Towards "Primary" TAVI: Transcatheter Aortic Valve Implantation without Computerised Tomography, Transoesophageal Echocardiography or General Anaesthesia

Does Retrospective Data Provide Support for the Concept?

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Abstract

Background: In the elective setting, advanced adjunctive technology is appropriately used to aid TAVI. However, extensive pre-procedural work-up may not be possible in an acute setting.

Methods: We examined retrospective data from early TAVI practice to inform the concept of "primary" acute TAVI. Data was examined from two UK TAVI centres (2007-2012) prior to routine use of computerised tomography (CT). 30-day and 1 year clinical outcomes were assessed. Mortality tracking was obtained as of December 2012.

Results: 384 underwent TAVI at the two sites during this period. Patients were aged 81.4±7.0 years. 46.3% were male. Logistic EuroSCORE was 19.2±11.6. Peak aortic valve gradient and aortic valve area were 79.7±25.2mmHg and 0.62±0.20cm2 respectively. Aortic annular size was assessed by transthoracic echo (TTE; 73.4%) or transoesophageal echo (TOE; 24.5%) and was 23.1±2.4mm. Iliofemoral assessment was by invasive contrast angiography (99.5%). Procedures were performed under local anaesthetic (39.1%), local anaesthetic and anaesthetic sedation (46.0%), or general anaesthesia (14.9%). Device implantation was predominantly with the CoreValve self-expanding prosthesis (87.7%), via the femoral approach (90.7%). Procedural imaging was TTE (85%), TOE (3.4%), or none (11.6%). Device implantation success rate was 96.1%. Procedural complications included death (0.8%) and emergency valve-in-valve implantation (3.1%). Aortic regurgitation ≥grade2 (moderate/severe) was observed in 12.5%. Mortality rates were 9.3%, (30-day) and 15.2% (one-year).

Conclusion: A minimalist approach to TAVI does not offer contemporary levels of procedural success. A 95% success rate may be considered acceptable in emergency or urgent settings. A self-expanding prosthesis may be particularly suited to this clinical scenario.

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Introduction

Aortic stenosis affects 5% of people over the age of 75 years [1]. Left untreated, prognosis is poor. Trans-catheter aortic valve implantation (TAVI) has become an established treatment for patients with

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severe symptomatic aortic stenosis who are at an intermediate or high risk for surgery [2, 3].

Patient selection remains fundamental to achieving successful outcomes with TAVI. A key step in the selection process is systematic anatomical work-up from access site to implantation site using multi-modality imaging. The most important aspect of anatomical screening involves assessment of the aortic valvular complex and the peripheral arterial vasculature, allowing identification of the optimal prosthesis size and the most appropriate access route. In the elective setting, multi-slice computed tomography (MSCT) of the aortic valve complex, aorta, and iliofemoral vessels is the gold standard assessment [4]. General anesthesia (GA) is usually required when transesophageal echocardiography (TEE) is used, both for the comfort of the patient and to maintain a secure airway [5].

However, patients with severe aortic stenosis may present as urgent or emergency cases and be unable to undergo standard investigations due to clinical instability or renal dysfunction. Balloon aortic valvuloplasty "bridging" to TAVI may be used but is not low-risk in this setting [6]. The use of emergency TAVI is increasing [7-11].

During the early use of TAVI, computed tomography (CT) pre-assessment was not routine. We used retrospective data to analyze whether a minimalist approach to TAVI, with minimal use of CT, TEE, and GA, could yield reasonable TAVI outcomes and thus whether this approach could be appropriately used in urgent or emergency settings as "primary" TAVI.

Materials and Methods

Patient Population

The study population comprised 384 consecutive patients from two high-volume centers (Brighton and Belfast) in the United Kingdom over a 5-year period (2007–2012). Patients were assessed using iliofemoral angiography and TTE. MSCT or TEE was used in only a minority of cases during this period. Valve sizing was based on a combination of TTE annular measurements (which provide an anteroposterior measurement) and the aortogram (which provides a lateral measurement). The optimal implant was derived from aortography starting in the anterior-posterior/

caudal 15° projection, adjusting according to the initial image. A self-expanding CoreValve prosthesis was used in most cases, and the degree of oversizing was at the discretion of the operators.

