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Trans-catheter aortic valve implantation: Contemporary practice and the future

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Abstract

With increasing life expectancy, the epidemic of valvular heart disease, especially aortic stenosis, is becoming more prevalent. Transcatheter aortic valve implantation (TAVI) has emerged as an alternative therapy for patients with significant aortic valve disease. It offers a less invasive procedure in comparison to surgical aortic valve replacement and an attractive substitute from the patient's perspective. The evidence for TAVI in inoperable and high risk surgical patients is now established and in the intermediate risk group has been accumulating rapidly and is looking favourable for TAVI.

However, the full 'TAVI story' is still unfolding. Technological advances in devices and delivery systems are evolving with the aim to improve the function and durability of TAVI and to simplify the procedure while enhancing safety. The incidence of vascular injury and pacemaker requirement post TAVI remains an issue and further development in this regard is therefore of utmost importance, particularly as lower risk and potentially younger patients are treated. Moreover, the evidence concerning long-term durability of the TAVI prostheses continues to accumulate. Whilst TAVI is proving to be an invaluable tool for inoperable and high risk patients, more trial evidence is needed before it encompases lower risk populations and moreover, its use as a first line treatment worldwide in most healthcare systems is limited by the costs associated with the prosthesis. (Cardiol J 2017; 24, 2: 206–215)

Key words: trascatheter aortic valve implantation, surgical aortic valve replacement, evidence-base, complication, cost-effectiveness

Introduction

Life expectancy in Europe is still on the rise. In 2000, the average life expectancy in the United Kingdom was 78 years but by 2013 it reached 81.1 years [1]. With advancing age, the prevalence of certain diseases is changing. D'Arcy et al. [2] spoke of the "next cardiac epidemic" in 2011 due to the increasing prevalence of valvular heart disease, particularly aortic stenosis (AS), observed with the ageing population. The prevalence of any degree of calcific, degenerative AS consists of up to 40% of people aged 80 years and over [3]. More importantly, severe symptomatic AS carries a poor prognosis if left untreated. With the advancement of trans-catheter techniques, a lower complication profile and increased world-wide availability has meant that more patients are being referred for consideration of this treatment. Trans-catheter aortic valve implantation (TAVI) is already the mainstream therapy for inoperable and high risk AS patients. A large number of patients have received this treatment as it has evolved over the past 10 years and in Germany in 2015, more patients with aortic valve disease received a TAVI rather than surgical aortic valve replacement (sAVR). In this article, some light is shed on the most recent advances and where the future may lie.

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Table 1. Summary of European Society of Cardiology and American Heart Association guidelines that encompass transcatheter aortic valve implantation (TAVI).

Recommendation	Class	Level	Year
European Society of Cardiology			
TAVI is indicated in patients with severe symptomatic AS who are not suitable for AVR as assessed by a 'Heart Team' and who are likely to gain improvement in their quality of life and to have a life expectancy of more than 1 year after consideration of their comorbidities	I	B	2012
TAVI should be considered in high-risk patients with severe symptomatic AS who may still be suitable for surgery, but in whom TAVI is favoured by a 'Heart Team' based on the individual risk profile and anatomic suitability	IIa	B	2012
American Heart Association			
TAVI is recommended in patients who meet an indication for AVR who have prohibitive risk of surgical AVR and a predicted post-TAVR survival > 12 months	I	B	2014
TAVI is a reasonable alternative to surgical AVR in patients who meet an indication for AVR and who have high surgical risk for surgical AVR	IIa	B	2014
TAVI is NOT recommended in patients in whom existing comorbidities would preclude the expected benefit from correction of AS	III	B	2014

AS — aortic stenosis; AVR — aortic valve replacement; TAVR — transcatheter aortic valve replacement

Current utility of trans-catheter aortic valve intervention

Transcatheter aortic valve implantation represents one of the most significant technological advances made in cardiovascular medicine over the last decade. Since TAVI was first described by Alan Crieber in 2002, it has made its way into the European Society of Cardiology [4] and American Heart Association guidelines [5] (Table 1) and has become the 'standard of care' for inoperable and high risk groups of patients with severe AS. Table 1 summarizes the current guidelines that refer to TAVI.

