Perspective

Transcatheter aortic valve implantation: The transfemoral versus the transapical approach

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Introduction

Transcatheter aortic valve implantation (TAVI) is emerging as a viable alternative to conventional surgical aortic valve replacement in high risk and surgically inoperable patients who have severe symptomatic aortic stenosis. A comprehensive review of this new technology has recently been published as an "expert consensus document" (1). This document, however, did not address the relative merits of the transapical versus the transfemoral approach to TAVI. The chosen approach is largely dictated by the quality and adequacy of the aortoiliac and femoral arteries and whether the vessels can support large catheter access. The relative merits of the transfemoral and transapical approaches continue to evolve. In this article, we aim to review the published results of TAVI in high risk or inoperable patients with severe aortic stenosis with an emphasis on comparing the outcomes between the transapical versus transfemoral techniques.

It is estimated that TAVI has been employed in more than forty thousand patients worldwide and there is published data on over five thousand patients (1). Although most of this information has been obtained from registries and other observational studies, there is one prospective, multicenter, randomized study of the clinical outcomes after insertion of the Edwards SAPIEN transcatheter valve (2-5). This trial, called Placement of Aortic Transcatheter Valves (PARTNER), included two populations of patients with severe, symptomatic aortic stenosis: Cohort A, deemed at high risk for conventional surgery and Cohort B, considered surgically inoperable.

The PARTNER trial

Evidence supporting a benefit of TAVI compared to "standard" medical care was provided by cohort B (n=358) of the PARTNER trial (2,4). Patients who were inoperable were assigned to TAVI via transfemoral approach or to standard care (which for most patients included balloon valvuloplasty). The early (30-day) mortality was higher in the TAVI group, but this difference was not statistically significant. The stroke rate was significantly higher in the TAVI group compared to standard care (6.7% versus 1.7% at 30-days). Vascular complications and bleeding were also common in the TAVI group. One year after the procedure, mortality was significantly lower with TAVI compared to standard medical care (30.7% versus 50.7 %). At two years, the mortality rate was 43.4% with TAVI compared to 68% with standard care. Moderate to severe paravalvular aortic regurgitation was seen in 11.8% of TAVI patients. The beneficial impact of TAVI versus "standard" therapy on mortality in PARTNER Cohort B patients is consistent with other published observational studies. Thus, survival is substantially improved by TAVI despite a significant risk of stroke and other complications related to the procedure.

Comparisons of the results of TAVI to conventional surgical aortic valve replacement are provided by cohort A (n=699) of the PARTNER trial (3,5). Patients in this cohort were high risk, but considered to be operable. Mortality rates in the surgical and TAVI groups were not statistically significantly different at 30-days (3.4% versus 6.5%), at one year (24.3% versus 26.8%), and at two years (33.9% *vs.* 35%). The early stroke rate was higher with TAVI than with surgical valve replacement (5.5% versus 2.4% at 30-days). TAVI was associated with more early vascular complications (11% versus 3.2%) while surgical valve replacement was associated with more peri-procedural bleeding (19.5%

versus 9.3%) and new-onset atrial fibrillation (16% *vs.* 8.6%). The primary endpoint of the PARTNER Cohort A trial was all-cause mortality at 1 year and in this regard the non-inferiority of TAVI versus conventional aortic valve replacement was established.

The PARTNER trial, coupled with a relatively large registry experience, shows that TAVI provides a clear and significant survival benefit when compared to standard medical care. For high-risk operable patients, PARTNER Cohort A shows that early survival with TAVI is not inferior to surgical aortic valve replacement. Most patients experience favorable outcomes with improved functional status and quality of life. Despite a relatively high complication rate, TAVI represents an evolving alternative in the management strategies for patients who are either very high risk or deemed inoperable. An unanswered question revolves around the issue of implantation techniques and the optimal approach for TAVI. Outcome data from seven reports comparing the transfemoral to transapical approach are reviewed below (6-13).

Transfemoral versus transapical approach to TAVI

Studies comparing the transfemoral to the transapical approach have included almost 5,000 patients (6-13). Five of the comparison studies summarized herein utilized the Edwards SAPIEN valve. In our assessment of the two approaches we present information from the PARTNER trial as a background for comparison of outcomes with transfemoral and transapical approaches. We recognize that comparisons of the results amongst different reports are limited by differences in patient selection, risk profiles, and co-morbidities.