All TAVI case data were entered prospectively into local dedicated databases based on a predetermined dataset agreed upon by the Society for Cardiothoracic Surgery in Great Britain and Ireland and the British Cardiovascular Intervention Society. This included information on patient demographics, risk factors, and outcome measures. Data consistency was assured by internal audit undertaken independently. Peri-procedural and post-procedural complications were reported according to definitions defined within the national dataset at the time [5]. All data were cross-checked prior to uploading to the Central Cardiac Audit Database. Mortality tracking was obtained via the Medical Research Information Service for the English cohort and via the General Register Office of Northern Ireland for the Northern Irish cohort. Mortality tracking was successful in 100% of cases.

Endpoints

The primary endpoint of the study was all-cause mortality assessed at 30 days and 1 year. The secondary endpoint was in-hospital major adverse cardiovascular events (MACE), defined as a composite of in-hospital death, myocardial infarction, and stroke.

Definitions

Device success was defined as implantation of a single functioning prosthetic valve within the aortic annulus, with stable hemodynamics, absence of severe paravalvular aortic regurgitation, and no peri-procedural mortality or conversion to emergency open valve surgery. Safety and efficacy endpoints were defined using Valve Academic Research Consortium (VARC) definitions [7].

Statistical Analysis

Categorical data are presented as percentages, and comparisons between groups were performed using Chi-square tests. Continuous data are presented as mean ± standard deviation (SD) or median (interquartile range), and comparisons between groups were performed with two-sample t-tests. Time-to-event data analysis was performed using Cox propor-

tional hazards models. A Kaplan-Meier survival curve was drawn to assess differences between groups for time-to-event data. Analyses were performed using Stata 10.1 (StataCorp, College Station, TX, USA).

Results

Patient Demographics and Pre-Procedural Characteristics

Baseline demographics including risk factors are shown in Table 1. Patients were aged 81.4 ± 7.0 years, and 46.3% were male. Mean logistic EuroSCORE was 19.2 ± 11.0. Approximately one-quarter of patients (28.8%) had significant coronary artery disease involving at least one epicardial coronary artery, 15.8% had extensive aortic calcification, and mean creatinine was 127.7 ± 80 mmol[-1].

TAVI was indicated for significant aortic stenosis in 90.3% of cases, aortic regurgitation in 4.7%, and mixed aortic valve disease in 5.0%. "Valve-in-valve" due to previous surgical bio-prosthesis failure represented 5.7% of cases, and 1.8% of cases were for true bicuspid valve stenosis (Table 2).

Pre-procedural assessment of the aortic valve complex, including annular measurement, was made by TTE (73.4%), TEE (24.5%), or MSCT (0.5%). Mean annular diameter in the overall patient cohort was 23.1 ± 2.4 mm. Mean peak aortic gradient was 79.7 ± 25.2 mmHg, and mean valve area was 0.62 ± 0.20 cm² (Table 2). Analysis of vessel diameter, tortuosity, and calcification was made by iliofemoral angiography (99.5%) or MSCT (0.5%; Table 2).

With regard to procedural anesthesia, GA was used in 14.9% of cases, usually for "surgical" approaches to TAVI. Most procedures were performed under local anesthesia (lignocaine 1%) with either intravenous paracetamol (39.1%) or conscious sedation (remifentanil/propofol; 46%).

Peri-Procedural Characteristics

Peri-procedural characteristics are shown in Table 2. Most patients (87.7%) underwent TAVI using the self-expanding CoreValve prosthesis (Medtronic CoreValve System, Medtronic, Luxembourg). Procedures were performed via the retrograde transfemoral (90.7%), subclavian (4.9%), axillary (0.5%), direct aortic (2.3%), or trans-apical approach (1.3%). Other

