Development of a Veterans Affairs Hybrid Operating Room for Transcatheter Aortic Valve Replacement in the Cardiac Catheterization Laboratory

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IMPORTANCE Transcatheter aortic valve replacement (TAVR) revolutionized the treatment of aortic stenosis. Developing a TAVR program with a custom-built hybrid operating room (HOR) outside the surgical operating room area poses unique challenges in Veterans Affairs (VA) institutions.

OBJECTIVE To present the process by which the San Francisco VA Medical Center developed a VA-approved TAVR program, in which an HOR exists in a cardiac catheterization laboratory, as a guideline for future programs.

DESIGN, SETTING, AND PARTICIPANTS Retrospective review of each required approval process for developing an HOR in a cardiac catheterization laboratory in a VA designated for complex surgery. Participants included San Francisco VA Medical Center health care professionals and individuals responsible for new program initiation in VA institutions.

EXPOSURES External reviews by industry vendors, the VA Central Office, and the Office for Construction, Facilities, and Management and an internal Healthcare Failure Mode and Effect Analysis.

MAIN OUTCOMES AND MEASURES The timeline for each process.

RESULTS Developing a TAVR program required vetting and approval from industry vendors, who provided training and expertise. Architectural plans for construction of the HOR began in 2010-2011, followed by approval from Edwards Lifesciences, Inc, in 2012 and fundamentals training on February 8 and 9, 2013. Following a pilot launch of the first VA TAVR program at the Houston VA Medical Center, subsequent programs were required to submit a plan to the VA Central Office for proposed restructuring of their clinical programs. After the San Francisco VA Medical Center proposal submission on February 3, 2013, a site visit consisting of a National Chief of Catheterization Laboratory Managers, a cardiac surgeon, and an interventional cardiologist with TAVR experience was conducted on April 12, 2013. During construction, HOR plans were inspected by the Office for Construction, Facilities, and Management followed by on-site inspection on August 8, 2013, to assess the adequacy of the HOR, newly built restricted corridors, equipment storage areas, and altered staff and patient flow patterns. Last, a Healthcare Failure Mode and Effect Analysis was performed to mitigate any negative effects of the HOR not being colocated in the surgical operating room area. Approval was then granted on November 13, 2013. Our first 10 TAVR cases were successfully completed as of April 2, 2014.

CONCLUSIONS AND RELEVANCE The primary factor for development of a successful TAVR program is integration of the heart valve team. Particular adaptations to the cardiac catheterization laboratory environment are required to accommodate an uncompromised HOR in which cardiac and vascular surgeons can be as comfortable as their interventional cardiology colleagues.

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Transcatheter aortic valve replacement (TAVR) has demonstrated significant improvement in survival compared with medical therapy for inoperable patients with severe symptomatic aortic stenosis in the Placement of Aortic Transcatheter Valves (PARTNER)1,2 and CoreValve Extreme Risk Iliofemoral US Pivotal trials.3 Compared with surgical aortic valve replacement in patients with aortic stenosis and high risk of morbidity or mortality, TAVR demonstrated equivalent survival results with the Edwards SAPIEN transcatheter heart valve (Edwards Lifesciences, Inc)4,5 and better survival with the CoreValve System (Medtronic, Inc),6 although the risk assessment methods differed somewhat between the 2 trials. In 2012, a multisociety guideline from the Society for Cardiovascular Angiography and Interventions (SCAI), American Association for Thoracic Surgery (AATS), Society for Cardiovascular Angiography and Interventions (SCAI), and Society for Thoracic Surgeons (STS) was created to define operator and institutional requirements for developing TAVR programs in the United States.7 This guideline has been used by the Centers for Medicare and Medicaid Services to determine TAVR reimbursement. As such, the development of TAVR programs in the private and academic sectors have been well established, irrespective of whether the hybrid operating room (HOR) exists in the surgical suite or cardiac catheterization laboratory (CCL). On the other hand, such guidelines had not been developed in the Veterans Affairs (VA) medical facilities. The Methodist E. DeBakey VA Medical Center in Houston, Texas, was the first VA institution in the country to establish a TAVR program using a US Food and Drug Administration-approved device and performed their first case on December 21, 2011. They published8,9 their experiences establishing a TAVR program in the VA institution as well as their early results. This pilot experience was relied on to develop formalized processes for evaluating VA institutions that seek to develop an approved TAVR program. Our objective was to conduct a retrospective review to outline the process and timeline for developing a VA-approved TAVR program at the San Francisco VA Medical Center (SFVAMC), where the HOR and its accompanying infrastructure are in the CCL rather than surgery area, as a guide for future programs.

