Transcatheter Aortic Valve Intervention Complications and Challenges

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Since the first in man transcatheter aortic valve intervention (TAVI) performed by Dr. Alain Cribier in 2002 in a non-operable aortic stenosis (AS) patient, TAVI has changed the lives of so many patients for whom medical treatment was, up to then, the only option.

TAVI aortic stenosis

1. Introduction

Overall, the incidence of complications after TAVI has decreased significantly due to the increase in experience, the use of CCT as the main imaging modality for evaluating the feasibility of TAVI, the significant technological advancements in the design of the prostheses, and the decrease in the size of the sheaths.

2. Paravalvular Regurgitation or Leak

The incidence of PVL after TAVI has decreased significantly in the last two decades, due to the detailed pre-procedural evaluation with improvements in patient and prosthesis selection (avoiding under-sizing, recognizing the importance of severe valvular calcifications in predicting the risk of PVL), the technological advancements seen in the design of prosthetic valves and the increased experience. However, with the exception of the PARTNER 3 study, which showed similar rates of moderate-to-severe PVL in TAVI and SAVR, all other studies showed a higher incidence of PVL after TAVI as compared to SAVR, with 22–29% of patients having mild PVL and an incidence of moderate-to-severe PVL between 0.6–3.7% after balloon-expandable, and between 3.5–5.3% after self-expandable valves [1][2][3][4]. We know that the presence of moderate-to-severe PVL after TAVI is associated with increased mortality, but the significance of mild PVL after TAVI remains undefined [1]. The treatment of PVL depends on the severity and the consequences of PVL. In patients with significant PVL, balloon post-dilatation, valve-in-valve TAVI, percutaneous closure with a plug, surgical intervention or medical treatment should all be considered on a case-by-case basis.

3. New Pacemaker Implantation and New Left Bundle Branch Block (LBBB)

Even though, over the years, the incidence of new conduction abnormalities and pacemaker implantation has decreased, most studies still show a higher incidence of conduction abnormalities after TAVI as compared to SAVR, in particular for self-expanding valves, with a reported incidence of 17–25% for new pacemaker implantation in more recent trials [2][4]. In the PARTNER 3 trial, there was no difference between the TAVI and SAVR groups regrading new pacemaker implantation, but the incidence of new left bundle branch block was higher in the balloon-expandable TAVI group as compared to the SAVR group (22% vs. 8%) [3]. The risk of conduction abnormalities and new pacemaker implantation is higher in the first 2 days after TAVI and is significantly increased in patients with baseline right bundle branch block, severe annular calcifications and a lower implant depth, whereas a higher deployment of the valve has been associated with a decreased risk of new conduction abnormalities after TAVI [5][6][7]. The data regarding the prognostic impact of new left-bundle branch block and pacemaker after TAVI are controversial. In the SURTAVI trial, survival at 1 year was not different in patients with a new pacemaker compared to the overall population, whereas in other studies, mortality was significantly increased in TAVI patients with a new pacemaker, in particular for pacemaker-dependent patients [2][8]. In a sub-analysis of the PARTNER 2 trial, new-onset LBBB was associated with significantly increased all-cause and cardiovascular mortality, hospitalization and pacemaker implantation [9]. These patients should be closely followed up and, in patients with a QRS duration of >150 ms and prolonged PR >240 msec, continuous ECG monitoring or electrophysiologic testing might be considered to guide the decision for pacemaker implantation [10].

4. Embolic Events

Stroke is a feared and devastating complication, associated with increased mortality, cognitive impairment, important functional and social consequences, and high costs. Although the risk of most TAVI complications has decreased in the last 10 years, the risk of TAVI-related stroke has remained stable at an incidence of about 2%; however, this is slightly lower with the newer generation of valves, between 1.1–1.2% [3][4][11][12]. Moreover, even in the absence of symptoms, most TAVI patients have defects identified on cerebral MRI that may be associated with the development of cognitive impairment [13]. TAVI-related stroke is mainly caused by the embolization of debris from the valve or the vasculature and is less often related to arrhythmia. The size of the debris is correlated to the size of the cerebral lesion. The risk of stroke is higher in women as compared to men; it is higher in the first days after TAVI, it is slightly lower in balloon-expandable than in self-expandable valves, and it is not related to the use of pre- or post-dilatation nor the anti-platelet or anticoagulant treatment used [3][4][11][12][13][14][15].