Table 1. Patient demographics

Characteristic		TAVI N=384
Age yr (mean±SD)		81.4 ±7.0 (384)
Male sex (%) no./total no.		46.3 (177/382)
Height cm (mean±SD)		165±9.3
Weight kg (mean±SD)		74.1±15.2 (382)
Caucasian		99.4 (382/384)
Logistic EuroSCORE (mean±SD)		
NYHA class (%) no./total no.		
	II	9.9 (38/383)
	II	66.3 (254/383)
	IV	22.5 (86/383)
Coronary artery disease (%) no./total no.		
	Left main stem	2.4 (9/381)
	1 vessel with diameter stenosis >50%	13.1 (50/382)
	2 vessel with diameter stenosis >50%	7.3 (28/382)
	3 vessel with diameter stenosis >50%	6.0 (23/382)
Extensive calcification of the acending aorta (%) no./total no.		15.8 (60/380)
Previous myocardial infarction (%) no./total no.		23.8 (91/383)
Previous intervention (%) no./total no.		
	Coronary artery bypass surgery	21.7 (83/382)
	Surgical valve replacement	6.5 (25/382)
	Other operation requring opening of the pericardium	1.8 (7/382)
	Percutaneous coronary intervention	24.0 (92/383)
	Balloon aortic valvuloplasty	10.2 (39/384)
Diabetes disease (%) no./total no.		21.4 (82/383)
Pulmonary disease (%) no./total no.		
	Asthma	19.3 (74/383)
	Chronic obstructive pulmonary disease	3.7 (14/383)
Neurological disease (%) no./total no.		
	Transient ischaemic attack	4.7 (18/384)
	Cerebrovascular accident	8.9 (34/384)
	Other neurological condition	3.9 (15/384)
Peripheral vascular disease (%) no./total no.		25.5 (97/380)
Permenant pacemaker (%) no./total no.		
	Pre TAVI prophylaxis	6.0 (23/383)
	Previous PPM insertion	3.4 (13/383)
Atrial fibrillation (%) no./total no.		18.8 (72/383)
Creatinine (mean±SD)		127.7±80.0 (378)

NYHA = New York Heart Association; TAVI = Transcatheter aortic valve implantation; PPM = Permanent pacemaker

Table 2. Pre-procedural characteristics.

Pre-procedural characteristics	TAVI N=384
Heart team meeting (%) no./total no.	100 (384/384)
Primary reason for TAVI (%) no./total no.	
High risk for surgical AVR	65.0 (249/383)
Formally turned down for surgical AVR	30.6 (117/383)
Patient refused surgical AVR	4.4 (17/383)
Aortic valve aetiology (%) no./total no.	
Degenerative	89.8 (344/383)
Rheumatic	2.3 (9/383)
Failed bioprosthesis	5.7 (22/383)
Bicuspid	1.8 (7/383)
Aortic valve pathology (%) no./total no.	
Stenosis	90.3 (346/383)
Regurgitation	4.7 (18/383)
Mixed	5.0 (19/383)
Pre-procedural assessment of the aortic valve complex	
Aortic annular measurement method (%) no./total no.	
TTE	73.4 (281/383)
TOE	24.5 (94.383)
Contrast aortography	1.6 (6/383)
CT with valve perimetry	0.5 (2/383)
Aortic valve measurements (mean±SD)	
Aortic valve area - cm2	0.62±0.2 (380)
Peak aortic valve gradient - mmHg	79.7±25.17 (382)
Aortic annular diameter - mm	23.1±2.4 (381)
Left ventricular function (%) no./total no.	
Good 50-60	79.8 (305/382)
Moderate 30-50	14.9 (57/382)
Poor <30	5.2 (20/382)
Pulmonary hypertension (%) no./total no.	
PA systolic >60mmHg	13.0 (50/384)
Pre-procedural assessment of the illiofemoral vessels	
Contrast illiofemoral angiography	99.5 (383/381)
CT	0.5 (2/383)
Anaesthesia	
Local anaesthetic and IV paracetmaol	39.1 (150/383)
Local anaesthetic and conscious sedation	46.0 (176/383)
General anaesthesia	14.9 (57/383)

AVR = aortic valve replacement; TTE = transthoracic echocardiogram; TOE = transoesophageal echocardiogram
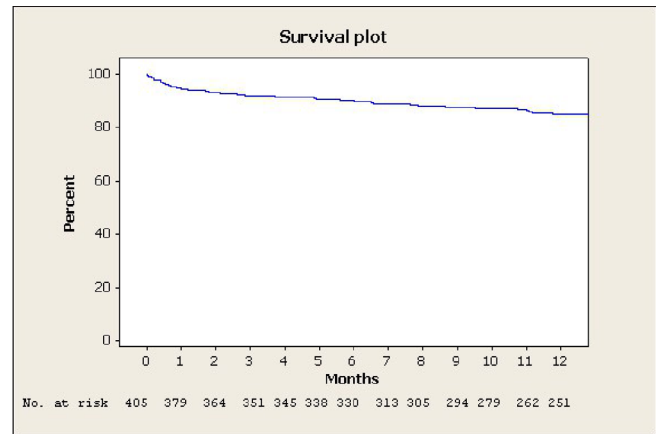
Figure 1. Kaplan-Meier survival curve for all patients to 1 year.