In the United Kingdom 3,980 TAVIs were performed before 2012 and the number has increased dramatically since with more than 1800 cases done during 2014 alone [6]. Whilst in Germany 15,964 were done between 2011 and 2013 [7], in France 3,972 [8], between 2010 and 2012 and in the United States 12,182 TAVIs were performed between November 2011 and June 2013 [9]. Conversely, the Asian TAVR registry suggested smaller numbers of cases performed in comparison to Europe and the United States with 848 cases done in 5 Asians countries between March 2011 and September 2014 [10]. This was largely due to regulatory issues. It is noteworthy that the number of TAVIs performed in Germany since 2013 has surpassed the number of isolated sAVR cases [11]. Figure 1 summarizes the upward trend of TAVI in Europe per million population as per 2011 [12]; It also demonstrates the differences between different health care systems.

Case selection

Whilst there are some variations among centres/countries, the overall care pathway of patients undergoing TAVI is relatively standardized. Decision-making in the investigation and treatment of these patients is achieved with the 'Heart Team', a multidisciplinary group of interventional cardiologists, cardiothoracic surgeons, imaging specialists, anaesthesiologists and care-of-the-elderly physicians.

Once a suitable patient is identified, he or she completes a thorough work-up that includes multiple imagining modalities including trans-thoracic echocardiography, three-dimensional (3D) assessment of the aortic annulus (using transesophageal echocardiography or cardiac computed tomography [CT]), CT aortogram and peripheral angiography, coronary angiography and pulmonary function testing. Key steps in pre-operative imaging include assessment of: aortic valve morphology, distribution and extent of valve calcification, annular dimensions, dimensions of the sinuses and sinotubular function, distance of the coronary ostia to the aortic annulus, and peripheral artery diameter, calcification and tortuosity.

Annular dimensions are key measurements in TAVI valve sizing. Choosing the correct valve size is important as undersizing the prosthesis can result in device migration and embolization or significant paravalvular aortic leak (PVL). On the other hand, oversizing increases the risk of life threatening complications such as annular rupture and the risk of vascular injury as bigger

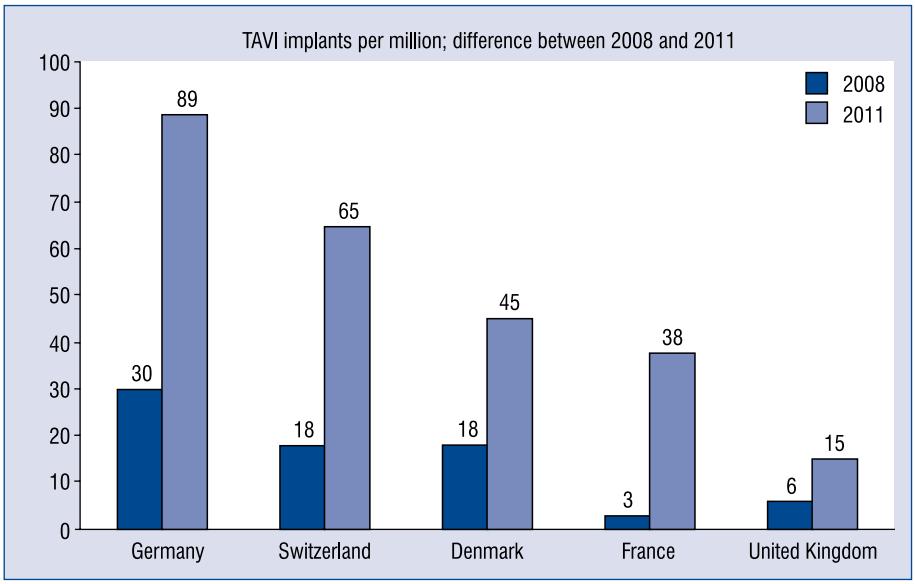

Figure 1. Summary of the upward trend of transcatheter aortic valve implantation (TAVI) in Europe per million population as per 2011.

delivery systems are needed. Inaccurate valve sizing is also associated with altered valve mechanics. Consequent under- or over-expansion of the valve leads to redundancy of leaflet tissue or leaflet non-coaptation resulting in transvalvular regurgitation.

