

The versatility of transapical access: Will it lead to a completely new approach to valvular therapy?

Christian Shults, Rebecca Gunter, Vinod H. Thourani

Joseph B. Whitehead Department of Surgery, Division of Cardiothoracic Surgery, Emory University School of Medicine Atlanta, GA, USA

Corresponding to: Vinod H. Thourani, MD. Emory University Hospital Midtown, 550 Peachtree Street, 6th Floor Medical Office Tower, Cardiac Surgery, Atlanta, Georgia, 30308, USA. Email: vthoura@emory.edu.

Submitted May 21. Accepted for publication Jun 27, 2012.

DOI: 10.3978/j.issn.2225-319X.2012.06.14

Introduction

Historically, the treatment of aortic stenosis (AS) has been open aortic valve replacement (AVR) utilizing cardiopulmonary bypass (SAVR) via either a median sternotomy or minimally invasive techniques. These techniques have produced durable results with low morbidity and acceptable long-term survival (1). However, at least 30% of patients with severe symptomatic aortic stenosis do not undergo surgical replacement of the aortic valve, due to advanced age, left ventricular dysfunction, or the presence of multiple coexisting conditions (2). In an effort to provide a practical alternative and mitigate risk in this elderly, frail population, transcatheter strategies of aortic valve replacement have been developed. In 2002, Cribier performed the first transcatheter aortic valve replacement (TAVR) through a transvenous, transeptal technique (3). In the subsequent decade, TAVR has evolved and is currently being performed primarily via a retrograde transfemoral (TF), a direct left ventricular transapical (TA), or direct transaortic (TAo) techniques. Most programs have established a femoral-first approach to TAVR, reserving the TA approach for patients with severe, lesion-limiting aortoiliac disease. Transaortic AVR has recently gained traction with more sites utilizing this procedure with either an upper partial mini-median sternotomy or right lateral thoracotomy. However, with the advent of the SAPIEN XT and the Esheath technology (Edwards Lifescience, Irvine, CA), the percentage of patients able to receive TF TAVR will increase.

This article will evaluate the role of the transapical approach by evaluating the indications (both before and after the development of the SAPIENXT valve) for and

outcomes following TA-TAVR. It will also evaluate the established and theoretical advantages of a TA approach, as well as the unique aspects of the TA access that could facilitate new approaches to valvular therapies even beyond the aortic valve.

Indications

Generally, TAVR is indicated for the treatment of symptomatic patients with severe aortic stenosis, defined as an aortic valve area of ≤ 0.8 cm² and a mean aortic-valve gradient ≥ 40 mmHg, or a peak aortic-jet velocity ≥ 4.0 meters per second. The current indications for TAVR in the United States include patients who are not considered surgical candidates for traditional SAVR. Most recently, the FDA is reviewing the approval of TAVR in high-risk surgical patients: that is, those patients with a Society of Thoracic Surgeons (STS) predicted risk of mortality (PROM) score of $\geq 8\%$. Outside the US, the indications for transapical TAVR are quite varied and are dependent upon institutional and geographic conditions.

PARTNER cohort A was the first prospective study to compare SAVR with the TA approach to TAVR using the Edwards SAPIEN heart-valve system. Under the PARTNER trial, TA-TAVR was indicated for patients who qualified for TAVR implantation, but had peripheral arteries that could not accommodate the large French sheaths required (22 French for the 23-mm valve and 24 French for the 26-mm valve) (4). Ilio-femoral vessel characteristics that precluded safe placement of the 22F or 24F introducer sheath included such factors as severe calcification, severe tortuosity, or vessel diameter < 7 mm for the 22 F sheath

or <8 mm for the 24 F sheath (applicable for transfemoral subjects only) (4).

Currently only available in the US in the PARTNER 2 trial, the newest version of the Edwards SAPIEN Valve, the SAPIEN XT, is notably different from earlier models, in that it has a balloon-expandable cobalt chromium frame, which allows deployment through smaller sheaths and smaller vessels. Whereas the previous generation 23 mm valve required a 22 French sheath and a 7 mm vessel, the SAPIEN XT 23 mm valve and Novaflex deployment system can be deployed through an 18 French sheath and a 6 mm vessel. Likewise, while the previous generation 26 mm valve required a 24 French sheath and a vessel diameter greater than 8mm, the SAPIEN XT 26 mm valve may now be deployed through a 19 French sheath and a vessel with a minimum diameter of 6.5 mm. A 29 mm SAPIEN XT valve, which may be delivered through a 20 French sheath and a 7 mm vessel, is now available in Europe.

