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ORIGINAL RESEARCH

Suprasternal Versus Transfemoral Access for Transcatheter Aortic Valve Replacement: Insights From a Propensity Score Matched Analysis

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BACKGROUND: Suprasternal access is an alternative access strategy for transcatheter aortic valve replacement (TAVR) where the innominate artery is cannulated from an incision above the sternal notch. To date, suprasternal access has never been compared with transfemoral TAVR. Thus, we sought to assess safety, feasibility, and early clinical outcomes between suprasternal and transfemoral access for patients undergoing TAVR.

METHODS AND RESULTS: We evaluated patients from 2 institutional prospective, observational registries containing 1348 patients. Patients were selected in a 2:1 ratio (transfemoral:suprasternal) on the basis of propensity score matching. The primary outcome was in-hospital mortality, and secondary outcomes included the incidence of ischemic stroke, major bleeding, vascular injury, left bundle-branch block, and permanent pacemaker implantation at 30-day follow-up. Propensity score matching identified 89 patients undergoing suprasternal TAVR and 159 patients undergoing transfemoral TAVR suitable for analysis. There was no significant difference between suprasternal TAVR and transfemoral TAVR with respect to in-hospital mortality (1.1% versus 0.6%; odds ratio [OR], 1.80; 95% CI, 0.11–29.06; *P*=0.680). No patients in either cohort suffered an ischemic stroke. The incidence of major bleeding (2.2% versus 2.5%; OR, 0.89; 95% CI, 0.16–4.96; *P*=0.895) and vascular injury (1.1% versus 1.9%; OR, 0.59; 95% CI, 0.06–5.77; *P*=0.651) did not differ significantly. The frequency of left bundle-branch block (9.4% versus 15.8%; OR, 0.56; 95% CI, 0.24–1.30; *P*=0.177) and permanent pacemaker implantation (11.2% versus 5.9%; OR, 2.01; 95% CI, 0.75–5.45; *P*=0.169) were not statistically significantly different.

CONCLUSIONS: Suprasternal TAVR was safe and achieved promising short-term clinical outcomes when compared with transfemoral TAVR. Future studies seeking to identify the optimal alternative access site should evaluate suprasternal TAVR access alongside other substitutes for transfemoral TAVR.

Key Words: access site ■ aortic stenosis ■ suprasternal ■ transcatheter aortic valve implantation ■ transfemoral aortic valve implantation

Alternative vascular access options for transcatheter aortic valve replacement (TAVR) have expanded over the past decade from the transapical approach, used in ≈30% of patients in the PARTNER A (Placement of Aortic Transcatheter Valves) trial, to include carotid, subclavian, axillary, and transcaval routes.[1] Facilitated by shrinking vascular sheaths, improved delivery systems, and growing

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CLINICAL PERSPECTIVE

What Is New?

- Suprasternal access for transcatheter aortic valve replacement (TAVR) has been studied in selected patients with severe aortic stenosis, yielding promising early results. However, it has never been compared with transfemoral access.
- This analysis constitutes the first comparison of suprasternal and transfemoral access for patients undergoing TAVR.
- The incidences of in-hospital mortality, major bleeding, vascular complications, left bundle-branch block, or permanent pacemaker implantation for patients who underwent suprasternal TAVR were not significantly different from those undergoing transfemoral TAVR.

What Are the Clinical Implications?

- Suprasternal TAVR is a viable alternative access platform for TAVR in patients who are ineligible for traditional, transfemoral TAVR.
- Future prospective studies should directly compare suprasternal TAVR with other alternative access techniques (ie, transcarotid, axillary, or subclavian access) in an effort to determine the optimal access route based on patient-level and anatomic factors.

Nonstandard Abbreviations and Acronyms

PPI	permanent pacemaker implantation
SS-TAVR	suprasternal transcatheter aortic valve replacement
TAVR	transcatheter aortic valve replacement
TF-TAVR	transfemoral transcatheter aortic valve replacement

operator experience, these alternative access sites have performed comparably with traditional transfemoral access in nonrandomized studies.[2-4] Despite these encouraging results, each alternative access site is associated with its own unique technical challenges and risks such as stroke, vascular injury, and conduction abnormalities.

Our group previously reported high procedural success rates in the initial experience with suprasternal access, which uses a minimally invasive surgical technique to expose and directly cannulate the innominate artery through a small incision above the sternal notch.[5] By avoiding diseased and small-caliber peripheral arteries, suprasternal access is an attractive option for patients with advanced peripheral vascular disease. Furthermore, suprasternal access provides an anatomically favorable approach with excellent exposure of the innominate artery. This helps optimize valve positioning and deployment by aligning the delivery system with the curvature of the aorta while also completely avoiding wire manipulation of the transverse aortic arch. No head-to-head comparisons in the literature have assessed how TAVR via a suprasternal approach compares with transfemoral transcatheter aortic valve replacement (TF-TAVR). Thus, we evaluated clinical outcomes for patients who underwent suprasternal transcatheter aortic valve replacement (SS-TAVR) with a matched cohort of patients who underwent TF-TAVR.

METHODS

Patient Selection

A total of 1348 consecutive patients with severe aortic stenosis who underwent TAVR between 2016 and 2019 at Columbia University Medical Center (New York, NY) and Princeton Baptist Medical Center (Birmingham, AL) were enrolled in a prospective, observational registry. Baseline demographic data, comorbidities, operative details, and aspects of the patients' postprocedural clinical course were abstracted from the electronic medical record. Patients undergoing SS-TAVR were compared with a cohort of patients undergoing TF-TAVR participating in a parallel, prospective, observational registry from Columbia University Medical Center. SS-TAVR became the dominant alternative access site for patients not eligible for TF-TAVR at both participating institutions after 2016.

The primary end point of the analysis was in-hospital mortality, and secondary end points included the incidence of ischemic stroke, vascular complications, major bleeding, moderate or greater paravalvular regurgitation, length of hospital stay, permanent pacemaker implantation (PPI), new left bundle-branch block (LBBB) or atrial fibrillation, and 30-day readmission. LBBB and PPI were treated as mutually exclusive outcomes, and the odds of new LBBB, atrial fibrillation, and PPI were calculated from the subset of patients in the matched cohorts without baseline LBBB, atrial fibrillation, or cardiac implantable electronic devices (a combination of permanent pacemakers and automated implantable cardiac defibrillators). Outcomes were assessed according to the Valve Academic Research Consortium-2 definitions.[6] The institutional review boards at both medical centers approved this study, and the need for informed consent was waived. The data that support the findings of this study are available from the corresponding author upon reasonable request.