The aortic valve annulus is defined as a virtual plane at the level of the hinge points of the three cusps and in the majority of cases is elliptical. Therefore, the use of a 3D imaging modality that allows measurements of the annulus diameter in two orthogonal plane as well as measurements of the perimeter and area is essential, and thus allows for calculation of the 'virtual' annulus diameter.

Many centres perform peripheral 3D constructed CT and peripheral angiography to assess the suitability of aorto-ileofemoral arterial system for trans-femoral TAVI. The default route for TAVI is trans-femoral and as such the numbers of non-trans-femoral cases (subclavian, trans-apical and trans-aortic) have declined in recent years.

Once the valve is implanted, operators check for any vascular injury, conduction defects, aortic regurgitation or pericardial effusion. The absence of complications would then herald the end of the procedure and the patient is then transferred usually to a level 2 care facility for monitoring. Most patients are being considered for early discharge (by day 3) if no further complications arise. Subsequent to discharge, patients usually have follow up at 4–6 weeks with echocardiography and electrocardiogram, and then annually thereafter.

Current devices

Whilst there are several TAVI valves in use worldwide, the two prostheses that are supported by the largest body of evidence and experience are: 1) the balloon expanding Edwards SAPIEN (Edwards Lifesciences, Irvine, CA, USA) and 2) the self-expanding Medtronic CoreValve (Medtronic, Minneapolis, MN, USA). They have different characteristics, anatomical requirements and echocardiographic appearances but they both provide excellent outcomes with their latest generations, the Sapien 3 and Evolute R.

The original Edwards SAPIEN was a balloon expandable device that had a stainless steel support frame with a bovine pericardial valve and a fabric skirt within it. This device was implanted via a transfemoral or transapical/transaortic approach. The Sapien XT (made of a cobalt-chromium alloy) was delivered on a more sophisticated, lower-profile delivery system. The third generation of the Edwards SAPIEN valve, Sapien 3 has an additional outer skirt that has minimized PVL. It also has the advantage of an even smaller and 'double flexing' delivery system — the 'Commander'™.

The self-expanding CoreValve is self-centering and partially repositionable. It is made of a nitinol stent with porcine pericardial leaflets. The nitinol stent has three zones. The lower zone that applies high radial forces within left ventricular outflow tract (LVOT) and the annulus anchoring the valve,

the middle zone that carries a controlled force to avoid jailing the coronary ostia and an upper zone with low radial forces which functions to orient the valve in the direction of aortic root axis. The valve is intended to sit in a supra-annular position. The second generation, Evolut R valve, has a smaller delivery system, a lower frame height, fully recapturable and repositionable and available for transfemoral or transaortic routes.

The ideal TAVI valve would be low profile, have minimal risk of PVL and would be fully repositionable/retrievable. Newer generation, commercially available devices, have gone some way to achieving these goals.

The Lotus Valve (Boston-Scientific, Natick, Massachusetts, USA) is pre-mounted on the delivery system. It can be retrieved, repositioned and redeployed any time prior to release. It is delivered via the trans-femoral approach only and consists of a woven nitinol frame with valve leaflets of bovine pericardium. The ventricular portion of the valve is surrounded by an adaptive seal. On deployment, it shortens mechanically in a controlled way, providing additional radial strength compared to traditional self-expandable nitinol devices. The Lotus valve carries a higher rate of post procedural pacemaker requirement [13, 14].

Direct Flow (Direct Flow Medical, Santa Rosa, CA, USA) is a self-expanding valve with a novel metal free 'double ring' design with two aortic (upper) and ventricular (lower) inflatable rings. The rings contain non-compliant angioplasty balloon technology and are connected by a tubular bridging system. Each ring can be pressurised (through the normal saline/contrast) independently to allow for inflating/deflating the rings and hence retrieval before deployment. After obtaining the optimal position, the rings are filled with a polymer. The bovine pericardial valve is attached to a cuff that conforms to the annulus. Owing to the speed of deployment, Direct Flow does not require rapid pacing. It provides excellent sealing but suffers from higher gradient. Direct Flow is available only for the transfemoral approach.

