = transcatheter aortic valve replacement; TF = transfemoral.

TABLE 1 Baseline Characteristics

	NRCA TF-TAVR (n = 1,023)	RCT TF-TAVR (n = 415)	p Value
Age, yrs	84.78 ± 7.72	83.57 ± 7.59	0.007
Male	579/1,023 (56.6)	224/415 (54.0)	0.36
Society of Thoracic Surgeons score	10.86 ± 3.73	11.58 ± 4.50	0.004
Logistic EuroSCORE	24.25 ± 15.11	28.14 ± 16.94	<0.0001
New York Heart Association functional class			
III	487/1,023 (47.6)	187/415 (45.1)	0.38
IV	494/1,023 (48.3)	203/415 (48.9)	0.83
Coronary artery disease	771/1,021 (75.5)	300/415 (72.3)	0.20
Previous myocardial infarction	234/1,013 (23.1)	97/412 (23.5)	0.86
Previous CABG	378/1,020 (37.1)	154/415 (37.1)	0.99
Previous PCI	387/1,021 (37.9)	128/413 (31.0)	0.01
Previous balloon aortic valvuloplasty	244/1,013 (24.1)	58/415 (14.0)	<0.0001
Cerebral vascular disease	210/1,006 (20.9)	104/398 (26.1)	0.03
Peripheral vascular disease	276/1,008 (27.4)	138/412 (33.5)	0.02
COPD			
Any	439/1,023 (42.9)	182/415 (43.9)	0.74
Oxygen-dependent	115/1,023 (11.2)	63/415 (15.2)	0.04
Creatinine level >2 mg/dl, or 177 μmol/l	150/1,020 (14.7)	84/414 (20.3)	0.010
Major arrhythmia	549/1,020 (53.8)	202/415 (48.7)	0.08
Permanent pacemaker	229/1,021 (22.4)	83/415 (20.0)	0.31
Pulmonary hypertension	393/1,021 (38.5)	127/303 (41.9)	0.28
Frail condition	132/1,021 (12.9)	51/301 (16.9)	0.08
Aortic-valve area, cm^2	0.66 ± 0.19	0.65 ± 0.19	0.44
Aortic-valve mean gradient, mm Hg	44.51 ± 14.46	43.68 ± 14.89	0.34
Left ventricular ejection fraction, %	52.5 ± 13.5	53.3 ± 12.8	0.45
Moderate or severe mitral regurgitation	188/973 (19.3)	64/385 (16.6)	0.25

Values are mean ± SD or n/N (%).

CABG = coronary artery bypass graft; COPD = chronic obstructive pulmonary disease; EuroSCORE = European System for Cardiac Operative Risk Evaluation; NRCA = Nonrandomized Continued Access registry; PCI = percutaneous coronary intervention; RCT = randomized controlled trial; TAVR = transcatheter aortic valve replacement; TF = transfemoral.

previous balloon aortic valvuloplasty, but fewer had cerebrovascular disease, peripheral arterial disease, renal disease, or oxygen-dependent chronic obstructive pulmonary disease. The baseline echocardiography data were similar between the 2 groups with no significant difference in the aortic valve area (0.66 ± 0.19 cm^2 vs. 0.65 ± 0.19 cm^2, $p = 0.44$), mean gradient across the aortic valve (44.5 ± 14.5 mm Hg vs. 43.7 ± 14.9 mm Hg, $p = 0.34$), or left ventricular ejection fraction (52.1 ± 13.2% vs. 52.7 ± 13.7%, $p = 0.48$) in the NRCA and RCT patients, respectively.

TABLE 2 Procedural Characteristics

	NRCA TF-TAVR (n = 1,023)	RCT TF-TAVR (n = 415)	p Value
Surgical cutdown, %	49.1	76.8	<0.0001
Total procedure time, min	117.64 ± 56.91	145.10 ± 82.37	<0.0001
Contrast use, ml	140.77 ± 162.53	141.21 ± 86.64	0.95
Post-dilation	9.4	36.7	<0.0001
Valve sizing			
23 mm, %	52.7	51.0	0.56
26 mm, %	47.2	49.0	0.54

Values are % or median ± SD.

Abbreviations as in Table 1.

The procedural differences between the 2 groups are displayed in Table 2. In the NRCA registry, fewer patients underwent surgical cutdown for arterial access (49.1% vs. 76.8%, $p < 0.0001$), fewer received balloon post-dilation after valve deployment (9.4% vs. 36.7%, $p < 0.0001$), and procedure duration was significantly shorter (117.6 ± 57.0 min vs. 145.1 ± 82.3 min, $p < 0.0001$). There was no significant difference in the rate of moderate or severe paravalvular regurgitation between the 2 cohorts (11.3% vs 10.8%, $p = 0.78$), as displayed in Figure 2.