Cerebral embolic protection devices have been developed for capturing and removing embolic material during TAVI, with the hope of reducing periprocedural stroke. The most used device is the Sentinel cerebral embolic protection device (Boston Scientific). It consists of two filters within a single 6-French delivery catheter, which are placed percutaneously before TAVI, into the brachiocephalic artery (proximal filter) and the left common carotid artery (distal filter), using a right radial or brachial artery access. The use of Sentinel is safe, with a feasibility of >90% and a low rate of complications; however, although it has been shown to significantly reduce new ischemic brain lesions post-TAVI, there is no clear evidence proving a decrease in stroke incidence after TAVI [13][15]. The recent PROTECTED TAVR trial failed to show a significant difference in the incidence of stroke after TAVI in patients with and without the cerebral protection device, even if the incidence of disabling stroke was numerically lower. Whether the negative results of this trial are more related to the design of the trial than to the lack of effectiveness of the device is a matter of debate. The residual stroke risk may be related to smaller debris particles that may pass the filters, to an eventual malapposition of the filters or to embolization through the left vertebral artery, which is not covered [15]. Future studies, such as the BHF PROTECT-TAVI trial, will hopefully shed more light on the effectiveness of cerebral protection devices.

5. Vascular Complications

Access site-related vascular complications remain the most frequent complication after TAVI and are associated with worse short- and long-term outcomes. In the STS/ACC TVT registry, 9.6% of TAVI patients had a vascular complication, and 7.6% of patients had an access site bleeding event [16]. However, the incidence of access site-related complications has decreased over the years, owing to a decrease in the size of the sheaths and of the anti-thrombotic treatment used, the utilization of Doppler echocardiography for determining the best site for vascular puncture, and the use of percutaneous vascular closure devices. Prompt and efficient diagnoses and management are necessary for achieving bleeding control, which is usually carried out via crossover angiography from the contralateral femoral artery or, more recently, from the radial artery. Limited dissection or perforation can usually be managed with prolonged occlusive balloon inflation, whereas percutaneous deployment of a stent, thrombin injection or surgical repair can be used in cases with more extensive, flow-limiting dissection or bleeding, or in cases with hemodynamic instability or threatened limb circulation [17].

6. Valve Durability and Valve-in-Valve TAVR

Transcatheter valve durability remains one of the limiting aspects to the extension of TAVI in younger patients. Studies have shown that transcatheter valves, in particular supra-annular self-expandable valves, have lower gradients and higher effective orifice areas as compared to surgically implanted bioprostheses, values which are stable over 2 and up to 8 years of follow up, with low rates of structural valve deterioration or bioprosthetic valve failure, comparable to those seen in SAVR patients [1][2][3][4][18][19][20][21]. Although the data are encouraging, it should be pointed out that most of this evidence comes from older patients and cannot be extended to younger patients. In the current guidelines, the limiting age for considering TAVR is 75 years in the European guidelines, and 65 years of age in the American guidelines [22][23]. The patient's comorbidities and the individual expected life expectancy as compared to the durability of the prosthesis should be taken into consideration in the decision making, but in the absence of evidence, SAVR remains the treatment of choice in young patients with severe AS and indication for intervention [22][23]. Although in daily practice researchers see more and more and more young patients and patients at low surgical risk asking us about the possibility of performing TAVI, mainly related to the fear of the surgical intervention, TAVI should be strongly discouraged, and patients should be reassured and informed about the actual risks of the surgical intervention in their case. We should stress the higher risks of stroke, PVL and conduction disturbances related to TAVI as compared to SAVR, the absence or the limited data available in these groups of patients, and the risks related to a second intervention. Whenever a biological surgical or transcatheter valve is implanted in a younger patient, the risk of two or more interventions is high, and a careful life management plan should be considered [24]. Performing SAVR after TAVI is associated with a higher risk as compared to SAVR on a native valve; the resection of the prosthesis requires in most cases a more extensive surgery with associated root or ascending aorta replacement [24].