Preprocedural Evaluation and Procedural Technique

All patients referred for TAVR underwent computed tomography scanning using a standardized protocol to assess cardiac and peripheral vascular morphology (Figure 1).[7] Valve sizing was made on the basis of computed tomography measurements of the aortic annulus and perimeter, sinus of Valsalva, sinotubular junction, and the distance between the aortic valve annulus and ostia of the coronary arteries. Peripheral vessels, including the innominate artery, were also evaluated from non-ECG gated helical scans using <2 mm-thick slices. SS-TAVR was considered in patients in whom transfemoral access was deemed unfavorable by the heart valve team at each institution. Factors that influenced this decision included small (minimum lumen diameter ≤5 mm), tortuous, or highly calcified femoral arteries as well as aortic pathology (ie, atheroma, aneurysm) and morbid obesity. The innominate artery's suitability for SS-TAVR was determined by the size of the vessel (minimum lumen diameter ≥7 mm) as well as the burden and location of calcification. In addition, patients were excluded from SS-TAVR if the distance between the sternal notch and the innominate arteriotomy site exceeded 5 cm. SS-TAVR was performed in a hybrid operating room designed to facilitate the surgical and fluoroscopic aspects of the procedure. The layout and setup of the room as well as the key procedural steps have been described previously and are highlighted in Figure 2 and Videos S1 through S4.[8]

Statistical Analysis

Data are expressed as frequencies and percentages for categorical variables. Continuous variables are

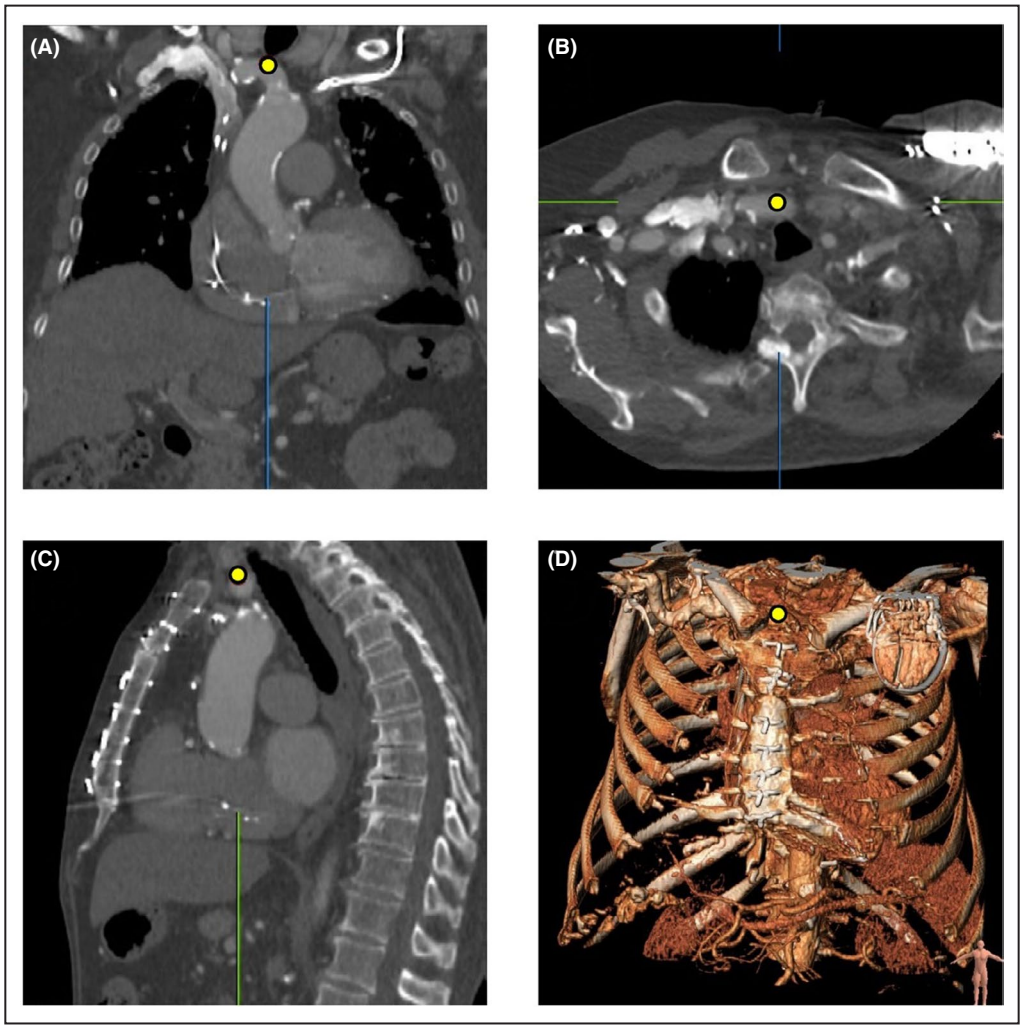

Figure 1. Preprocedural imaging assessment for suprasternal transcatheter aortic valve replacement.
Multislice computed tomography identifying the innominate artery and the planned arteriotomy site (demarcated by the yellow dot) from (**A**) coronal, (**B**) axial, and (**C**) sagittal views of the chest. A 3-dimensional reconstruction (**D**) of the relevant anatomy identifies the arteriotomy site in relation to the surrounding structures.