Methods

Industry Evaluation and Approval

Similar to non-VA institutions, the ability of any program to offer TAVR depends on the initial evaluation and approval of the facilities, operators, a heart valve team, institutional commitment, and other factors provided by the relevant industry partners. The SFVAMC, with the University of California San Francisco Medical Center as an academic partner, applied to Edwards Lifesciences, Inc, to be a TAVR site on September 29, 2011. Factors considered included the total volume of percutaneous coronary interventions, the total volume of heart valve surgical procedures and subset of surgical aortic valve replacements at the institution and by each surgeon, the number of structural heart interventions and endovascular abdominal and thoracic aortic aneurysm repairs, whether there was a multidisciplinary heart valve clinic, the educational outreach and referral patterns, identification of the dedicated echocardiographer and cardiac anesthesiologist, whether the team worked collaboratively, and whether there was an HOR. The Edwards SAPIEN TAVR system was approved by the US Food and Drug Administration on November 2, 2011. In 2012, Edwards Lifesciences, Inc, performed a site visit of our initial proposed TAVR room, as well as the new dedicated HOR that was being constructed, and approved the TAVR procedures in both rooms. They also met with our team several times to initiate the process. Members of the TAVR team, including specialists in cardiology, cardiac surgery, radiology, and anesthesia, along with CCL and operating room (OR) staff completed online training courses in November 2012. The site launch was performed on January 10, 2013, and fundamentals training for the Edwards SAPIEN was attended on February 8 and 9, 2013.

HOR Planning

The planning and construction process for the new HOR began in 2011. While our initial plan was to modify a surgical OR to be an HOR, several factors influenced our choice to build the initial TAVR HORs in the CCL. An HOR already existed for vascular surgery in our surgical OR, but its fluoroscopic system required an upgrade for TAVR capability and the room was too small for cardiac surgery. While a lead-lined surgical OR the same size as our current cardiac surgical OR could be renovated, there were already plans in place to expand the surgical ORs by building above the emergency department. Although this construction was slated to take place in 2015, this large space was ideal for building 2 large HORs in the surgery department. Rather than taking an OR off-line to then be replaced within a few years, we opted to build within the CCL area, in which the storage area allowed for HOR construction without taking either CCL or surgical OR rooms off-line. Furthermore, since 2007, we had already built a large CCL with TAVR in mind that occurred before angiographic vendors began offering equipment specifically designed and labeled for HOR applications. This CCL had adequate space for anesthesia and perfusion and OR-grade air exchanges. Stainless steel ducting of the airflow was the only missing component at that time, so we took the opportunity to create 2 HORs in the CCL, first building the state-of-the-art HOR in the prior CCL storage space and then upgrading to stainless steel ducting in the prior CCL room. Our intention was never to choose between CCL and surgical suites; we had a long-term vision of creating 4 HORs, with 2 in the CCL and 2 in the surgery department.

VA Proposal for Restructuring Clinical Programs

While the Houston VA Medical Center was the first to initiate a TAVR, all subsequent TAVR programs, including those in the Houston VA Medical Center retrospectively, were considered new programs and required submission of a proposal for restructuring clinical services and programs to the VA Central Office. The description of and rationale for offering TAVR and its expected clinical effects were straightforward. The relevant aspects of this business plan related to the projected workload and the current and desired infrastructure to support the program. The proposed workload included the number of eli-
The VA Central Office formally evaluated our proposal and initiated a site visit that comprised 3 members—a cardiothoracic surgeon with TAVR experience, an interventional cardiologist with TAVR experience, and a nurse who was the National Chief of Catheterization Laboratory Managers and had substantial experience managing site visits for new programs (B.S.). An extensive site review was conducted that involved 11 sections: data collection, staffing allocation, clinical privileges, infection control standards, policy and procedure evaluation, radiation safety standards, cardiology reporting, emergency transportation planning, supply allocation, bed use and coding/billing for service, and joint commission itemized standards. Data collection was extensive and included the population base; number of hospital beds at each level of care; bed occupancy and diversion rates; catchment area; numbers of all cardiac procedures performed, including noninvasive diagnostically testing, hours of operation, volume per day, and associated full-time-equivalent positions for staffing; number of procedural rooms available per day; nursing level of experience and nurse to patient ratio at each level of care; available equipment; and similar information for other ancillary services, including radiology, vascular surgery, electrophysiology, cardiology clinics, pharmacy, and laboratory services. Infection control standards that were scrutinized to meet OR standards included features such as appropriate temperature and humidity control; airflow in liters per minute; stainless steel duct work; drop ceilings; scrub sinks; a dirty utility room; sterile storage areas; standard operating procedures and manuals for cleaning of equipment, ancillary items, and terminal cleaning of the room; and restricted and semirestricted areas to limit traffic. The full-site review resulted in a 43-page summary document prepared by the site visitors, together with a brief summary evaluation form that focused on the leadership support for TAVR; facility business plan, space, and workload; infrastructure and resources for preprocedural, intraprocedural, and postprocedural care; clinical operator training, credentialing, and expertise; and facility standards for care, clinical processes, and quality oversight.