The 30-day outcomes are displayed in Table 3. Adverse events, including death, cardiac death, stroke, and transient ischemic attacks were numerically less in the NRCA registry, but not significantly different than in the RCT. Vascular complications (8.0% vs. 15.7%, $p < 0.0001$) and major bleeding (6.8% vs. 15.3%, $p < 0.0001$) were significantly lower in the NRCA registry versus the RCT.

The 1-year outcomes are also displayed in Table 3. Death rates were significantly lower in the NRCA cohort than in the RCT (19.0% vs. 25.3%, $p = 0.009$) and cardiac death tended to be lower (8.4% vs. 11.1%, $p = 0.12$). Stroke or transient ischemic attack (6.2% vs. 8.7%, $p = 0.10$) and stroke alone (5.0% vs. 7.1%, $p = 0.13$), also tended to be lower. The Kaplan-Meier curves for death are shown in Figure 3.

DISCUSSION

The main finding in this study is that outcomes in the NRCA registry, including over 1,000 consecutive TF-TAVR patients were equivalent or superior to those of the RCT. In particular, major vascular and bleeding complications at 30 days were significantly lower in the NRCA cohort. The 1-year mortality in the NRCA group was significantly lower than in the RCT population (19.0% vs. 25.3%, $p = 0.009$), whereas rates of neurologic events trended lower.

There are a number of factors that might contribute to the improved outcomes in the NRCA group. Although this group was significantly older, fewer patients had cerebrovascular disease, peripheral arterial disease, renal disease, or oxygen-dependent chronic obstructive pulmonary disease; the mean STS and mean logistic EuroSCORE in the NRCA registry patients were significantly lower. These differences in baseline characteristics may be explained in part by improved patient selection as a result of

investigator experience and in part by increased availability of the transapical access approach in the NRCA group (11). These factors likely contributed to the dramatic reduction in vascular and bleeding complications, both of which decreased by >50%, and likely translated into the significant reduction in 1-year mortality seen in the NRCA patients (12,13).

Another important finding in this study is that with increased experience, procedural times and outcomes improved. In the RCT, the mean number of patients treated per site was only 15, whereas in the NRCA portion, it increased to 38 patients per site. In conjunction with this change, procedure time decreased by a man of 28 min per case or roughly 20%. Interestingly, the rate of post-dilation of the Sapien valve after deployment was significantly lower in the NRCA patients, yet the degree of paravalvular regurgitation was no different than that of the RCT. This finding may be explained by enhanced operator experience with valve sizing and by the increased availability of the transapical approach, resulting in less need to deploy a 23-mm valve because of femoral or iliac vessel size limitations. In addition, reports were published after completion of the RCT, suggesting higher rates of neurologic events when post-dilation was performed after TAVR, which may have affected post-dilation rates in the NRCA (14,15). Finally, changes in the delivery

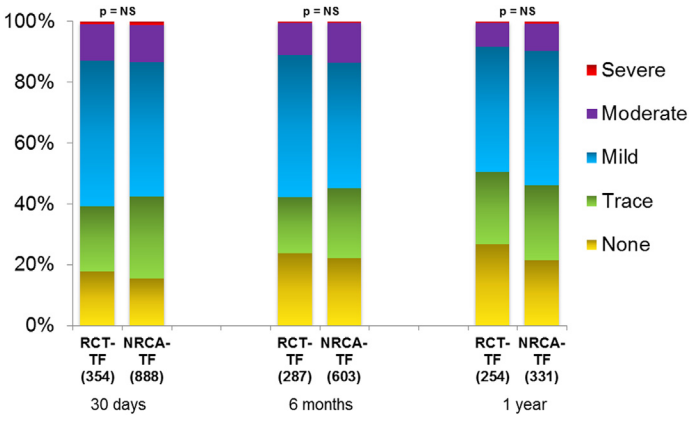

FIGURE 2 Paravalvular Regurgitation

Chart demonstrating the degree of paravalvular regurgitation at 30 days, 6 months, and 1 year in each group. NS = not significant; other abbreviations as in Figure 1.