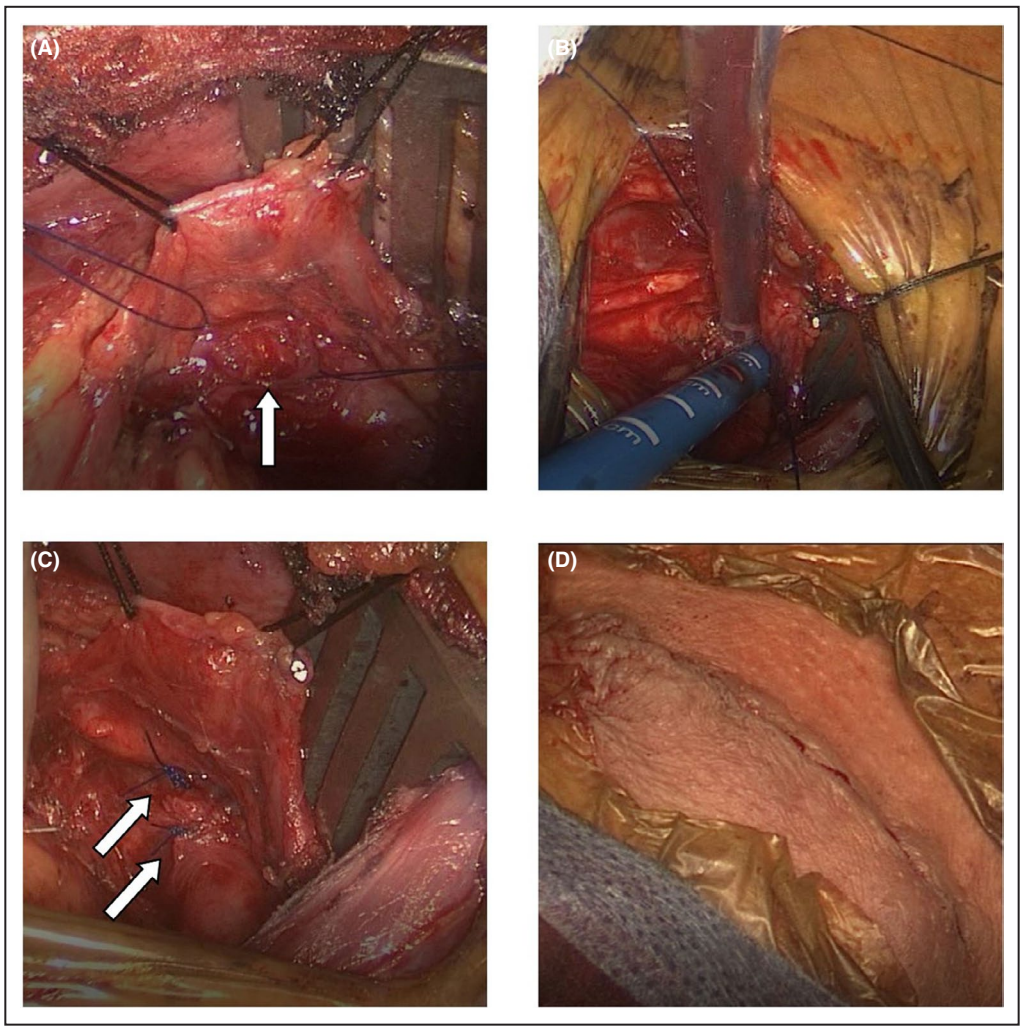

Figure 2. Procedural steps in suprasternal transcatheter aortic valve replacement.
A, Dissection to the level of the innominate artery, with the planned arteriotomy site identified by the arrow; (**B**) the Edwards Commander Delivery System positioned in the innominate artery prior to valve deployment; (**C**) the arteriotomy site sutured after valve deployment; and (**D**) a representative image of the surgical wound after suturing.

expressed as either means (standard deviation) or medians (interquartile range) depending on normality, which was tested via quantile-quantile plots, and were compared using the t test or Mann-Whitney test. Categorical variables were compared using the chi-square or Fisher's exact test depending on size (≤5). Logistic regression was performed with access site as the dependent variable and all preoperative risk variables in Table 1 as independent variables. Variables in the model were checked for collinearity using the variance inflation factor, and none of the factors were found to be collinear.

Propensity score matching was performed using a model with access site as the dependent variable and the same variables from Table 1 as the independent variables (Figure 3). Patients were matched with a 2:1 ratio (transfemoral:suprasternal) using a 0.2 caliper. Matching success was determined by a standardized mean difference <0.2 on variables following the match.[9] Other pre-, intra-, and postoperative characteristics after matching are noted in Tables 2 and 3. Group outcomes were then compared via univariable logistic regression. To determine influence of valve type (ie, self-expandable versus balloon) on the study outcomes, separate multivariable logistic regressions for outcomes with sufficient events had both access site and self/balloon-expanding valves as independent variables.

All statistical analyses and figures were generated using R statistical software (version 3.6.1, R Foundation for Statistical Computing, Vienna, Austria). Missing data are described in Tables S1 and S2. Missing preoperative data (<1% for all variables) were imputed to either the median or mode.

Table 1. Preoperative Characteristics of Pre–Score-Matched Patients

Patient Characteristics	Unadjusted Transfemoral (N=1246)	Unadjusted Suprasternal (N=102)	SMD
Age, y, median (IQR)	83.0 (77.0–88.0)	80.5 (74.0–85.0)	0.325*
Male, n (%)	656 (52.6)	59 (57.8)	0.105
BMI, median (IQR)	26.6 (23.4–30.2)	25.6 (22.1–30.4)	0.077
Diabetes mellitus, n (%)	371 (29.8)	41 (40.2)	0.220*
CLD, n (%)	118 (9.5)	35 (34.3)	0.630*
CHF, n (%)	890 (71.4)	58 (56.9)	0.307*
LVEF, median (IQR)	60.0 (51.0–67.0)	51.0 (40.0–60.0)	0.505*
Prior cardiac surgery, n (%)	277 (22.2)	46 (45.1)	0.499*
Moderate/Severe MR, n (%)	307 (24.6)	11 (10.8)	0.369*
Moderate/Severe TR, n (%)	332 (26.6)	5 (4.9)	0.625*
Prior stroke, n (%)	184 (14.8)	15 (14.7)	0.002
Hyperlipidemia, n (%)	959 (77.0)	84 (82.4)	0.134
Hypertension, n (%)	1135 (91.1)	93 (91.2)	0.003
Atrial fibrillation, n (%)	440 (35.3)	49 (48.0)	0.260*
PVD, n (%)	104 (8.3)	45 (44.1)	0.890*
CKD, n (%)	402 (32.3)	23 (22.5)	0.219*
MI, n (%)	121 (9.7)	25 (24.5)	0.401*
eGFR, median (IQR)	61.7 (45.9–80.4)	65.4 (42.0–83.1)	0.035

BMI indicates body mass index; CHF, chronic heart failure; CKD, chronic kidney disease; CLD, chronic lung disease; eGFR, glomerular filtration rate; IQR, interquartile range; LVEF, left ventricular ejection fraction; MI, myocardial infarction; MR, mitral regurgitation; PVD, peripheral arterial disease; SMD, standardized mean difference; and TR, tricuspid regurgitation.