Mortality

The 30-day mortality in the PARTNER trial was higher in the transapical cohort than in the transfemoral group (3). Our analysis of the reports summarized in *Table 1* shows a similar trend. The two smaller studies, comparing the transfemoral to the transapical approach, showed differences in mortality that were not statistically significant (6,10). In four larger studies (7,8,11,13), statistical differences were not reported, but three of these showed differences in mortality that were almost twice that seen with the transfemoral approach (8,11,13). In a fifth study, mortality was reported to be significantly lower with the transfemoral approach compared with a "non-femoral" approach (5.5% versus 10.7%), in which 85% percent of patients underwent the transapical approach (12). Thus, early mortality appears to be higher with the transapical approach compared to the transfemoral approach. However, it must be recognized that there are differences in underlying co-morbidities between the two groups that may confound conclusions about mortality.

Stroke

The overall incidence of stroke in the seven studies of transfemoral versus transapical approaches is lower than that seen in the PARTNER trial and similar to that reported in the TAVI registries (*Table 2*). When the transfemoral and transapical data are compared, the incidence of stroke appears to be slightly higher with the transfemoral approach (2.4-6%) than with the transapical approach (0-4.4%). This trend was not seen in two reports (12,13). Likewise, a tendency for a higher rate of stroke with transfemoral access was not reported in the PARTNER trial (3).

Vascular complications

Accurate comparison of vascular complication rates amongst studies shown in *Table 3* is made difficult by the inconsistent definition of 'vascular complication' in different studies. For example, some studies emphasize "access site complications" (7), whilst most others report "vascular complications". Others include bleeding as an access site complication. However, within each study, vascular complications were more common with the transfemoral (5.5-28.4%) than with the transapical approach (2.4-8%). A similar incidence of vascular complications was reported in the PARTNER trial and in the registries (*Table 3*).

Paravalvular aortic regurgitation

Some studies report paravalvular aortic regurgitation rates (moderate and severe) after TAVI as low as approximately 2% (8). Other investigators report a substantially higher frequency with a range of 15.6-22% for transfemoral (10,12) and 9-21% for transapical approaches. In two large studies (12,13), the incidence of paravalvular regurgitation was higher with the transfemoral approach. It appears, therefore, that there is little, if any, difference in the incidence of aortic regurgitation between the two techniques. However, it is possible that different valves are associated with differences in the aortic regurgitation. This is an important complication with a significant impact on survival.

Table 1 Transcatheter aortic valve implantation: Mortality data

	30 days	One year	Two years
PARTNER trial (2-5)			
Partner trial B			
TAVI	5.0	30.7	43.4
Standard care	2.8	50.7	68
Partner trial A			
TAVI	3.4	24.3	33.9
Surgical AVR	6.5	26.8	35
TAVI registries (1)			
Range	5-12%	15-24%	26-38%
TAVI: Apical *vs.* Femoral approach			
Himbert, *et al.* (6)			
Femoral, n=51	8	19	
Apical, n=24	8 (16*)	26	
Rodes-Cabau, *et al.* (7)			
Femoral, n=168	9.5	25	
Apical, n=177	11.3	22	
Thomas, *et al.* (8,9)			
Femoral, n=463	6.3	18.9	
Apical, n=575	10.3	27.9	
Ewe, *et al.* (10)			
Femoral, n=45	11.1	19.8	
Apical, n=59	8.5	14.3	
Lefevre, *et al.* (11)			
Femoral, n=61	8.2	21.3	
Apical, n=69	18.8	50.7	
Moat, *et al.* (12)			
Femoral, n=599	5.5	18.5	22.5
Nonfemoral, n=271	10.7	27.7	36.7
Gilard, *et al.* (13)			
Femoral, n=2293	8.5	21.7	
Apical, n=567	13.9	32.3	

Data are expressed as percentages. *in hospital mortality

New pacemaker

High grade A-V block requiring implantation of a cardiac pacemaker was reported in approximately 3.4-3.8% of patients in the PARTNER trial (2,3). Comparison of the transfemoral and transapical approaches indicate that new pacemakers were utilized in 1.8-15.2% of patients with the transfemoral approach and in 3.4-13.6% of patients with the transapical approach. The requirement for pacemakers is higher in the registries, (approximately 2-8% with the Edwards SAPIEN valve and 19-42% with the Medtronic Core Valve) (1). Thus, it appears that there are no significant differences in the requirement for a pacemaker between the transfemoral and transapical techniques, but the type of valve implanted may have an impact on the periprocedural need for a pacemaker (13).