Outcomes with TA-TAVR

The treatment arm of the PARTNER trial1A included both TF and TA techniques, using a TF-first approach. Of the 348 Cohort A TAVR patients, 104 were transapical. Initial results with TA-TAVR during the PARTNER A trial demonstrated a 30-day mortality of 8.7%, stroke rate of 7% and death or stroke rate of 15.4%. One-year outcomes included a mortality rate of 29.1%, stroke rate of 10.8% and death/stroke rate of 34.8%. These procedures were done at the initial 14 sites, with a mean of 7.4 patients enrolled per site. Although significantly better than medical therapy, these results did not compare favorably with standard SAVR, which had 30-day mortality, stroke and death/stroke rates of 7.6%, 5.5%, and 12.0%, respectively, and one-year rates of 25.3%, 7%, and 29.7%, respectively (4). Additional transapical experience (n=822) was accumulated after the randomization period in the non-randomized continued access (NRCA-TA) cohort of the PARTNER trial, which was presented by Dewey, Mack, Thourani *et al.* at the Annual Scientific Meeting of the Society of Thoracic Surgeons 2012. This represents the experience of 22 total centers averaging 38.3 TA-TAVR implantations per center. This additional data allowed for a focused analysis of the transapical subset and the results of TA-TAVR implantation after these centers had gained experience and were more comfortable with the procedure.

Dewey and colleagues conducted an ad hoc analysis of The PARTNER Trial NRCA-TA outcomes, and

compared them to the results seen in cohort A with pre-market approval (PMA-TA) and surgical AVR. Endpoints of emphasis included: mortality [clinical events committee (CEC) adjudicated], stroke (CEC adjudicated), and NYHA symptom improvement. Although comparison of NRCA-TA to PMA-TA is not standard due to the non-randomized NRCA-TA cohort, NRCA-TA patient characteristics were comparable to those of the randomized cohort. The all-cause mortality, stroke, and mortality/stroke rates for each group were as follows:

Mortality: PMA-TA 29.1%, AVR 25.3%, NRCA-TA 23.6%;

Stroke: PMA-TA 10.8%, AVR 7.0%, NRCA-TA 3.7%;

Mortality or Stroke: PMA-TA 34.8%, AVR 29.7%, NRCA-TA 25.7%.

Additionally, NRCA-TA early return to function, as shown by NYHA functional class, was significantly improved at 30 days when compared to conventional AVR and PMA-TA (P=0.0004; P=0.0001).

Advantages of the trans-apical approach

The theoretical benefits of the TA approach to TAVR stem from the ability to place the delivery system directly into the heart with a very small distance between the point of operator manipulation and the point of deployment. This shorter distance allows more direct control of the catheter and more direct feedback from it, facilitating more precise deployment. It also results in less stored energy in the delivery system that can affect the precision of deployment. The proximity of the operator to the valve eases crossing of the native valve with the delivery system. Avoiding passage of the delivery system around the aortic arch, which can in many cases be atherosclerotic and plaque-laden, theoretically lessens the stroke risk of TAVR. TA access also avoids complex iliofemoral disease that can lead to dissection, occlusions, and perforation. In the age of ever-decreasing sheath sizes, the TA approach is able to accommodate much larger sheath sizes, which could translate into less implanted valve damage as a result of crimping done to facilitate placement within smaller sheaths. Pasic and colleagues (Berlin, Germany), in their report of their first 175 consecutive TA-TAVR patients, achieved a 5.1% 30-day mortality and 3.6% mortality for patients without cardiogenic shock (5). These rates of mortality in a single center represent their initial 175 cases and rival mortality rates in any TF series, clearly demonstrating that once proficiency is achieved, equipoise in terms of early

mortality can be achieved. However, the question of long-term mortality following TA-AVR has yet to be answered.

How TA access is changing valvular therapy

Assuming program proficiency with the TA approach, it is likely that the outcomes of TA placement would be non-inferior, and perhaps superior, to TF in the long-term, with decreased rates of stroke and paravalvular leak. As centers gain experience with the implantation technique, the initial complication rates fall and the benefits of the approach become apparent.

Due to the greater level of control and more precise deployment, the TA approach has proven beneficial in more complex situations, such as valve-in-valve implantation in patients with prior failure of AVR/MVR. Webb *et al.* reported the first multi-center series of valve-in-valve implantations, using their data of 24 high-risk patients with failed aortic (n=10), mitral (n=7), pulmonary (n=6), or tricuspid (n=1) bioprostheses (6). In the aortic series, a failed initial attempt at aortic valve-in-valve deployment was salvaged using a TA approach, which allowed more “co-axial” views of the valve during deployment. Likewise, in the mitral group, after discouraging initial attempts at transeptal and transatrial deployment, the TA approach was attempted, and all 5 subsequent mitral implantations were successfully and relatively easily accomplished. Implantations in all valve groups were successful with immediate restoration of satisfactory valve function in all but one patient. No patient had more than mild regurgitation after implantation. No patients died during the procedure. Thirty-day mortality was 4.2%. Mortality was related primarily to implanter lack of experience early in this high-risk series. At a median follow-up of 135 days (IQR 46 to 254 days; maximum 1,045 days), 91.7% of patients remained alive with satisfactory valve function.

