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Establishment of a transcatheter aortic valve program and heart valve team at a Veterans Affairs facility

Faisal G. Bakaeen, M.D.[a,b,c,*], Biswajit Kar, M.D.[b,c,d], Danny Chu, M.D.[a,b,c], Lorraine D. Cornwell, M.D.[a,b], Alvin Blaustein, M.D.[b,d], Glenn N. Levine, M.D.[b,d], David Paniagua, M.D.[b,c,d], Hani Jneid, M.D.[b,d], Corey Jensen, M.D.[b], Prasad V. Atluri, M.D.[b], Carlos F. Bechara, M.D.[b,e], Panos Kougias, M.D.[b,e], Chris Pawlak, M.H.A.[b], Biykem Bozkurt, M.D.[b,d], Thomas A. Burdon, M.D.[f], Blase A. Carabello, M.D.[b,c,d]

[a]Division of Cardiothoracic Surgery, Michael E. DeBakey Department of Surgery, Baylor College of Medicine, OCL 112, 2002 Holcombe Blvd., Houston, TX 77030, USA; [b]Michael E. DeBakey Veterans Affairs Medical Center, Houston, TX, USA; [c]Texas Heart Institute at St. Luke's Episcopal Hospital, Houston, TX, USA; [d]Department of Cardiology, Baylor College of Medicine, Houston, TX, USA; [e]Division of Vascular Surgery, Baylor College of Medicine, Houston, TX, USA; [f]Department of Cardiothoracic Surgery, Stanford University, Palo Alto, CA, USA

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Abstract

BACKGROUND: The US Food and Drug Administration recently approved a transcatheter aortic valve for patients for whom open heart surgery is prohibitively risky.

METHODS: A multidisciplinary heart valve team partnered with administration to launch a transcatheter aortic valve replacement (TAVR) program. Clinical registries were used to show robust valve caseloads and outcomes at our Veterans Affairs (VA) facility and to project future volumes. A TAVR business plan was approved by the VA leadership as part of a multiphase project to upgrade and expand our surgical facilities.

RESULTS: The heart valve team completed a training program that included simulations and visits to established TAVR centers. Patients were evaluated and screened through a streamlined process, and the program was initiated successfully.

CONCLUSIONS: Establishing a TAVR program at a VA facility requires a multidisciplinary team with experience in heart valve and endovascular therapies and a supportive administration willing to invest in a sophisticated infrastructure.

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More than 9.3 million veterans are 65 years of age or older.[1] In the elderly, calcific aortic stenosis (AS) is the chief cause of surgical valve replacement in the Western world. If left untreated, AS is lethal; the average survival after symptom onset is 3 years.[2]

Aortic valve replacement (AVR) is the standard of care for patients with severe symptomatic AS. However, not all

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* Corresponding author. Tel.: +1-832-489-3202; fax: +1-713-794-7352.

E-mail address: fbakaeen@bcm.edu

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patients with severe AS are referred for surgical consideration, and some of those referred are not deemed surgical candidates by the evaluating surgeon. Reports from our center[3] and another Veterans Affairs (VA) hospital[4] have stated that only 60% of patients with severe AS undergo AVR. Likewise, reports from academic centers in the United States indicate that only half of patients with severe AS undergo AVR.[5,6] In general, older age, high surgical risk, comorbidities, and poor patient functional status or frailty appear to be the most common reasons why physicians choose medical treatment over surgery for their AS patients.

The landmark Placement of AoRtic TraNscathetER Valves trial[7] enrolled patients with severe symptomatic AS who were deemed to be at too high of a risk to undergo conventional AVR. Patients were assigned randomly to medical therapy or transcatheter AVR (TAVR) with the Sapien valve (Edwards Lifesciences, Irvine, CA). The results associated TAVR with a marked reduction in all-cause mortality at 1 year. This finding was the basis for the US Food and Drug Administration (FDA) approval, in November 2011, of the Sapien Transcatheter Heart Valve for treating AS patients who are not eligible for traditional AVR.[8] It is estimated that 40,000 patients worldwide have undergone TAVR with various transcatheter devices.[9]

The integration of TAVR into a patient care plan is complex. A recent collaborative expert consensus document elegantly outlined the current state of the evidence supporting the use of TAVR and the steps necessary for the responsible adoption and diffusion of this promising technology.[9] Our hospital undertook an ambitious effort to launch a TAVR program and was the first VA facility to use the commercially available Sapien valve to treat veterans with severe AS. Here, we highlight unique considerations in the treatment of AS in the veteran population. We also identify the challenges involved in initiating a TAVR program in the VA system, and we describe our approach to these challenges.

Methods

Producing data in support of TAVR at our facility

A preliminary examination of echocardiographic and catheterization laboratory case logs and the national VA cardiothoracic surgery database (Continuous Improvement in Cardiac Surgery Program [CICSP])[10–12] was performed to estimate heart valve caseloads and AS treatment outcomes at our facility. In addition, these data were used to project future volumes and patterns of referral.[3] A prospective screening log was created to track all patients with severe AS who were not candidates for traditional AVR and who could benefit from TAVR.

Putting together a multidisciplinary heart valve team

After the results of the Placement of AoRtic TraNscathetER Valves trial[7] were published, we initiated our effort to launch a TAVR program at our hospital in anticipation of the FDA approval of the Sapien valve. A multidisciplinary Heart Valve Team (HVT) was formed, consisting of cardiothoracic surgeons, interventional cardiologists, cardiologists with expertise in valvular disease and heart failure, vascular surgeons, anesthesiologists, cardiovascular imaging specialists, and radiologists, partnered with a high-level administrator who served as an advocate for the project. Lead members of this team were tasked to visit a TAVR center of excellence to determine what infrastructure, imaging, and hybrid operating room (OR) resources would be needed to launch a TAVR program. A weekly valve clinic was instituted that streamlined the care of all patients with valvular heart disease. In addition, the HVT met once a week to discuss potential TAVR cases.

The business plan

The VA health system comprises 21 Veterans Integrated Service Networks (VISNs) that cover different geographic regions that cross state lines. Cardiac surgery is performed at 42 facilities, and the Houston VA hospital is 1 of 3 that perform heart surgery in VISN 16. A business plan to launch a TAVR program was prepared that included a needs assessment and a cost analysis. The projected number of patients who would be outsourced to nearby hospitals if we did not have TAVR at our facility was 20 in 2012, 30 in 2013, and 40 in 2014. The private cost for this procedure is $85,000. Therefore, during the first 3 years of the program, the Houston VA will save $7.6 million in fees by having the capability to perform this procedure in-house.

Our hospital administration and VISN 16 leadership approved the business plan as part of a multiphase project to upgrade and expand our surgical facilities, including a hybrid OR and imaging equipment. The business proposal included physicians, nurses, respiratory therapists, physical therapists, and midlevel providers, including a TAVR coordinator.

Approaching the TAVR vendor

A detailed presentation was made to Edwards Lifesciences in early 2011 to convince the company to make the Houston VA one of the sites at which the Sapien valve would be used commercially after FDA approval. With approximately 70 aortic valve cases a year and a consistently low observed-to-expected mortality ratio according to the CICSP risk model, our hospital had a good track record. Also, we previously showed that our cardiac surgery outcomes compare favorably with those of nongovernmental hospitals.[13,14]

Over a period of 6 months, Edwards' representatives made multiple visits to our facility, meeting key clinical and