*Indicated significant pre-matching differences.

RESULTS

Unmatched Demographics

Baseline characteristics of the unmatched cohorts are presented in Table 1. There were no age or sex differences in the sample populations, but SS-TAVR recipients (n=102) were older and more likely to have comorbidities like diabetes mellitus, atrial fibrillation, and chronic lung disease than their TF-TAVR counterparts (n=1246). Moreover, they were more likely to have a prior history of cardiac surgery and peripheral vascular disease (44.1% versus 8.3%).

A cohort of 31 patients who were deemed ineligible for TF-TAVR and underwent nonsuprasternal alternative access for TAVR at Columbia University Medical Center during the study period are presented in Tables S3 and S4. All 31 patients were ineligible for SS-TAVR because of a high burden of calcium in the innominate artery, which precluded safe, direct cannulation of the artery, and underwent TAVR via transapical (n=3), transaortic (n=10), transcarotid (n=5), and transaxillary or subclavian (n=13) access. Tables S5 and S6 analyze a restricted cohort of the nonsuprasternal alternative access group of patients who underwent transcarotid, transaxillary, or subclavian access for TAVR to provide a more direct comparison with patients who did not require transthoracic access for TAVR.

Propensity Score Matching Results

Matching identified a total of 248 patients suitable for analysis, which included 159 patients who underwent TF-TAVR and 89 who underwent SS-TAVR, 46 (51.7%) from Columbia University Medical Center and 43 (48.3%) from Princeton Baptist Medical Center. Matching successfully eliminated any major differences between the 2 cohorts (Tables 2 and 3, Figure 3). Of note, the frequency of baseline LBBB and cardiac implantable electronic devices was similar in the matched cohorts.

Echocardiographic and procedural details of the suprasternal and transfemoral cohorts are highlighted in Table 3. The majority of patients undergoing SS-TAVR received a self-expanding prosthesis. Although all SS-TAVR cases were performed under general anesthesia, and per protocol, all patients boarded in the intensive care unit after the procedure, 87.6% of patients were extubated in the operating room and the median length of intensive care unit stay was 1 day. On average, patients undergoing SS-TAVR stayed 3 days following the procedure, compared with 2 days following the procedure for patients undergoing TF-TAVR (P=0.018). Technical success was achieved in all matched and unmatched SS-TAVR cases, and there were no patients who required median sternotomy, mechanical circulatory support, or conversion to surgical aortic valve replacement. Moderate or greater

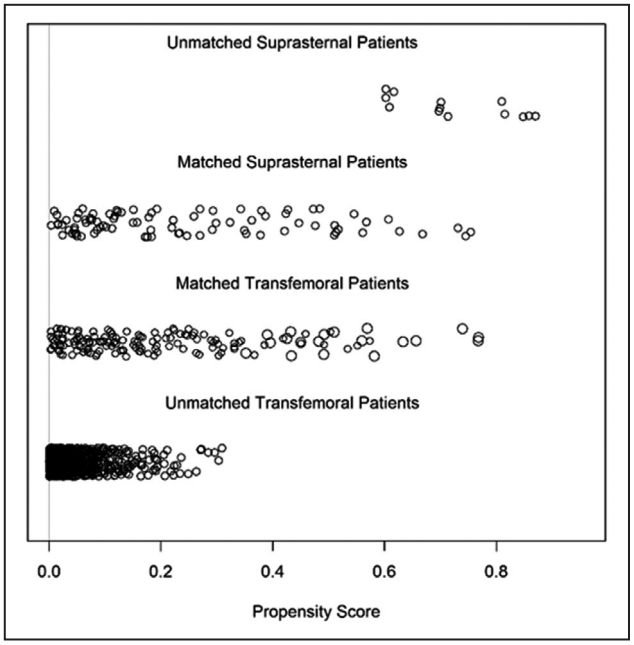

Figure 3. Distribution of propensity score matches for matched and unmatched patients.
Propensity scores among the matched suprasternal and transfemoral patients are similar, and only a small fraction of suprasternal access patients were not able to be matched with counterparts in the transfemoral cohort.

paravalvular leak occurred in 3 patients undergoing SS-TAVR and 1 patient undergoing TF-TAVR.

In-hospital mortality occurred in 1 patient in both the SS-TAVR and TF-TAVR cohorts (Figure 4; 1.1% versus 0.6%, odds ratio [OR], 1.80; 95% CI, 0.11–29.06; *P*=0.680). Importantly, no patients in the 89-person matched SS-TAVR cohort suffered an ischemic stroke or transient ischemic attack. Major vascular complications were rare in the SS-TAVR cohort as well, occurring in 3 patients versus 1 patient undergoing TF-TAVR (OR, 0.59; 95% CI, 0.06–5.77; *P*=0.651). One patient among these 3 patients in the SS-TAVR cohort with major vascular complications required emergent operative intervention after developing airway compromise from an expanding neck hematoma. Operative exploration identified an intramuscular bleed adjacent to engorged veins from a recently created arteriovenous fistula for dialysis access. Overall, Valve Academic Research Consortium major bleeding was observed in similar proportions of patients undergoing SS-TAVR and TF-TAVR (2.2% versus 2.5%; OR, 0.89; 95% CI, 0.16–4.96; *P*=0.895).

The incidence of arrhythmias and conduction abnormalities after SS-TAVR and TF-TAVR was also similar. New atrial fibrillation occurred in 2.0% of patients undergoing SS-TAVR versus 4.4% of patients undergoing TF-TAVR (OR, 0.44; 95% CI, 0.05–4.08; *P*=0.473). Similarly, the incidence of new LBBB was comparable between the SS-TAVR and TF-TAVR cohorts (9.4% versus 15.8%; OR, 0.56; 95% CI, 0.24–1.30; *P*=0.177). PPI occurred in 11.2% (n=9) of SS-TAVR recipients versus 5.9% (n=8) of TF-TAVR recipients: Although numerically higher in SS-TAVR recipients, this difference was not statistically significant (OR, 2.01; 95% CI, 0.75–5.45; *P*=0.169). Moreover, a single, composite end point of new LBBB and PPI revealed no differences between SS-TAVR and TF-TAVR (17.1% versus 23.0%; OR, 0.69; 95% CI, 0.33–1.44; *P*=0.325), independent of the type of valve—balloon or self-expandable—that was implanted (OR, 0.58; 95% CI, 0.26–1.29; *P*=0.182).