The Portico valve (St. Jude Medical, Minneapolis, MN, USA) is a nitinol self-expanding re-sheathable device which consists of bovine pericardial leaflets and a porcine pericardial sealing cuff. It is similar to the Evolut R and provides open stent cell design to allow access to coronary arteries.

The Symetis Acurate (Symetis SA, Ecublens, Switzerland) is another self-expanding nitinol stent valve with porcine pericardial leaflets which are available for both trans-apical and trans-femoral approaches. This valve has an upper crown for supra-annular anchoring to minimize protrusion into left ventricle and a lower crown that is designed to protrude only minimally into the LVOT. It has inner and outer pericardial skirts to minimize PVL.

The JenaValve (JenaValve Technology GmbH, Munich, Germany) is a self-expanding valve consisting of porcine pericardial leaflets attached to a crown shaped self-expanding nitinol stent. It has three 'feelers' which are to be seated in the aortic sinuses at the base of native leaflets. The feelers in combination with the stent arms in the lower part of the prosthesis allow clipping the native valve leaflets which enable operators to accurately position the prosthesis. Rapid pacing is not required during prosthesis positioning and release. It can be used with both trans-femoral and trans-apical approaches. The clipping mechanism is particularly useful in non-calcified valves or when aortic regurgitation is the primary pathology.

Tables 2 and 3 summarize some features of the commonly available prostheses and their delivery systems.

Potential complications

Vascular injury

The risk of significant vascular damage has decreased with lower profile valve delivery systems, but remains around 5–8%. By default, trans-femoral cases are usually fully percutaneous nowadays when previously the femoral arteriotomy was a direct surgical cut-down. The omission of these traumatic surgical steps have meant that patients can undergo TAVI under conscious sedation as oppose to general anaesthesia and there is a general trend towards a less invasive, conscious sedation approach across the world. The fully percutaneous approach, including ultrasound-guided puncture of the femoral artery and the use of pre-closure suture systems have also refined the technique.

The two main vascular closure devices (VCD) that have been used in TAVI are the ProStar XL (Abbott, Vascular, Santa Clara, California) and PerClose ProGlide (Abbott, Vascular, Santa Clara, California). These are suture-based devices and they replicate surgical closure. The devices were tested in interventional radiology randomized clinical trials that concluded their safe and effective use and non-inferiority to open surgical cut-down (PEVAR trial [15]).

In TAVI, the use of VCD improved procedure safety and reduced complications, however the

Table 2. Prostheses types and their main advantages (according to manufancturer).

Device	Manufacturer	Size [mm]	Deployment	Main advantage
Sapien XT	Edwards Lifesciences	20–29	Balloon expandable	Studied in large scale trials
Sapien S3	Edwards Lifesciences	20–29	Balloon expandable	Low profile delivery system Distal skirt that reduces PVL
CoreValve	Medtronic	23–31	Self-expanding	Studied in large trials
CoreValve Evolut R	Medtronic	23–29	Self-expanding	Low profile delivery system
Lotus Valve	Boston Scientific	23–27	Mechanical expansion	Repositionable and retrievable valve
Portico	St. Jude Medical	23–25	Self-expanding	Low profile delivery system Repositionable and retrievable valve
Direct Flow	Direct Flow Medical	25–29	Inflatable aortic and ventricular rings	Optimal control over deployment
CENTERA	Edwards Lifesciences	23–26	Motorised expansion	Ultra-low profile delivery system

PVL — paravalvular aortic leak

Table 3. Examples of some of the available delivery systems.