**VA TAVR White Paper**

In June 6, 2013, the VA cardiology departments received a TAVR Working Group white paper that included internal guidelines for program development. Critical elements involved the heart valve team’s approach to care for patients with severe aortic stenosis, including a minimum of 2 on-site cardiologists and 2 on-site interventional cardiologists as well as echocardiographers with expertise in transesophageal echocardiograms, cardiac computed tomography and/or magnetic resonance imaging specialists, heart failure specialists, electrophysiologists, peripheral vascular interventionists, cardiology anesthesiologists, and a heart valve coordinator. On-site cardiac surgery and interventional cardiology programs were recommended in a VA medical center that was compliant with complex surgery requirements and whose ongoing quality monitoring did not suggest high outlier status in morbidity or mortality for 2 years before TAVR initiation. Suggested volume requirements included 100 or more career aortic valve replacements, 25 or more in 1 year, or 50 or more in 2 years and at least 20 in the year before TAVR initiation, along with experience with patients with high-risk surgical aortic valve replacement for the cardiovascular surgeon and 500 or more since training or 75 or more interventional cardiovascular procedures in the year before TAVR, with proficiency in structural heart disease interventions for the interventional cardiologist. An HOR was essential; it could be either in the OR or CCL, but it should be compliant with OR sterility and environmental criteria, with a fixed fluoroscopic imaging system, invasive hemodynamic monitors, and sufficient space.

**Results**

The SFVAMC submitted its proposal for clinical restructuring to the VA Central Office on February 3, 2013. Simulation exercises of TAVR procedures were performed using the entire CCL and OR teams on January 10, February 11, and February 25, 2013. These exercises were designed to simulate the TAVR procedure, and TAVR disaster drills were conducted to simulate complications requiring conversion to open surgery, including surgical aortic valve replacement, vascular complications, and sternotomy. The simulation on February 11, 2013, was built around a planned live balloon aortic valvuloplasty and was videotaped from 4 different vantage points for team review. The site visit was conducted on April 12, 2013. Key recommendations were to create a semirestricted area in the CCL such that OR attire was required in the peripheral support area of the restricted sterile HOR environment. Unnecessary traffic would thus be limited. This represented the single largest change in workflow for the CCL staff and others who visit the
laboratory regularly, such as housekeeping personnel, medical records clerks, family members, and consultation teams, all of whom had to adjust to the reality that no one could walk directly back to the control rooms except in approved scrubs or “bunny suits” and surgical hats. Furthermore, the storage area for sterile OR and catheterization supplies needed to be colocated in the CCL. Development of the semirestricted zone occurred just after the site visit; the blueprint is shown in the Figure.

On June 3, 2013, the Office of Construction, Facilities, and Management provided us with the HOR specifications recommended for the CCL, which included the aforementioned restricted zones and traffic patterns as well as policies and procedures for proper surgical attire, surgical hand antisepsis, skin antisepsis, maintenance of a sterile field, surgical counts, electrocautery, fire safety, care of contaminated instruments, environmental cleaning and disinfection, and waste disposal. Other important aspects involved adequate surgical lighting, line isolation monitors for each isolated power system, appropriate use and removal of anesthetic gases and equipment, and acceptable heating, ventilation, and air conditioning criteria, including room temperature and humidity control, proper air quality, air volume exchanges, and airflow. The Office of Construction, Facilities, and Management also created recommendations for designing an HOR in the CCL environment. One of the challenges noted was that the implementation time was typically 1 to 2 years from HOR planning to completion of construction. Design considerations included a ceiling height of 2.90 m to 2.97 m to accommodate the rigid vertical space requirements of the fluoroscopic imaging systems. Other room requirements included lead-lined walls, separate control and equipment rooms, increased ceiling support for the equipment booms, positive pressure and laminar airflow for OR-level sterility (the latter is not currently present in our surgical ORs), and adequate space for all support equipment and supplies (recommended as 83.61-130 m²). The second HOR, which was designed in 2011, was completed just before the Office of Construction, Facilities, and Management site visit on August 8, 2013, and met all the new design features, including the laminar airflow requirement, although the space was just less than the recommended 83.61 m² owing to the space premium at our facility. To compensate for this, no fixed cabinetry was installed in the room. Every supply cabinet is on wheels, and an adjacent area was created for additional carts to be immediately available outside the room. This creates a modular functionality that proves its value when the room is also used for vascular procedures, coronary procedures, pacemaker implantation, and implantable cardioverter-defibrillator implants, and other cases but requires additional organization, planning, and preparation for each case because no supplies remain in the room between cases.