Readmissions within the 30 days following the procedure were higher for patients undergoing SS-TAVR compared with patients undergoing TF-TAVR (10.1% versus 4.4%), but this difference was only statistically significant in a multivariable model adjusting for the type of valve (self-expanding versus balloon) implanted (OR, 3.02; 95% CI, 1.01–9.00; *P*=0.048 with multivariable adjustment versus OR, 2.44; 95% CI, 0.88–6.80; *P*=0.087 in the univariable model). No patients sustained severe acute kidney injuries requiring hemodialysis at 30 days. One TF-TAVR recipient died within the 30-day postprocedure period after being discharged such that 30-day mortality occurred in a total of 2 patients undergoing TF-TAVR compared with 1 patient undergoing SS-TAVR.

DISCUSSION

This analysis constitutes the first comparison of suprasternal alternative access versus traditional, transfemoral access for TAVR. The principal findings are 4-fold: (1) SS-TAVR is feasible and practical when compared with TF-TAVR in a cohort enriched with comorbidities and classically at high risk for adverse outcomes; (2) in-hospital mortality following SS-TAVR was similar to TF-TAVR; (3) there were no ischemic strokes immediately following SS-TAVR; and (4) incident arrhythmias and conduction abnormalities like atrial fibrillation and LBBB occurred with similar frequency in the SS-TAVR and TF-TAVR cohorts, as did the need for PPI.

Although the frequency of non–TF-TAVR is declining from its peak in the early TAVR experience, when ≈30% of patients were not candidates for transfemoral access, ≈5% of TAVR procedures are still performed with alternative access in contemporary registries.[10] Declining sheath size and adjunctive techniques like intravascular lithotripsy to facilitate transfemoral access are helpful, but unlikely to render alternative access obsolete.[11] They are also not without their own drawbacks: Cost for adjunctive therapies may be prohibitive, and transfemoral access has been shown to narrow the femoral artery,[12] which may have lasting consequences for certain

Table 2. Preoperative Characteristics of Post–Score-Matched Patients

Patient Characteristics	Adjusted Transfemoral (N=159)	Adjusted Suprasternal (N=89)	SMD
Age, y, median (IQR)	81.0 (75.0–86.0)	81.0 (74.0–85.0)	0.006
Male, n (%)	89 (56.0)	51 (57.3)	0.027
BMI, median (IQR)	28.8 (24.2–33.0)	25.8 (22.1–30.9)	0.091
Diabetes mellitus, n (%)	62 (39.0)	37 (41.6)	0.053
CLD, n (%)	41 (25.8)	25 (28.1)	0.052
CHF, n (%)	93 (58.5)	50 (56.2)	0.047
LVEF, median (IQR)	55.0 (40.5–60.0)	50.0 (40.0–60.0)	0.039
Prior cardiac surgery, n (%)	58 (36.5)	36 (40.4)	0.082
Moderate/severe MR, n (%)	25 (15.7)	11 (12.4)	0.097
Moderate/severe TR, n (%)	12 (7.5)	5 (5.6)	0.078
Prior stroke, n (%)	18 (11.3)	11 (12.4)	0.032
Hyperlipidemia, n (%)	123 (77.4)	74 (83.1)	0.146
Hypertension, n (%)	147 (92.5)	80 (89.9)	0.091
Atrial fibrillation, n (%)	68 (42.8)	39 (43.8)	0.021
LBBB, n (%)	13 (8.2)	4 (4.5)	0.152
CIED, n (%)	24 (15.1)	9 (10.1)	0.151
PVD, n (%)	50 (31.4)	32 (36.0)	0.095
CKD, n (%)	44 (27.7)	21 (23.6)	0.093
MI, n (%)	31 (19.5)	19 (21.3)	0.046
eGFR, median (IQR)	62.6 (46.2–80.3)	65.9 (41.9–82.7)	0.003

BMI indicates body mass index; CHF, chronic heart failure; CIED, cardiac implantable electronic device (ie, pacemaker and automated implantable cardiac defibrillator); CKD, chronic kidney disease; CLD, chronic lung disease; eGFR, glomerular filtration rate; IQR, interquartile range; LBBB, left bundle-branch block; LVEF, left ventricular ejection fraction; MI, myocardial infarction; MR, mitral regurgitation; PVD, peripheral arterial disease; SMD, standardized mean difference; and TR, tricuspid regurgitation.

high-risk patients, like those with peripheral vascular disease, who stand to benefit the most from alternative access options. Moreover, vascular complications were reported in 2.0%[13] and 3.8%[14] of patients from 2 recently published trials evaluating TF-TAVR in patients at low surgical risk, and such complications, while rare, still have serious consequences on patient quality of life and survival.[15] As such, identifying the optimal alternative access strategy remains an important decision for comprehensive (level 1) valve centers.[16]

Suprasternal access for TAVR evolved out of a direct aortic approach first described by Bapat and colleagues a decade ago, where the ascending aorta is cannulated via a limited sternotomy or right thoracotomy.[17] This technique was successful, but the prolonged recovery times associated with the operation prompted a search for a less invasive technique. The suprasternal approach was then developed, whereby the innominate artery—an unbranched vessel usually measuring ≈18 mm in diameter and typically free of significant atherosclerotic disease—is directly accessed through a small incision above the sternal notch, akin to what is routinely done during mediastinoscopy.[18] Kiser and colleagues reported short-term clinical outcomes from the first series of 4 SS-TAVR recipients, with excellent technical success, no Valve Academic Research Consortium-2 major bleeding, vascular injury, or stroke. One patient in the series required PPI. SS-TAVR has since expanded beyond Kiser's single-site and single-surgeon experience to be used in an array of patient populations and clinical scenarios, including patients with morbid obesity, advanced peripheral vascular disease, or cardiogenic shock and even a pediatric patient with congenital aortic valvulopathy.[5,8,19,20]