Prosthesis	Size [mm]	Delivery system	Femoral sheath size
Sapien XT	20	NovaFlex	16 Fr eSheath
Sapien S3	23	Commander	14 Fr eSheath
	26	Commander	14 Fr eSheath
	29	Commander	16 Fr eSheath
CoreValve	23	DCS-C4-18FR-23	18 Fr
	26–31	DCS-C4-18FR	18 Fr
Evolut R	23–29	EnVeo R 14Fr-eqivalent	14 Fr
Lotus	23	Lotus valve system	18 Fr
	26–29	Lotus valve system	20 Fr
Portico	23–25	Portico TF delivery system	18 Fr
Direct Flow	25–27	Direct Flow delivery system	18 Fr

data on the best VCD in TAVI is still contradictory. An awareness of potential harm with check angiography and 'cross-over' access from the contralateral side has improved safety in this regard. The current evidence is that the use of VCDs has a learning curve and in experienced hands they are effective, reduce complications and are likely to influence early mobility and discharge of TAVI patients [16, 17].

Paravalvular aortic leak

Paravalvular aortic leak is an important complication of TAVI that is associated with increased mortality for both balloon-expandable and self-expanding valves. In early series, TAVI was associated with PVL in more than 80% of patients. PVL was common with earlier valve designs as a result of incomplete apposition of the prosthesis to the aortic annulus. The principal contributing mechanisms were undersized prostheses, suboptimal positioning and/or challenging anatomy of the aortic root and valve (e.g. eccentric or heavy calcification).

The incidence of moderate or severe PVL has been reported to be between 2% and 17% in randomized trials and major registries. Many studies have shown that PVL predicts increased mortality [18, 19] and have emphasized that it should be minimized or avoided if at all possible. More sophisticated aortic annulus sizing (with 3D imaging

Table 4. Rate of complications as per trials and registries.

	Year	CVA	Pacing	Vascular	Bleeding	AKI
Trial						
PARTNER B [31]	2010	6.7%	3.4%	30.7%	16.8%[$]	0
PARTNER A [32]	2011	5.5%	3.8%	17%	9.3%[$]	1.2%
CoreValve Extreme Risk [33]	2014	4%	21.6%	8.2%	12.7%*	11.8%
CoreValve High Risk [34]	2014	4.9%	19.8%	5.9%	13.6%*	6%
PARTNER II [35]	2016	6.4%	8.5%	7.9%	10.4%*	1.3%
NOTION [36]	2015	2.8%	34.1%	5.6%	11.3%	0.7%
Registry						
FRANCE II [8]	2012	4.1%	15.6%	4.7%	1.2%*	N/R
UK TAVI [6]	2016	2.6%	10.2%	3.5%	N/R	N/R
STS/AAC[#] [9]	2014 ^	2.2%	11%	4.2%	4.3%	2.2%
GARY[#] [7]	2015	1.5%	17.5%	4.1%	26.3%	N/R
Asian[#] [10]	2016	3.8%	9.5%	5%[$]	6.4%*	3.3%
Australian-New Zealand [37]	2014	5.3%	28.4%	7.6%	7%	6.5%

[$]Major bleeding; *Life threatening or disabling bleed; ^ Outcomes of year 2014; [#]In-hospital outcomes; CVA — cerebrovascular accident; AKI — acute kidney injury; N/R — not reported

modalities), various technological advances, such as the addition of a 'sealing' skirt to the frame of the valve as with Sapien 3, and judicious use of post-dilatation are examples of the concerted efforts to tackle this particular complication. Further studies are needed to verify exactly why paravalvular aortic regurgitation has such a negative effect on survival.

Permanent pacemaker requirement

The risk of significant conduction disturbance following TAVI is 10–25%. The incidence is variable for different devices as some have a higher pacemaker requirement with the valves than others [20, 21]. This has been addressed with device design and also positioning within the native aortic valve. There is some evidence to suggest that a higher prosthesis implantation lessens the incidence of complete heart block [20].

Stroke

The incidence of stroke after TAVI is between 1.7% and 8.4% depending on the clinical definition. Strokes after TAVI may differ in nature from those after sAVR. It is possible that showers of cerebral emboli at different time-points during TAVI cause a more diffuse brain injury manifesting as a subtle cognitive impairment rather than an overt neurological event such as hemiplegia. These kinds of events are difficult to diagnose and indeed adjudicate in clinical trials.

There are a number of cerebral 'embolic protection/deflection' devices currently available to reduce the risk of cerebral micro-embolization. The application of these devices requires extra caution and is only advised in certain high risk groups of patients.