Table 2 Transcatheter aortic valve implantation: Stroke data

	30 days	One year	Two years
PARTNER trial (2-5)			
Partner trial B			
TAVI	6.7	11.2	13.8
Standard care	1.7	5.5	5.5
Partner trial A			
TAVI	5.5	8.7	11.2
Surgical AVR	2.4	4.3	6.5
TAVI registries (1)			
Range	2-5		
TAVI: Apical *vs.* Femoral approach			
Himbert, *et al*. (6)			
Femoral	6		
Apical	0		
Rodes-Cabau, *et al*. (7)			
Femoral	3		
Apical	1.7		
Thomas, *et al*. (8,9)			
Femoral	2.4		
Apical	2.6		
Ewe, *et al*. (10)			
Femoral	4.4		
Apical	3.4		
Lefevre, *et al*. (11)			
Femoral	5.3	10.3	
Apical	1.5	7	
Moat, *et al*. (12)			
Femoral	4		
Nonfemoral	4.1		
Gilard, *et al*. (13)			
Femoral	3.7		
Apical	4.4		

Data are expressed as percentages

Other complications

Following TAVI, approximately 10-20% of the patients require blood transfusion, but there appears to be only relatively small differences in bleeding complications between transapical or transfemoral approaches. Renal failure requiring dialysis appears to be more frequent with the transapical than with transfemoral approach. Embolization is only slightly more frequent with the transfemoral than with the transapical approach. It should be recognized that these modest differences have not been statistically validated.

Comment

In properly selected high risk patients with severe symptomatic aortic stenosis, TAVI offers a survival benefit

Table 3 Transcatheter aortic valve implantation: Complications

	Vascular complication	Aortic regurgitation	New pacemaker	Major bleeding	Renal failure
PARTNER trial (2-5)					
Partner trial B					
TAVI	16.8	11.8	3.4	20.6	1.1
Standard care	1.1		5	3.9	1.7
Partner trial A					
TAVI	11		3.8	9.3	2.9
Surgical AVR	3.2		3.6	19.5	3.0
TAVI registries (1)					
Range	2-28		2-42		
TAVI: Apical *vs*. Femoral approach					
Himbert, *et al*. (6)					
Femoral	12	20	6		
Apical	8	13	4		
Rodes-Cabau, *et al*. (7)					
Femoral	13.1*		3.6		1.8
Apical	13.0*		6.2		3.4
Thomas, *et al*. (8)					
Femoral	10.6	1.5	6.7	9.9	1.3
Apical	2.4	2.3	7.3	8.9	7.1
Ewe *et al*. (10)					
Femoral	17.8	22	4.4	6.7	
Apical	5.1	21	3.4	15.3	
Lefevre *et al*. (11)					
Femoral	28.4		1.8	23	0
Apical	4.7		5.8	21	3
Moat *et al*. (12)					
Femoral	8.4	15.6			
Nonfemoral	1.9	9.1			
Gilard, *et al*. (13)					
Femoral	5.5	15.6	15.2	2.7	
Apical	1.9	9	13.6	4.8	

Data are presented as percentages. *Access site complications

(up to two years) that is comparable to conventional surgical aortic valve replacement, albeit at a higher risk for stroke. In this article we focused on the relative effectiveness and complications of the transfemoral and transapical approaches to the TAVI procedure. The transapical approach appears to be associated with a higher mortality than the transfemoral approach. Renal failure requiring dialysis also appears to be more frequent with the transapical approach. By contrast, the risk of stroke and perhaps embolization, as well as a variety of vascular complications, are more common with the transfemoral approach. In the absence of a randomized controlled study, the ability to discriminate true differences between the transapical and transfemoral approaches to TAVI is clearly limited by an inherent patient selection bias.

Virtually all physicians consider the transfemoral route

as the preferred approach due to the perception that it is less invasive and generally avoids surgical incisions. The transapical approach is used when peripheral vascular access is poor or impossible. Thus, those patients selected for the transapical approach comprise a group of patients more likely to have a disseminated vasculopathy with an increased risk for death and complications.

With growing experience in TAVI and the development of improved valves and smaller delivery sheaths, a reduction in peri-procedural complications can be expected. The current literature does not support a clear superiority of one approach to TAVI over the other. Recognizing that approximately half of all deaths in this high risk group of TAVI patients are non-cardiac, factors other than TAVI technology are obviously important. Multidisciplinary collaboration with improved patient selection and advanced technology will promote progressive safe application of this promising technique.

Addendem

The procedures discussed herein consist of a valve implantation (TAVI), not a valve replacement (TAVR). Accordingly, we use the term implantation (14).

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