valve systems used were the Edwards Sapien (Edwards Life Science, Irvine, CA, USA) in 7.3% of cases and the Portico valve (St. Jude Medical, Minneapolis, MN, USA) in 5.0% of cases. Most (86%) patients underwent percutaneous pre-closure using the Prostar vascular closure system (Perclose Inc., Menlo Park, CA, USA).

Implantation was performed under contrast aortography (100%) with or without additional TTE (85%). Peri-procedural TEE was utilized in 3.4% of cases. Post-procedure para-valvular aortic regurgitation was assessed using hemodynamics, TTE, and contrast aortography.

Device Success and Complications

Device implantation success was achieved in 96.1% of cases (Table 4). Three patients (0.8%) died intra-procedure. Twelve patients (3.1%) required emergency second valve implantation at the time of the index procedure for on-table severe paravalvular aortic regurgitation (PAR). No patient required conversion to emergency open valve surgery. Five patients (1.3%) required subsequent "valve-in-valve" implantation as a separate procedure.

In-hospital complications are detailed in Table 4. In-hospital MACE rate was 6.0%. The incidences of stroke and myocardial infarction were 2.0% and 0.3%, respectively. Post-procedural aortic regurgitation grade by fluoroscopic aortography was 0 (37.3%), 1 (45.6%), 2 (12%), or >2 (0.8%). Post-procedure aortic regurgitation grade by TTE was zero (36.2%), mild (52.2%), moderate (10%), or severe (0.5%). VARC-de-

Table 3. Pre-procedural characteristics.

Characteristics	TAVI N=384
Delivery approach	
Retrograde trans-femoral	90.7 (348/384)
Axillary	0.5 (2/384)
Subclavian	4.9 (19/384)
Trans-apical	1.3 (5/384)
Direct aortic	2.3 (9/384)
Delivery sheath size	
16g	0.5 (2/384)
18g	97.4 (374/384)
>20g	0.5 (2/384)
Valve manufacturer	
Medtronic CoreValve	87.7 (336/383)
Edwards Sapien	7.3 (28/383)
St Jude Portico	5.0 (19/383)
Valve Size (mm)	
23mm	6.8 (26/384)
26mm	45.8 (176/384
29mm	40.4 (155/384)
31mm	4.9 (19/384)
BAV prior to TAVI insertion	
Yes	85.2 (327/384)
No	14.6 (56/384)
BAV sizes (mm)	
18	8.8 (34/384)
20	21.3 (82/384)
22	36.7 (141/384)
25	14.3 (55/384)
26	2.1 (8/384)
28	0.8 (3/384)
Peri-procedural imaging - (%) no./total no.	
Contrast Aortography	100 (383/383)
Additional TTE	85.6 (328/383)
Additional TOE	3.4 (13/383)
No additional imaging	11.6 (42/383)
Post procedure aortic regurgitation by TTE	
0 (None)	36.2 (138)
I Mild)	52.2 (199/381)
II (Moderate)	10 (38/381)
III (Severe)	0.5 (2/381)

Table 3 (cont.). Pre-procedural characteristics.

Characteristics	TAVI N=384
Post procedure aortic regurgitation by fluroscopy	
0 (None)	37.3 (140//381
I Mild)	45.6 (171/381
II (Moderate)	12 (45/381
III (Severe)	0.8 (3/381
Vascular closure technique	
Surgical closure	12.8 (49/384)
Pre-closure percutaneous device closure	80.0 (307/384)
Manuel pressure	5.2 (20/384)
Surgical closure and pre-closure percutaneous device closure	1.3 (5/384)
Median total volume of contrast administered (IQR) mls	180 (20-400)

TTE = transthoracic echocardiogram; TOE = transoesophageal echocardiogram

fined major and minor bleeding was seen in 3.7% and 5.8% of patients, respectively.