The results of this study compare favorably with other analyses evaluating TF-TAVR against the 2 dominant forms of alternative access—transcarotid and transaxillary/subclavian access. SS-TAVR was associated with lower in-hospital and 30-day mortality (1.1%) than the rates (4.2% and 5.1%) cited in recent meta-analyses of transaxillary/subclavian[21] and transcarotid[3] access, respectively. However, the lack of randomization, small sample size, and low in-hospital and 30-day mortality rate in this study's TF-TAVR comparator group are important caveats that should temper any suggestions that SS-TAVR is superior to these other alternative access routes. Furthermore, in-hospital and 30-day mortality are generally rare following TAVR and may be confounded by a number of variables like prosthesis type and local hospital practices.[22]

Table 3. Echocardiographic and Procedural Characteristics in the Matched Cohorts

Patient Characteristics	Transfemoral (N=159)	Suprasternal (N=89)	*P* Value	SMD
Valve area, median (IQR)	0.8 (0.7–1.0)	0.8 (0.6–0.9)	0.045	0.320
Peak gradient, median (IQR)	67.2 (49.8–81.6)	64.0 (50.8–72.0)	0.186	0.158
Expandable valve			<0.001	0.783
Self-expandable	36 (22.6)	52 (58.4)		
Balloon expandable	123 (77.4)	37 (41.6)		
Valve type, n (%)			<0.001	1.760
Corevalve	0 (0.0)	1 (1.1)		
Edwards Sapien	1 (0.6)	0 (0.0)		
Evolut R	34 (21.4)	51 (57.3)		
S3	124 (78.0)	37 (41.6)		
Valve size, n (%)			<0.001	0.710
20	2 (1.3)	0 (0.0)		
23	53 (33.3)	15 (16.9)		
26	52 (32.7)	27 (30.3)		
27	2 (1.3)	0 (0.0)		
29	47 (29.6)	30 (33.7)		
34	3 (1.9)	17 (19.1)		
General anesthesia, n (%)	99 (62.3)	89 (100.0)	<0.001	1.101
OR extubation, n (%)	153 (96.2)	78 (87.6)	0.021	0.319
Days on ventilator, median (IQR)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.121	0.038
ICU stay days, median (IQR)	0.0 (0.0–1.0)	1.0 (1.0–2.0)	<0.001	0.537
Postoperative LOS days, median (IQR)	2.0 (2.0–4.0)	3.0 (2.0–4.0)	0.018	0.022

ICU indicates intensive care unit; IQR, interquartile range; LOS, length of stay; OR, operating room; and SMD, standardized mean difference.

Instead, other end points like the incidence of ischemic stroke and conduction disturbance may be more meaningful when deciphering the value of SS-TAVR. Ischemic stroke, for example, is a feared complication of any transcarotid or transaxillary intervention and may result from dislodged plaque during manipulation of the access-site vessel, sheath or wire disruption of plaque in the transverse aortic arch, or directly from calcified native aortic valve leaflets during prosthesis deployment. These concerns were substantiated by a recent analysis with planned postprocedure magnetic resonance imaging, which found more ischemic lesions in the cerebral hemisphere ipsilateral to the carotid access point used for TAVR.[23] The incidence of clinically relevant 30-day cerebrovascular events in multiple transcarotid TAVR studies is not exceedingly high—occurring in 4.2% of patients from a recently published analysis of patients from the Society of Thoracic Surgeons/Transcatheter Valve Therapies registry.[24-29] In contrast, transaxillary or subclavian approaches have demonstrated higher rates of stroke than suprasternal or transcarotid access (≈7–8%), raising concern that these less central access points may cause embolization to the cerebral vasculature more readily.[29] Thus, the findings of our analysis are compatible with similarly designed studies reporting the frequency of periprocedural ischemic stroke, and suggest that SS-TAVR is just as, if not more, safe than these other forms of alternative access.

We hypothesized that SS-TAVR would have an advantage over TF-TAVR with regard to conduction disturbances because the transcatheter valve can be better aligned with the aortic annulus from the innominate artery than from the femoral artery. This theoretical benefit was thought to be more relevant for self-expanding valve systems with delivery catheters that lack active flexion and rely on aortic angulation and wire positioning in the ascending aorta to achieve coaxiality. Whether a non–statistically significant reduction in the odds of new LBBB or PPI in the SS-TAVR cohort represents a clinically meaningful difference is unclear and may warrant additional study. The higher incidence of postprocedural readmission should also be investigated further in larger studies, although it does not appear to be linked with late conduction disturbances, which traditionally occur more frequently with self-expanding prostheses.

Limitations

The study design imposes a number of limitations, which should be considered when putting the findings of this study into context. First of all, although