Ventricular injury

Left and right ventricular injury peri-procedurally is well documented. Whilst the injury is usually traumatic, coronary obstruction as a cause of ventricular injury (peri-procedural myocardial infarction) has also been referred to, the rate of which is less than 1% [22]. Right ventricular injury is commonly caused by the temporary pacing wire perforation, and left ventricular injury is caused by the stiff wire perforation but a much rarer complication. Traumatic left or right ventricular injury usually manifests itself with pericardial effusion and tamponade. The rate of pericardial effusion and tamponade peri-TAVI is reported to be around 4% [23, 24]. Of note, in a series of cases, only 4 (23.5% of all causes of tamponade) were attributed to direct left ventricular wire perforation [24].

Overall, the complication rate associated with TAVI is decreasing with the advancement of technology and accumulating experience. The rates of stroke, bleeding and vascular complications in real life registries appear to be lower than that of the trials. The rates are likely to drop further once TAVI is performed more in intermediate risk patients. Table 4 lists the reported complications according to the corresponding trial and registry.

Table 5. A summary of the major completed transcatheter aortic valve implantation (TAVI) trials.

Randomised trial	Objective	Patients	Prosthesis	Year	Outcome
PARTNER B	TAVI superior to optimal medical therapy in non-operable severe AS patients	358	Edwards Sapien	2010	Significant reduction in mortality and hospitalization
PARTNER A	TAVI is non-inferior to sAVR in high risk surgical patients	699	Edwards Sapien	2011	TAVI and sAVR have similar rates of mortality at 1 year
PARTNER 2	TAVI is non-inferior to sAVR in intermediate risk patients	2032	Edwards Sapien XT	2016	TAVI is non-inferior in terms of mortality and stroke
CoreValve Pivotal high risk trial	TAVI is non-inferior and superior to sAVR	795	CoreValve	2014	TAVI is superior to sAVR
CoreValve Pivotal extreme risk trial	TAVI is superior to optimal medical therapy	506	CoreValve	2014	TAVI is safe and effective
NOTION trial	TAVI is non-inferior to sAVR in all comers	280	CoreValve	2015	TAVI is non-inferior to sAVR
DEFLECT III trial [38]	TriGuard cerebral protection evaluation	85	Edwards Sapien and CoreValve	2015	TriGuard is safe and effective
BRAVO-3 trial [39]	Bivalirudin vs. heparin in TAVI	802	Multiple	2015	Bivalirudin does not reduce bleeding
EMBOL-X [40]	Intra-aortic protection device	30	Sapien XT	2015	Reduced cerebral lesions

AS — aortic stenosis; sAVR — surgical aortic valve replacement

Table 6. Unpcoming randomised clinical trials in transcatheter aortic valve implantation (TAVI).

Trial	Objective	Date of completion
PARTNER 3	To determine safety and effectiveness of Sapien 3 in low risk patients in comparison to sAVR	2027
UK TAVI	To determine clinical effectiveness and cost-utility of TAVI in comparison to sAVR (high and intermediate risk)	2016
ACTIVATION	Percutaneous coronary intervention prior to TAVI	
GALILEO	Effect of rivaroxaban anticoagulation strategy in comparison to dual anti-platelet therapy	2018
TAVR UNLOAD	To determine safety and efficacy of TAVI in patients with *moderate* aortic stenosis and heart failure in comparison to optimal medical therapy	2020
STEP for patients prior to undergoing TAVR	Whether supervized exercise would improve frailty status of TAVI patients	2017

sAVR — surgical aortic valve replacement; TAVR — transcatheter aortic valve replacement

Current evidence

The number of randomized trials involving TAVI is rising, and whilst initially the main objectives of the trials were to demonstrate its non-inferiority to sAVR, current trials also compare different strategies in TAVI (Table 5). These randomized trials thus far have certainly demonstrated non-inferiority to sAVR in terms of mortality and stroke in high and intermediate risk patients and superiority to optimal medical therapy.

Upcoming trials

Table 6 shows examples of the upcoming randomized clinical trials in TAVI [25]. The topics and the research questions that are being asked have

Table 7. Reported registries' outcome.