A few (3.4%) patients had a pre-existing permanent pacemaker. Some (6.0%) underwent pre-procedure pacing due to known right bundle branch block (overall rate 20.3%), and 14.3% required post-procedure in-hospital permanent pacing.

30-Day and 1-Year Mortality

Mortality at 30 days was 9.3%. Mortality at 1 year was 15.2% (n = 45/296). A Kaplan-Meier survival curve for the entire patient cohort is shown in Figure 1.

Discussion

This study reports a large consecutive and all-inclusive historical series of patients who underwent TAVI with first-generation self-expanding devices. This series is unique in that it captures every TAVI case performed at two high-volume centers that systematically used a minimalist approach before MSCT became the imaging gold standard. It includes the entire "learning curve" and early experience from these centers, with robust short and long-term follow-up achieved in 100% of patients.

Table 4. Success rate and complications.

	TAVI N=384
Device success	
(%) no./total no.	96.1 (369/384)
On table death (%) no./total no.	0.8 (3/384)
Emergency on table valve in valve implantation for severe AR (%) no./total no.	3.1 (12/384)
Conversion to emergency open valve surgery	
(%) no./total no.	0.0 (0/383)
In Hospital MACE (In hospital death/MI/CVA)	
(%) no./total no.	5.8 (23/384)
Post procedural VARC defined complications (30-day)	
Myocardial infarction (%) no./total no.	0.3 (1/383)
CVA/TIA (%) no./total no.	2.0 (8/383)
Device embolization (%) no./total no.	0.3 (1/383)
Tamponade (%) no./total no.	2.1 (8/384)
Conduction abnormality requiring pacing (%) no./total no.	14.3 (55/384)
AR>2+ moderate/severe - TTE (%) no./total no.	10.5 (40/381)
AR>2+ moderate/severe - angiographic (%) no./total no.	12.8 (48/381)
Major and minor vascular access site injury (%) no./total no.	3.7 (14/383)
Major and minor bleeding (%) no./total no.	6.1 (23/377)
Haemofiltration/dialysis (%) no./total no.	1.0 (4/380)
Subsequent valve in valve implantation (%) no./total no.	1.3 (5/384)
Death (%) no./total no.	
30 day (%) no./total no.	9.3 (36/384)
1 year (%) no./total no.	15.2 (45/296)

CVA = cerebrovascular accident; TIA = transient ischaemic attack; AR = aortic regurgitation; TTE = transthoracic echocardiogram

Principle Findings

Within our patient cohort, 30-day mortality was 9.3%. This is comparable to rates in other historical registries: 7.1% in the UK TAVI registry [12], 10.4% in the Canadian registry [13], 8.5% in the SOURCE registry [14], 12.7% in the FRANCE registry [15], and 8.2% in the German registry [16]. Our all-comer results are also similar to those achieved in the randomized

PARTNER B (5.0%) [17] and PARTNER A (5.2%) [18] cohorts. Our 1-year mortality was 15.8%, which is comparable to rates in the overall UK TAVI registry, in which mortality was 21.4% at 1 year and 26.3% at 2 years [12].

While we do not advocate "routine use" of this technique, this minimalist method may represent an option for patients who present in an urgent or emergency setting. Our data suggest that reasonable results can be obtained using this strategy. Indeed, one might hope for improved results now that repositionable self-expanding prostheses are available.

Potential Roles for Primary TAVI

Bridging the acute aortic stenosis patient with balloon aortic valvuloplasty is often undertaken in the absence of full assessment, but this strategy is not ideal. While it may stabilize an acutely unwell patient, balloon aortic valvuloplasty is not a low-risk procedure. Contemporary data from the UK registry suggest a procedural complication rate of 6.3%, comprising death (2.4%), blood transfusion ≥ 2 U (1.2%), cardiac tamponade (1.0%), stroke (1.0%), vascular surgical repair (1.0%), coronary embolism (0.5%), and permanent pacemaker (0.2%). In this registry, mortality was 13.8% at 30 days and 36.3% at 12 months [6]. Furthermore, if primary TAVI is performed at the time of index admission, there would be no need for a second intervention, limiting patient risk and overall cost.