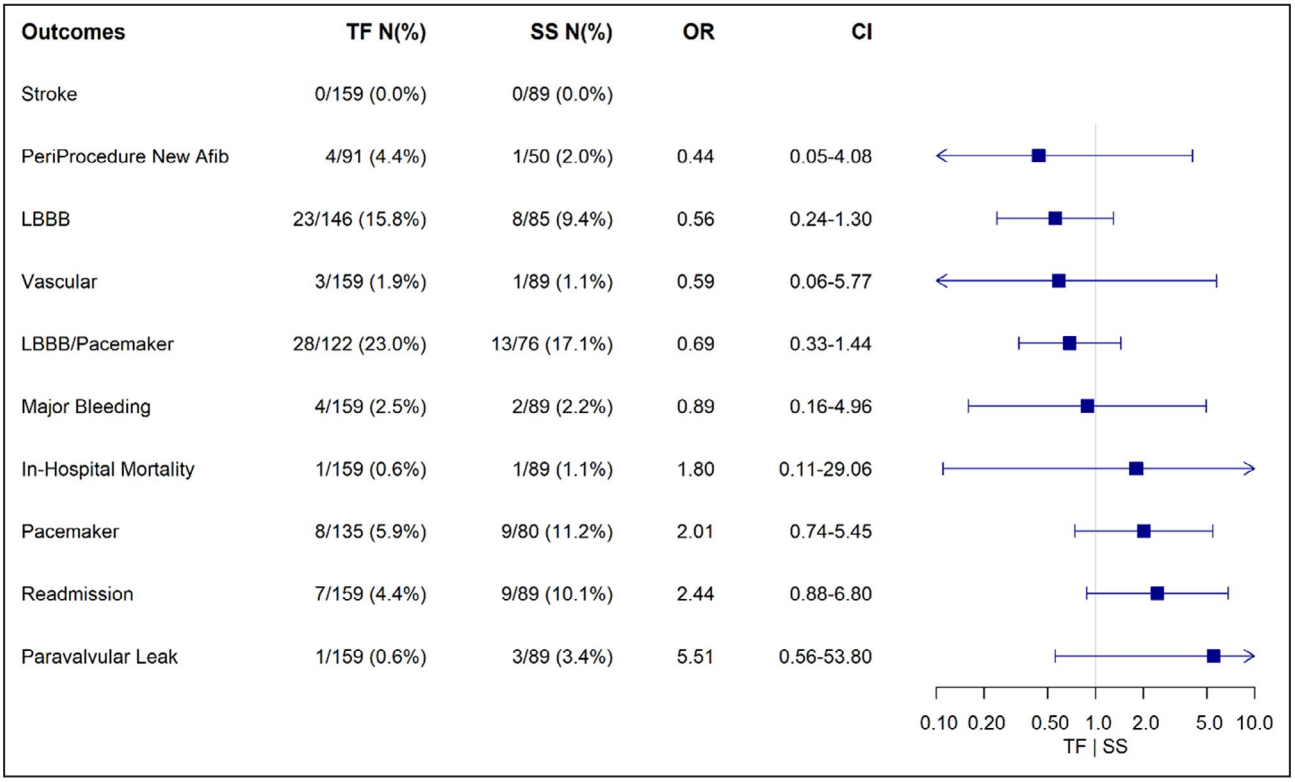

Figure 4. Forest plot of clinical outcomes following suprasternal and transfemoral transcatheter aortic valve replacement. There were no statistically significant differences between suprasternal and transfemoral transcatheter aortic valve replacement with respect to the listed outcomes. Dots correspond to odds ratios, and bars represent 95% CIs (arrows indicate interval extends beyond limits of the scale). Afib indicates atrial fibrillation; LBBB, left bundle branch block; OR, odds ratio; SS, suprasternal; and TF, transfemoral.

propensity score matching successfully erased differences between the SS-TAVR and TF-TAVR cohorts, it is not a substitute for randomization, and the results of the present analysis should only be considered hypothesis generating. Second, the transfemoral cohort was derived only from patients treated at Columbia University Medical Center, thereby introducing a potential source of bias during propensity score matching. However, we suspect this facet of the study design would only serve to accentuate differences between SS-TAVR and TF-TAVR and, therefore, provides a conservative view of SS-TAVR's benefits given the low rate of complications with TF-TAVR at Columbia University Medical Center. Third, while these results are encouraging, they may not be generalizable considering our group's extensive experience (preceding the 2016 onset of this analysis) with SS-TAVR. Every procedural technique has a learning curve and the adverse outcomes typically observed in the early period after adoption may not be reflected in the findings of this study given the time frame selected for analysis. Furthermore, the surgical technique is challenging: obtaining the optimal exposure of the innominate artery can be difficult and the lack of a simple surgical bailout if complications are encountered may limit widespread adoption of SS-TAVR. Nevertheless, all surgeons who participated in this study were trained to use a similar technique and we do not suspect there were significant inter-site differences in the procedural aspects of SS-TAVR. Finally, the small sample size, lack of event adjudication, and limited long-term follow-up preclude stronger inferences being drawn with respect to SS-TAVR's performance relative to TF-TAVR. A large, multicenter registry evaluating clinical end points (ie, mortality, conduction disturbances, and readmissions) and procedural aspects (ie, procedure time, operator radiation exposure) for multiple different alternative access approaches can address these limitations and should be the next step in identifying the optimal access route for non–TF-TAVR candidates.

CONCLUSIONS

Suprasternal access for TAVR is associated with low rates of in-hospital and 30-day mortality, ischemic stroke, and conduction abnormalities when compared with TF-TAVR in this propensity score matching analysis of patients with severe aortic stenosis. Accordingly,

alternative access options for non–TF-TAVR candidates should include suprasternal access, and further prospective studies will help match the right access technique with the right patient.

ARTICLE INFORMATION

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Supplementary Material

Tables S1–S6
Video S1-S4

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Supplemental Material

Imputation of Missing Data

Table S1. Missing Variables Pre-Match.

Field	N Missing (%)	Remediation
CCS Angina Class	29	Imputed to the Mode
PCI	1	Imputed to No
LVEF	1	Imputed to the median
Mitral Regurgitation	4	Imputed to the mode
Tricuspid Regurgitation	22	Imputed to the mode

CCS = Canadian Cardiology Society, PCI = percutaneous coronary intervention, LVEF = left ventricular ejection fraction

Table S2. Missing Variables Post-Match.

Field	N Missing (%)	Remediation
Peak Gradient	1	Imputed to the Median
Postop LOS	1	Imputed to the Median
LBBB	3	Marked as No
RBBB	2	Marked as No
Pacemaker	2	Marked as No
Paravalvular Leak	2	Marked as No

LOS = length of stay, LBBB = left bundle branch block, RBBB = right bundle branch block

A Review of Non-Suprasternal Alternative Access

Table S3. Baseline demographics and comorbidities of all patients who underwent TAVR via alternative access.

Patient Characteristics	Unadjusted Suprasternal N = 102	Unadjusted Non-Suprasternal N = 31	P-value
Age, median [IQR]	80.5 [74.0-85.0]	82.0 [78.5-86.5]	0.087
Male, n(%)	59 (57.8%)	17 (54.8%)	0.929
BMI, median [IQR]	25.7 [22.1-30.4]	26.6 [22.1-31.2]	0.655
Diabetes, n(%)	41 (40.2%)	6 (19.4%)	0.056
CLD, n(%)	35 (34.3%)	12 (38.7%)	0.815
CHF, n(%)	58 (56.9%)	28 (90.3%)	<0.001
LVEF, median [IQR]	51.0 [40.0-60.0]	60.0 [40.5-70.0]	0.084
Prior Cardiac Surgery, n(%)	46 (45.1%)	9 (29.0%)	0.167
Mod/Severe MR, n(%)	11 (10.8%)	6 (19.4%)	0.345
Mod/Severe TR, n(%)	5 (4.9%)	5 (16.1%)	0.053
Prior Stroke, n(%)	15 (14.7%)	3 (9.7%)	0.564
HLD, n(%)	84 (82.4%)	27 (87.1%)	0.783
HTN, n(%)	93 (91.2%)	31 (100.0%)	0.116
Afib, n(%)	49 (48.0%)	10 (32.3%)	0.179
PVD, n(%)	45 (44.1%)	17 (54.8%)	0.400
CKD, n(%)	23 (22.5%)	12 (38.7%)	0.120
MI, n(%)	25 (24.5%)	5 (16.1%)	0.462
eGFR, median [IQR]	65.4 [42.0-83.1]	49.0 [37.5-68.5]	0.038