Approval for the VA TAVR program was granted on October 18, 2013, contingent on completion of a Healthcare Failure Mode and Effect Analysis to mitigate any negative effects of the HOR not being colocated in the main surgical OR area. The Healthcare Failure Mode and Effect Analysis was used to determine risks and develop associated strategies to ensure proper surgical support should an open surgical conversion be necessary during a TAVR procedure in the HOR. The subprocess steps for evaluating failure modes were (1) preparation of a patient for TAVR, including readiness for an open surgical procedure; (2) provision for an open cardiac surgical procedure; (3) provision for vascular surgery; and (4) transportation from the HOR to the intensive care unit. Subprocess steps 1 and 4 did not require any additional actions beyond those already in place. Subprocess steps 2 and 3 were to provide checklists for each service that needed to bring equipment from the surgical OR to the CCL HOR. These checklists would be used before starting TAVR to ensure that all the equipment needed for surgery was present and functional. The checklist for anesthesia service was developed during the Healthcare Failure Mode and Effect Analysis process; the checklist for surgery service was already in existence for surgical aortic valve replacement conversion during the February simulation and was provided; the vascular surgery checklist was added; and the perfusion checklist for open cardiac surgery was provided for TAVR. A series of diagrams specific to the SFVAMC CCL HOR were constructed to delineate the location of equipment, supplies, and personnel at the start of TAVR to standardize room set-up during TAVR and for conversion to an open surgical procedure. The checklists and diagrams were incorporated into a standard operating procedure. A final simulation TAVR conversion to open surgical aortic valve replacement in the new HOR was performed on November 15, 2013, to finalize the Healthcare Failure Mode and Effect Analysis process. Since program approval from November 13, 2013, through April 2, 2014, our program has successfully performed 10 transfemoral TAVRs. Successful implantation occurred in 100% of patients, with no operative or 30-day mortality; 1 patient required a permanent pacemaker implantation.

Discussion

Since 2011, the VA institution has developed a rigorous evaluation process for developing a VA-approved TAVR program that exceeds and augments industry standards. Treatment of veterans with severe aortic stenosis using TAVR follows the expert consensus document developed by the SCAI/AATS/ACCF/STS in 2012. Similar to operator and institutional guidelines set forth by the SCAI/AATS/ACCF/STS, the VA TAVR guidelines were established by a VA interventional cardiologist, whose volume requirement was based on percutaneous coronary interventions rather than structural heart disease interventions. There was no difference in the surgeon's operative experience requirement.
Figure. Blueprint of the San Francisco Veterans Affairs Medical Center Cardiac Catheterization Laboratory
Semirestricted and Restricted Areas

Yellow areas represent the cardiac catheterization laboratory entrance and unrestricted area as well as the holding area. Green areas represent the 3 restricted cardiac catheterization laboratory rooms; room 3 is the hybrid operating room. Blue areas represent semirestricted corridors leading to restricted areas.
Regarding the construction of the HOR, the SCAI/AATS/ACCF/STS guidelines published in 2012 did not require an HOR, allowing the TAVR to be performed in the CCL or the HOR in the OR or a CCL.7,10 Most operators agree that an HOR yields the most ideal environment; however, in France, 72.7% of TAVRs occurred in a standard CCL, while only 16.5% occurred in an HOR and 10.8% in the OR.15 In contrast, in the United States, the STS and the American College of Cardiology Transcatheter Valve Therapy Registry12 demonstrated that only 14% of TAVRs were performed in a standard CCL, while 28% occurred in an HOR in a CCL and 57% occurred in an HOR in an OR. In the United States, most TAVRs were performed in HORs regardless of location, but many leading centers have HORs in both locations. We also have planned to establish HORs in both locations, although our surgical HOR will take longer to build using our existing ORs. Advantages and disadvantages exist for both OR and CCL locations. Advantages of having HORs in the surgical suites are that the sterile environment already exists, with all the equipment necessary for open cardiac surgical conversion when needed, and anesthetic gases and appropriate heating, ventilation, and air conditioning are in place. Disadvantages of having HORs in surgical suites are that rooms need lead-lined walls, ceilings must structurally support the fluoroscopy system's weight and be of sufficient height, and all the equipment from the CCL must be duplicated or brought up to deal with emergency endovascular procedures, including treatment of coronary occlusion or endovascular coverage for iliac rupture or dissection. Advantages of having HORs in CCLs are that the CCL layout is already in place for advanced angiography, with full CCL hemodynamic capability; the CCL is already lead-lined; and ceiling struts are already in place that are sufficient for the additional height and weight of the imaging systems. Disadvantages are the need to develop sterile and substerile areas and the need to transfer all the surgical equipment to the CCL for emergency conversion to open cardiac surgery.

