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CORRESPONDENCE

Research Correspondence

CoreValve Transcatheter Aortic Valve Implantation via the Subclavian Artery

Comparison With the Transfemoral Approach

To the Editor: Transcatheter aortic valve implantation (TAVI) has emerged as a promising alternative to surgical aortic valve replacement for patients with severe aortic stenosis considered to be at high operative risk. TAVI is most commonly performed via the femoral artery. However, the large-diameter delivery catheters of both the Edwards Sapien (Edwards Lifesciences, Irvine, California) and Medtronic CoreValve (Medtronic Inc., Minneapolis, Minnesota) systems preclude a transfemoral approach in a significant number of patients. The Sapien valve can be delivered using a transapical technique, but this is a more invasive procedure, and initial observational data suggest that outcomes are worse (1,2). A subclavian approach has been reported as a viable alternative for the CoreValve (3). However, there are limited data describing outcomes with this technique.

We analyzed a consecutive cohort of 288 patients implanted at 8 centers in the United Kingdom and Ireland between April 2007 and April 2010 to determine the characteristics and outcomes of patients undergoing CoreValve TAVI via a subclavian approach, compared with those treated transfemorally. Data were obtained by retrospective analysis of case notes and institutional databases. Principal outcome measures were procedural success, valve position, major vascular complications, and the 30-day incidence of death, stroke, and major adverse cardiovascular and cerebrovascular events (MACCE). Major vascular complications included retroperitoneal hemorrhage, limb ischemia, and any complication requiring percutaneous or surgical intervention. MACCE consisted of death, myocardial infarction, stroke, conversion to surgery, emergent percutaneous coronary intervention, cardiogenic shock, endocarditis, repeat valvular intervention, cardiac tamponade, and aortic dissection or rupture (4). Categorical variables were compared using the Fisher exact test and continuous variables using 2-tailed unpaired *t* tests for comparisons between groups and paired *t* tests for intragroup comparisons. Analyses were performed using Stata software (StataCorp LP, College Station, Texas).

The procedure was performed using a transfemoral approach in 253 patients (88.2%) and via the subclavian artery in 35 (11.8%). Demographics, procedural data, and 30-day outcomes are shown in Table 1. Logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation) scores were significantly higher in the subclavian cohort, as was the incidence of peripheral vascular disease, carotid artery disease, previous myocardial infarction, chronic obstructive pulmonary disease, and impaired left ventricular function.

Valve position was more frequently reported as "optimal" in the subclavian group. Major vascular complications were numerically more frequent in the femoral cohort, but blood transfusion was more common in the subclavian patients. Thirty-day mortality was 0% in subclavian patients versus 4.7% in femoral patients ($p = 0.30$). MACCE at 30 days showed a trend toward reduced events in the subclavian cohort (2.9% vs. 13.4%, $p = 0.09$).

Currently available TAVI systems require relatively large, healthy vessels for conventional transfemoral access. The Edwards Sapien valve has until recently been delivered via a 22- or 24-F catheter, precluding a femoral approach in up to 50% of patients. Major access site complications have been a significant source of morbidity and mortality, with an incidence of 10.6% in the largest reported Edwards transfemoral registry (1). The CoreValve is delivered via a smaller 18-F catheter, but a significant minority of patients remain unsuitable for femoral access.

The design of the Edwards valve permits a transapical approach in patients without suitable peripheral vessels. However, this procedure is more invasive, and early studies indicate that outcomes are worse, with significantly higher mortality both at 30 days and at 12 months, albeit in patients with higher EuroSCORE (1,2). A transapical technique is not routinely available with the CoreValve device. However, alternative vascular access is possible using the subclavian artery, which is less frequently affected by atheromatous disease and in most patients can accommodate an 18-F sheath.

Table 1 Comparison Between Subclavian and Transfemoral TAVI

Variable	Transfemoral (n = 253)	Subclavian (n = 35)	p Value
Baseline characteristics			
Age (yrs)	81.7 ± 6.4	80.6 ± 4.9	0.33
Logistic EuroSCORE (%)	19.1 ± 12.3	25.0 ± 14.7	0.02
Coronary artery disease	148 (58.5%)	26 (74.2%)	0.09
Previous MI	41 (16.2%)	12 (34.3%)	0.02
Previous PCI	61 (24.1%)	12 (34.3%)	0.22
Carotid artery disease	15 (5.9%)	6 (17.1%)	0.03
Peripheral vascular disease	54 (21.3%)	26 (74.2%)	<0.0001
COPD	47 (18.6%)	14 (40.0%)	0.007
LVEF <50%	94 (37.2%)	23 (65.7%)	0.004
Procedural results			
Procedural success	246 (97.2%)	35 (100%)	1.00
"Optimal" valve position	153 (60.5%)	31 (88.6%)	0.001
Major vascular complications	25 (9.9%)	1 (2.9%)	0.34
Blood transfusion	47 (18.6%)	13 (37.1%)	0.02
30-day outcomes			
Mortality	12 (4.7%)	0 (0%)	0.37
Stroke	11 (4.3%)	1 (2.9%)	0.86
MACCE	34 (13.4%)	1 (2.9%)	0.09

Data are expressed as mean ± SD or n (%).