IQR = interquartile range, BMI = body mass index, CLD = chronic lung disease, CHF = congestive heart failure, LVEF = left ventricular ejection fraction, MR = mitral regurgitation, TR = tricuspid regurgitation, HLD = hyperlipidemia, HTN = hypertension, Afib = atrial fibrillation, PVD = peripheral vascular disease, CKD = chronic kidney disease, MI = history of prior myocardial infarction, eGFR = estimated glomerular filtration rate.

Table S4. Outcomes for alternative access TAVR.

Clinical Outcomes	Unadjusted Suprasternal N = 102	Unadjusted Non-SS Alternative Access N = 31	P-value
Paravalvular Leak, n(%)	6 (5.8%)	0 (0.0%)	0.335
Pacemaker, n(%)	10 (9.8%)	6 (19.4%)	0.152
Major Bleeding, n(%)	3 (2.9%)	5 (16.1%)	0.017
Vascular Complication, n(%)	1 (0.9%)	5 (16.1%)	0.003
New Atrial Fibrillation, n(%)	2 (1.8%)	3 (9.7%)	0.083
Stroke, n(%)	1 (0.9%)	2 (6.5%)	0.136
In-Hospital Mortality, n(%)	1 (0.9%)	1 (3.2%)	0.413

All endpoints are defined according to criteria outlined in the main text.

Table S5. Baseline demographics and comorbidities of patients who underwent TAVR via transcarotid, transaxillary, or subclavian alternative access.

Patient Characteristics	Unadjusted Suprasternal N = 102	Unadjusted Non-Suprasternal N = 18	P-value
Age, median [IQR]	80.5 [74.0-85.0]	86.0 [81.3-87.8]	0.009
Male, n(%)	59 (57.8%)	10 (55.6%)	0.999
BMI, median [IQR]	25.7 [22.1-30.4]	24.8 [20.8-28.5]	0.453
Diabetes, n(%)	41 (40.2%)	3 (16.7%)	0.100
CLD, n(%)	35 (34.3%)	8 (44.4%)	0.576
CHF, n(%)	58 (56.9%)	16 (88.9%)	0.009
LVEF, median [IQR]	51.0 [40.0-60.0]	56.5 [30.0-62.8]	0.834
Prior Cardiac Surgery, n(%)	46 (45.1%)	5 (27.8%)	0.266
Mod/Severe MR, n(%)	11 (10.8%)	4 (22.2%)	0.334
Mod/Severe TR, n(%)	5 (4.9%)	5 (27.8%)	0.007
Prior Stroke, n(%)	15 (14.7%)	2 (11.1%)	0.999
HLD, n(%)	84 (82.4%)	16 (88.9%)	0.734
HTN, n(%)	93 (91.2%)	18 (100.0%)	0.352
Afib, n(%)	49 (48.0%)	6 (33.3%)	0.369
PVD, n(%)	45 (44.1%)	10 (55.6%)	0.521
CKD, n(%)	23 (22.5%)	8 (44.4%)	0.096
MI, n(%)	25 (24.5%)	2 (11.1%)	0.357
eGFR, median [IQR]	65.4 [42.0-83.1]	50.5 [39.3-59.5]	0.042

IQR = interquartile range, BMI = body mass index, CLD = chronic lung disease, CHF = congestive heart failure, LVEF = left ventricular ejection fraction, MR = mitral regurgitation, TR = tricuspid regurgitation, HLD = hyperlipidemia, HTN = hypertension, Afib = atrial fibrillation, PVD = peripheral vascular disease, CKD = chronic kidney disease, MI = history of prior myocardial infarction, eGFR = estimated glomerular filtration rate.

Table S6. Outcomes for transcarotid, transaxillary, and subclavian alternative access TAVR.

Clinical Outcomes	Unadjusted Suprasternal N = 102	Unadjusted Non-SS Alternative Access Subset N =18	P-value
Paravalvular Leak, n(%)	6 (5.8%)	0 (0.0%)	0.590
Pacemaker, n(%)	10 (9.8%)	3 (16.7%)	0.411
Major Bleeding, n(%)	3 (2.9%)	1 (5.6%)	0.483
Vascular Complication, n(%)	1 (0.9%)	0 (0.0%)	0.999
New Atrial Fibrillation, n(%)	2 (1.8%)	3 (16.7%)	0.024
Stroke, n(%)	1 (0.9%)	0 (0.0%)	0.999
In-Hospital Mortality, n(%)	1 (0.9%)	1 (5.6%)	0.279

All endpoints are defined according to criteria outlined in the main text.

Supplemental Video Legends:

Video S1. Exposing the innominate artery. A small incision is made above the sternal notch. The tissue planes down to the innominate artery are dissected in order to expose the vessel. Best viewed with Windows Media Player.

Video S2. Preparing for the arteriotomy. Tissue surrounding the innominate artery is exposed through atraumatic technique. Vascular sutures are placed in the vessel to facilitate closure at the end of the procedure. Best viewed with Windows Media Player.

Video S3. Delivery catheter insertion into the innominate artery. The vessel is directly cannulated and a stiff wire advanced through a sheath from the innominate artery into the left ventricle with the assistance of fluoroscopy (not shown). The Edwards Commander Delivery System is then advanced over the wire into the appropriate position. Best viewed with Windows Media Player.

Video S4. Closing the arteriotomy and reapproximating the subcutaneous tissue planes. The delivery system is removed and the arteriotomy closed. The tissue planes are reapproximated and incision closed (partially depicted) after adequate hemostasis is confirmed. Best viewed with Windows Media Player.