Emergency cardiac surgery during TAVR is rare (1% of cases), and the 2 most common causes for conversion are valve embolization into the left ventricle and procedure-related aortic injury, including annular rupture and aortic dissection and perforation.12-15 The rate of mortality caused by emergency cardiac surgery during TAVR was extremely high, ranging from 46% to 67%.12-15 The highest mortality rate was observed in patients with aortic dissection or perforation (80%), followed by annular rupture (67%), myocardial perforation (50%), prosthesis embolization (40%), and severe aortic regurgitation (33%).15 Of 24 patients who received emergency conversions in a German TAVR registry, 8 underwent surgery in an HOR in a CCL (2 deaths), 8 underwent surgery in a standard CCL (6 deaths), and 8 were transported to the OR for surgery (3 deaths). This study emphasized the need for on-site cardiac surgery and an HOR, regardless of location, to prevent the need for transportation to the OR or performing surgery in a standard CCL. In our first 10 cases, no emergency surgical conversion was necessary; however, our HOR is fully equipped for surgery. We performed routine femoral artery cutdowns on 8 patients, surgically removed a snared ruptured aortic leaflet through the femoral artery in 1 patient, and electively gave a patient cardiopulmonary bypass for TAVR. The expectation would be that the HOR can function as an OR for emergency surgical procedures. On the other hand, for TAVR in a surgical HOR, complications that require percutaneous intervention are also precarious if all the necessary equipment is not immediately available. Coronary artery obstruction, while rare (0.7% of cases) and most commonly affecting the left main artery, required emergency percutaneous coronary interventions in 75% of patients, with an 82% success rate and a 30-day mortality of 41%.16 Vascular complications during TAVR were common, ranging from 1.9% to 17.3% of cases, and increased mortality by 2.4- to 8.5-fold.17 While some vascular complications required surgery, many others required advanced endovascular stenting, ballooning, or intravascular ultrasound. An HOR, regardless of location, should be able to address complicated surgical and interventional complications.

Several articles18–22 have offered recommendations for building an HOR in the CCL. The VA Office of Construction, Facilities, and Management has developed its own recommendations, and while the process of developing an HOR in a CCL can be lengthy, these recommendations can more efficiently streamline the process for other centers. The overarching principle is to achieve standards for OR sterility in the HOR, including changing CCL patient and staff flow patterns, creating semirestricted and restricted zones for appropriate OR attire and limiting unnecessary traffic, and meeting room specifications such as required airflow exchanges, laminar airflow, stainless steel ducting, and temperature and humidity controls. The HOR must accommodate all necessary equipment; as such, special requirements for ceiling height and support are established to allow placement of the fluoroscopy imaging system, surgical lights, and booms as well as numerous monitors. The overall HOR space is ideally larger than that of a CCL or surgical OR because of the vast array of equipment and people. Equally important is establishing standard operating procedures in the CCL to achieve and maintain sterility with appropriate antisepsis, surgical counts, instrument cleaning, and terminal room cleaning.

Conclusions

Developing a VA-approved TAVR program requires an application for new program clinical restructuring with an extensive site visit. For HORs built in the CCL environment, additional challenges must be met. The HOR CCL must satisfy key elements of surgical sterility and preparation for surgical conversion, while its design should follow optimal design recommendations for ceiling height and support, air quality, and space. A Healthcare Failure Mode and Effect Analysis is ideal for mitigating the consequences of open surgical aortic valve replacement conversion in the HOR. Paramount for TAVR is the collaborative multidisciplinary heart valve team approach for caring for these elderly high-risk or inoperable patients with severe aortic stenosis.
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