COPD = chronic obstructive pulmonary disease; EuroSCORE = European System for Cardiac Operative Risk Evaluation; LVEF = left ventricular ejection fraction; MACCE = major adverse cardiovascular and cerebrovascular events; MI = myocardial infarction; PCI = percutaneous coronary intervention; TAVI = transcatheter aortic valve implantation.

In common with transapical series, we found that subclavian patients were a higher risk cohort than transfemoral patients, with significantly higher average EuroSCORE, more prevalent comorbidities, and more frequent impairment of left ventricular function. However, in contrast to major transapical registries, outcomes of subclavian TAVI were at least as good as in the transfemoral cohort, with 100% procedural success, 0% mortality at 30 days, and a strong trend toward reduced MACCE. The more frequent attainment of an "optimal" valve position in the subclavian cohort may reflect greater control of the deployment catheter, because the distance and tortuosity between the access site and valve are reduced.

One other national multicenter experience of 54 subclavian CoreValve TAVI cases has recently been reported, with very similar findings (3). Subclavian patients had significantly higher EuroSCORE and an increased incidence of peripheral vascular disease, coronary artery disease, prior myocardial infarction, and prior percutaneous coronary intervention than femoral patients. The 30-day mortality was 0% versus 6.1% in the femoral cohort ($p = 0.13$). "Suboptimal" valve positions were more frequently observed in femoral patients.

The findings of this study are limited by the relatively small number of subclavian patients, the registry design, and the absence of independent event adjudication. Nonetheless, the U.K. experience is consistent with existing data in demonstrating excellent outcomes with a subclavian approach in patients without suitable femoral access despite a higher risk profile, supporting the use of this technique for CoreValve TAVI in these patients. This contrasts with reported outcomes of transapical TAVI and raises the possibility that the subclavian approach may be preferable to transapical access in patients with peripheral vascular disease.

We conclude that TAVI via the subclavian artery is a safe and feasible alternative in patients without suitable femoral access.

Anouska M. Moynagh, MB
D. Julian A. Scott, MD
Andreas Baumbach, MD
Ali Khavandi, MB
Stephen J. Brecker, MD
Jean-Claude Laborde, MD
Sue Brown, BSc
Saqib Chowdhary, PhD
Duraisamy Saravanan, MB
Peter A. Crean, MD
Sinead Teehan, BNS
David Hildick-Smith, MD
Uday Trivedi, MD
Saib S. Khogali, MD
Moninder S. Bhabra, DM
David H. Roberts, MD
Kenneth P. Morgan, MB
***Daniel J. Blackman, MD**
for the UK CoreValve Collaborative

*Department of Cardiology
Leeds General Infirmary
Great George Street
Leeds, LS1 3EX
United Kingdom
E-mail: daniel.blackman@leedsth.nhs.uk

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Please note: Drs. Blackman, Brecker, and Hildick-Smith are proctors for Medtronic CoreValve. Dr. Laborde is a consultant for Medtronic CoreValve.

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Letters to the Editor

Multicenter Experience With Extraction of the Sprint Fidelis Implantable Cardioverter-Defibrillator Lead

We read with interest the recent multicenter report of the safe extraction experience with the Sprint Fidelis lead (Medtronic, Minneapolis, Minnesota) (1). Our single-center experience has been similar with no major complications in a series of 103 Fidelis extractions. We agree with the authors that the time has come to reconsider the recommendations for Fidelis lead management in light of this and other data. In addition to the established relationship between shock frequency and mortality (2), the morbidity of lead failure in these patients is severe and psychologically long-lasting, often leading to significant disability (3); this, coupled with the recently reported exponential increase in Fidelis lead failures over time, suggests that routine advice at the time of pulse generator replacement should now be to electively remove all normally functioning Fidelis leads (4). Because the risk of system infection is assumed by opening the pocket to replace the pulse generator, there is essentially no additional risk except that related