Registry	Country	Cases	Year	Mortality at 1 year	Stroke
FRANCE II	France	3,195	2012	24%	4.1%
STS/AAC	United States of America	12,182	2015	23.7%	4.1%
GARY	Germany	3,876	2014	24.3%	4.2%
UK TAVI	United Kingdom	3671	2015	18.3%	
Asian TAVR	Multiple	848	2016	10.8%	3.8%
Australian-New Zealand	Australia, New Zealand	540	2014	11.9%	8.2%

varied more recently and ask questions beyond merely demonstrating the efficacy of the technique.

Evidence from registries

The uptake of TAVI technology is increasing worldwide. Registries around the world are regularly publishing and updating their experience with TAVI. One-year mortality is somehow variable among different countries but the rate of stroke seems more consistent. Both outcome measures have decreased in recent years. Table 7 summarizes the two main outcomes (mortality and stroke) at 1 year reported by these registries according to their most recent publications.

Cost-effectiveness of TAVI

The debate over cost-effectiveness of TAVI is complicated with the following issues:

— The characteristics of the patients who are deemed suitable for TAVI (high risk elderly patients with multiple comorbidities);
— The life expectancy is relatively short for these patients even with successful treatment;
— The duration of economic modeling;
— The control group (TAVI vs. optimal medical therapy, and TAVI vs. sAVR);
— The healthcare/reimbursement system studied.

The index procedure of TAVI is more expensive than sAVR and any cost saving earned is usually through lower cost of hospitalization and follow-up. In the United Kingdom (Aug 2013), TAVI was found to be cost-effective when compared to optimal medical therapy (patients who were unsuitable for sAVR), but more costly and less effective when compared to sAVR (patients who were suitable for sAVR) [26]. Reynolds et al. [27] studied the PARTNER A cohort and concluded that trans-femoral TAVI was an attractive option when compared to sAVR but not transapical TAVI. When self-expanding prosthesis TAVI was compared to sAVR (CoreValve US. pivotal trial cohort), the authors concluded that TAVI provided meaningful clinical benefits with incremental costs considered acceptable by United States standards [28].

In summary, TAVI seems cost-effective when compared to medical therapy. Trans-femoral TAVI also seems cost-effective when compared to sAVR. It is very likely that the tide will shift in favour of TAVI when competition for alternative devices drives down device prices.

What lies ahead?

Arguably, the most frequently asked question in the TAVI arena is what happens to these prostheses long-term?

Dvir et al. [29] reported crude data in 2016 which suggested a 50% prosthesis degeneration rate within 8 years of implant. However, the number of cases at risk in the study was only 43 at 6 years and only 7 cases at 8 years. The jury is still out on this and future publications have much to add. The general feeling in the cardiology community is that TAVI prostheses are as durable a surgical bioprostheses although further research on this subject is eagerly awaited.

Considering recent results of PARTNER II and other intermediate risk studies such as UK TAVI and SURTAVI, it is very likely that the indications of TAVI will expand to cover intermediate risk patients, thus increasing the number of TAVIs worldwide even further. The expected increase in the uptake of TAVI will be consolidated by lower profile delivery systems, and predictable, repositionable and retrievable prostheses.

On the other hand, clinical practice simplification of the procedure (such as the introduction of conscious sedation, fully percutaneous approach and early mobility post TAVI) is likely to increase early discharge rates [30]. This approach is likely to make TAVI an even more cost-effective technique and more appealing to patients who are usually keen for quick recovery after a procedure.

Unanswered questions about co-morbidities such as co-existing coronary artery disease, mitral valve disease and pulmonary hypertension are likely to be clarified in the near future by further research (randomized and observational).

Finally, much of TAVI technology and experience is being utilized in the development of trans-catheter mitral valve interventions, the long-waited and expected next era of trans-catheter intervention.

Conclusions

Transcatheter aortic valve implantation is now a well-established therapy for aortic valve disease. The procedure is being simplified, the complication rate is being reduced and indications are expanding. It is an increasingly cost-effective treatment and is likely to become a first line option in the treatment of AS, particularly as device costs fall in the years to come.

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