Two small-volume single-center studies support this idea. Landes et al. recently reported 27 cases of urgent TAVI in patients admitted with refractory and persistent heart failure despite optimal medical therapy. Patients were more likely to be frail and have higher Society of Thoracic Surgeons score or EuroSCORE. Pre-procedural assessment used fewer imaging modalities, yet implantation success remained high and reached 96.3%, with no difference in rate of peri-procedural complications (VARC-2) compared with that among 342 elective patients. The patient groups had similar 30-day mortality rates and MACE [10].

Frecker et al. reported outcomes from 27 patients who underwent emergency TAVI presenting with cardiogenic shock due to acutely decompensated aortic stenosis. Three patients died within 72 hours of successful valve deployment, and a further six died within 1 month, giving a 30-day mortality of 33.3%,

which was significantly higher than that for electively treated patients (7.7%, $P < 0.0001$). Estimated 1-year survival was 59.3% in emergency and 82.7% in electively treated patients ($P = 0.0009$) [11].

Valve Type

Our data suggest that a self-expanding prosthesis may have advantages. First, current iterations are 14-F, which may be advantageous if no iliofemoral imaging has been performed. Second, minimizing rapid pacing make be useful if there are concerns about hemodynamic stability. Third, the risk of annular rupture from over-sizing is rare with self-expanding versus balloon-expandable valves, which are more dependent on accurate annular sizing as well as the degree and extent of calcification. Finally, if treating a failed surgical bioprosthesis, there is the advantage of supra-annular valve function and lower post-procedural gradients with self-expanding valves. The latest iteration also offers the advantage of being repositionable.

Limited Pre- and Peri-Procedural Imaging

One major concern with primary TAVI is the limited use of pre- and peri-procedural imaging, which plays a pivotal role in planning. MSCT is now considered the gold standard for pre-procedural TAVI assessment, and expert consensus guidelines exist on CT imaging prior to TAVI [4]. MSCT has several advantages over TTE and fluoroscopy-based staging techniques. These include a "single test assessment" of the vascular access site and the aortic valve complex and more accurate annular sizing and assessment of the aorta, which may impact the degree of post-procedural aortic regurgitation and the ability to predict appropriate fluoroscopic implant projections.

Echocardiography, by contrast, tends only to identify the antero-posterior diameter of the aortic annulus, which is smaller on average than the lateral-to-lateral aortic annular diameter. With a self-expanding prosthesis (as used in most patients in this study), allowance can be made for potential discrepancies and appropriate up-sizing when measurements are borderline. Irrespective, a retrospective study by Mylotte et al. found that CT-based annular analysis revealed incorrect CoreValve size selection by TTE in up to 50% of patients [19].

Paravalvular Aortic Regurgitation

There is now clear data to suggest that the precision of the annular measurement may impact the degree of PAR seen post-implant [20]. PAR ≥ 2+ (moderate to severe) is an independent predictor of short- and long-term mortality [21]. Therefore, minimizing PAR post-TAVI is important. In this series using a minimalist approach, 12.5% of patients exhibited PAR > 2+. This rate would need to be reduced if primary TAVI is to become a useful tool. Repositionable valves should prove valuable in this respect.

GA or Sedation

From a procedural aspect, limited use of TEE allows for conscious sedation rather than GA, which is associated with shorter implant time, decreased stay in the intensive care unit, and faster discharge from the hospital [22, 23].

Durand et al. undertook TAVI using the Edwards Sapien XT prosthesis in 151 consecutive patients using local anesthesia and fluoroscopy only. Conversion to GA was required in 3.3% of patients and was related to complications. Device success was similar to that in our series (95.4% vs. 96.1%), with similar 30-day mortality (6.6% vs. 9.3%) [24].

Cost-Effectiveness

TAVI is a cost-effective treatment. Cost per life-year gained is well within accepted values for commonly used cardiovascular technologies irrespective of geography and definition [25]. Primary TAVI should further impact cost-effectiveness as it limits the patient to one definitive treatment episode. Attizani et al. reported the use of a minimally invasive strategy in an elective population, defined as local anesthesia with or without conscious sedation, performed in the catheter lab without TEE guidance. They found this strategy to be cost-effective, with a cost saving of $16,000 per case compared with standard care [26].

Conclusion

A minimalist approach to TAVI does not offer contemporary levels of procedural success, but a 95% success rate may be considered acceptable in emergency or urgent settings. A self-expanding prosthesis may be particularly suited to this clinical scenario.

Conflict of Interest

Comment on this Article or Ask a Question

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