As seen in the prior series, TA access is not only changing aortic valve surgery, but mitral valve surgery as well. TA access to the mitral valve is a direct retrograde approach that allows full access to the mitral valve apparatus for both mitral valve replacement and repair. TA access also opens the possibility of mitral valve repair under TEE guidance. In a report by Seeburger *et al.* (7), transapical access to the mitral valve was utilized to repair the mitral valve with three neochords under TEE guidance. Using this approach, the prolapsed P2 leaflet was grasped by the device, and the neochords were measured and sewn to the ventricular apex. Final evaluation with TEE showed no evidence of prolapse

or MR, and the patient has done well.

Furthermore, we and others are expanding the role of TA access by deployment of ascending aortic stent grafts for ascending aortic dissections or pseudoaneurysms (8,9). It is entirely possible that in time TA access will be used for endovascular replacement of the aortic root utilizing branched endografts and PCI coronary stents.

Much of the criticism of the TA approach stems from the more invasive nature of the approach and the current requirement of a rib spreading thoracotomy. Patients often complain of prolonged postoperative pain with delayed recovery. Incising and then suturing the apex of the heart has also led to a higher incidence of intra- and post-operative bleeding. Approximately 10-20% of patients who receive a TA-TAVR will have significant bleeding complications requiring 1-3 units PRBC per case. To address this need, several companies (Apica, Entourage Cardioclose, MID Permasseal, Novogate, Spirx Closure) have emerged with apical access devices to reduce the incision size, reduce manipulation of the heart, and stabilize the incision with sutureless techniques. The objectives of these devices are to provide secure access with the ability to re-access, limit peri-sheath bleeding, and ultimately transition the TA approach to an entirely percutaneous one.

One company, Apica, has developed a one-handed percutaneous device that inserts a large coil into the heart, assuring access to the LV and apical valve delivery. The coil is conically-shaped and imparts radial compression to eliminate “peri-sheath” bleeding, and a sealing cap applies transmural compression for complete and dry closure.

Conclusions

Initial results of studies investigating the TA approach to TAVR appeared to indicate that it was a higher risk procedure, with increased rates of mortality and perioperative complications, compared to the TF approach. Subsequent studies have demonstrated this early data likely reflected operator inexperience with the technique and a sicker patient population rather than risks inherent to the procedure. In experienced centers, short-term results are now on par with TF results, though time will tell if long-term results will reflect the anticipated benefits of the TA approach. Early experience with more complex procedures such as valve-in-valve deployment to the aortic and mitral positions have shown the TA approach to be a safer and more precise approach to valve replacement than the TF approach. The TA approach is also changing the

way we think about valvular therapy with the advent of mitral valve repair or replacement under TEE guidance as well as the potential for full aortic root replacement via a valve/branched conduit. Beyond its role as an indispensable alternative access for TAVR in patients with severe aortoiliac disease, the TA approach is opening the door for a new generation of percutaneous structural heart therapies.

Acknowledgements

Disclosure: The authors declare no conflict of interest.

References

1. Thourani VH, Ailawadi G, Szeto WY, et al. Outcomes of surgical aortic valve replacement in high-risk patients: A multiinstitutional study. *Ann of Thorac Surg* 2011;91:49-56.
2. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med* 2010;363:1597-607.
3. Cribier A, Eltchaninoff H, Bash A, et al. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: First human case description. *Circulation* 2002;106:3006-8.
4. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med* 2011;364:2187-98.
5. Pasic M, Unbehaun A, Dreyse S, et al. Transapical Aortic Valve Implantation in 175 Consecutive Patients: Excellent Outcome in Very High-Risk Patients. *J Am Cardiol* 2010;56:813-820.
6. Webb JG, Wood DA, Ye J, et al. Transcatheter valve-in-valve implantation for failed bioprosthetic heart valves. *Circulation* 2010;121:1848-57.
7. Seeburger J, Borger MA, Tschernich H, et al. Transapical beating heart mitral valve repair. *Circ Cardiovasc Interv* 2010;3:611-2.
8. Uthoff H, Garcia-Covarrubias L, Samuels S, et al. Transapical endovascular aortic repair to treat complex aortic pathologies. *Ann Thorac Surg* 2012;93:1735-7.
9. Szeto WY, Moser WG, Desai ND, et al. Transapical deployment of endovascular thoracic aortic stent graft for an ascending aortic pseudoaneurysm. *Ann Thorac Surg* 2010;89:616-8.

Cite this article as: Shults C, Gunter R, Thourani VH. The versatility of transapical access: Will it lead to a completely new approach to valvular therapy? *Ann Cardiothorac Surg* 2012;1(2):220-223. DOI: 10.3978/j.issn.2225-319X.2012.06.14