TABLE 3 Clinical Outcomes at 30 Days and 1 Year

	30 Days			1 Year		
	NRCA TF-TAVR (n = 1,023)	RCT TF-TAVR (n = 415)	p Value	NRCA TF-TAVR (n = 1,023)	RCT TF-TAVR (n = 415)	p Value
Death						
From any cause	44 (4.3)	20 (4.8)	0.68	192 (19.0)	105 (25.3)	0.009
From cardiac causes	33 (3.2)	18 (4.3)	0.32	81 (8.4)	44 (11.1)	0.12
Repeat hospitalization	70 (7.1)	26 (6.5)	0.67	185 (19.6)	71 (18.9)	0.68
Death or repeat hospitalization	114 (11.1)	45 (10.8)	0.84	321 (31.7)	148 (35.7)	0.20
Stroke or transient ischemic attack						
Either	42 (4.2)	23 (5.6)	0.24	60 (6.2)	34 (8.7)	0.10
Transient ischemic attack	5 (0.5)	3 (0.7)	0.59	12 (1.3)	6 (1.6)	0.66
Stroke						
Minor	13 (1.3)	5 (1.2)	0.91	14 (1.4)	7 (1.8)	0.66
Major	24 (2.4)	15 (3.6)	0.20	35 (3.6)	21 (5.3)	0.14
Death from any cause or major stroke	64 (6.3)	31 (7.5)	0.41	209 (20.7)	112 (27.0)	0.009
Myocardial infarction	6 (0.6)	0 (0)	0.12	14 (1.5)	1 (0.3)	0.059
Vascular complication						
Any	160 (15.7)	115 (27.8)	<0.0001	169 (16.6)	115 (27.8)	<0.0001
Major	82 (8.0)	65 (15.7)	<0.0001	85 (8.4)	65 (15.7)	<0.0001
Renal failure—dialysis required	16 (1.6)	11 (2.7)	0.17	34 (3.6)	15 (3.7)	0.76
Hemorrhagic event						
Minor bleeding	9 (0.9)	31 (7.5)	<0.0001	12 (1.2)	36 (9.0)	<0.0001
Major bleeding	69 (6.8)	63 (15.3)	<0.0001	125 (12.9)	79 (19.6)	0.0004
Embolic event	18 (1.8)	4 (1.0)	0.26	19 (1.9)	5 (1.2)	0.38
Bradyarrhythmic event	69 (6.8)	18 (4.4)	0.08	80 (8.1)	22 (5.5)	0.09
Unplanned arterial vascular procedure	132 (12.9)	91 (21.9)	<0.0001	141 (13.9)	95 (23.1)	<0.0001

Values are n (%).
Abbreviations as in Table 1.

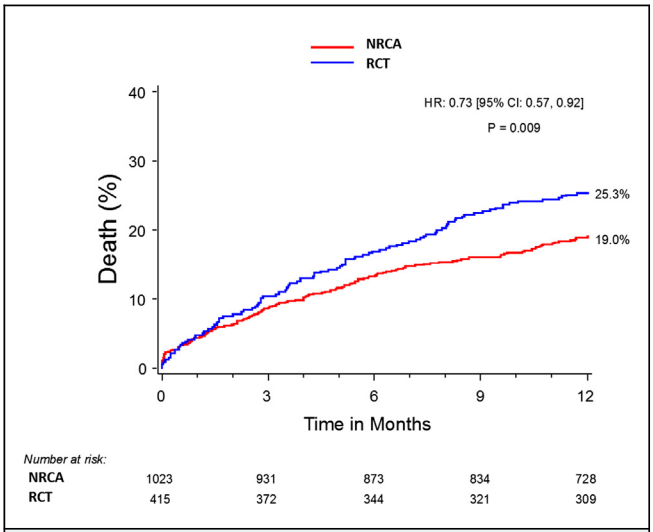

FIGURE 3 Kaplan-Meier Curves for Death

The Kaplan-Meier survival curves for each group. CI = confidence interval; HR = hazard ratio; other abbreviations as in Figure 1.

system from the RetroFlex 1 and 2 systems used in the RCT to the RetroFlex 3 system used in the NRCA may have allowed for more rapid crossing of the native valve and for more precise positioning during deployment of the valve. These differences may have affected the time of the procedure and the complication rate.

The NRCA registry represents the largest group of TF-TAVR patients in the United States with at least 1-year follow-up and the largest registry worldwide with core laboratory analyses and centralized adjudication of clinical events. The 81.1% 1-year survival in this cohort is identical to what was reported in the 463 TF-TAVR patients in the U.K. SOURCE (Sapien Aortic Bioprosthesis European Outcome) registry and similar to the 78.3% 1-year survival in the 2,361 TF-patients in the FRANCE 2 registry (16,17). The STS/ACC TVT (Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy) registry recently reported 30-day outcomes in 2,176 U.S. patients receiving TF-TAVR and found a 4.9% mortality, which is similar to our data from the NRCA registry (18). However, the median STS predicted operative mortality in the STS/ACC TVT registry was 7%, suggesting that this cohort was lower risk than that of the NRCA registry. One-year data from the STS/ACC TVT registry are not yet reported.

STUDY LIMITATIONS. Limitations include the differences in utilization of the transapical approach in the RCT and the NRCA registry and the temporal difference in enrollment in the 2 cohorts. The increased use of transapical TAVR in the NRCA may have led to a lower risk TF-TAVR patient population with fewer comorbidities, thereby resulting in improved outcomes in this group. A separate report details the results after transapical TAVR (19). Furthermore, the temporal difference makes the comparison of outcomes challenging because of differences in operator experience and enhancements in device technology, all of which likely contributed to varying degrees.

CONCLUSIONS

In the NRCA registry of the PARTNER trial, which included over 1,000 patients undergoing TF-TAVR, procedural complications and 1-year outcomes, including death, were significantly reduced compared with those of the RCT. The improved results may reflect superior patient selection, advances in device technology, and enhanced procedural skills.

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