Valve-in-valve TAVI has emerged as an appealing, less invasive alternative to surgical reintervention in patients with bioprosthetic valve failure, being associated with significantly lower rates of 30-day morbidity and mortality, a lower risk of bleeding and a shorter hospitalization [24][25][26][27]. Valve-in-valve TAVI is, at the moment, the preferred treatment option in older or multiple-comorbidity patients with degenerated, surgically implanted or transcatheter bioprosthetic valves. However, valve-in-valve TAVI can be associated with higher gradients and higher rates of patient–prosthesis mismatch (in particular for small initial bioprostheses), as well as with a higher risk of acute coronary obstruction. The obstruction of a coronary artery is a feared complication of valve-in-valve TAVI that can occur in about 2 to 3% of patients [26]. Coronary artery obstruction can be caused by direct obstruction of the coronary ostia by the underling valve leaflets, pushed outward, or indirectly by sequestering the sinus of Valsalva at the sino-tubular junction. When a second prosthesis is implanted in a patient with a previous transcatheter valve, the leaflets of the first prosthesis are pushed open upwards, sealing the stent frame circumferentially up to the commissure level. If the commissure level of the first prosthesis is above the sino-tubular junction and its stent frame is in close proximity to the sino-tubular junction, the risk of coronary sinus sequestration with TAV-in-TAV is high [28]. Pre-procedural CCT plays an important role in evaluating of the risk of coronary obstruction before valve-in-valve TAVI and TAV-in-TAV. Coronary artery obstruction with valve-in-valve TAVI can have catastrophic implications and, whenever the risk of coronary artery obstruction with valve-in-valve TAVI estimated by the pre-procedural CT is high, surgery should be considered instead. Several reports have shown the feasibility of bioprosthesis leaflet laceration with an electrocautery wire (BASILICA) before valve-in-valve TAVI, in order to prevent acute coronary artery obstruction; however, the procedure is only limited to high specialized centers, and is not feasible in all cases [29].

7. Coronary Access after TAVI

Many patients with AS have associated coronary artery disease, and about 10% of TAVI patients have an acute coronary syndrome in the first 2 years after TAVI, which is associated with a high mortality [30]. In general, the risk of difficult coronary artery access after TAVI is greater for supra-annular prostheses and with tall stent frames and small struts, but some studies have shown no significant differences between the type of prosthesis and the difficulty in obtaining coronary cannulation [31]. The incidence of unsuccessful coronary cannulation or unsuccessful PCI after TAVI varies between 3–7% in studies, to up to 35% of patients in real-world registry data, and the risk is higher for TAVI-in-TAVI procedures [31][32][33]. Maintaining good coronary access is particularly important for younger patients, and several strategies are available: implanting a valve with a sub-coronary frame position, obtaining commissural alignment for supra-annular valves and choosing prostheses with large open cells [24][34].

8. TAVI in Bicuspid Aortic Valve

Bicuspid aortic valves pose several challenges for TAVI, related to the often-asymmetrical aortic annulus, the presence of the raphe, which is often calcified, and the associated aortic root dilatation. Although studies with earlier prostheses have shown worse outcomes and a higher risk of PVL and aortic root injury, as compared to TAVI in tricuspid valves, more recent studies show no difference in the mortality and valve hemodynamics in TAVI in bicuspid vs. tricuspid aortic valves; however, the risk of significant PVL and stroke is higher [35][36]. There are little data about the anatomy of the bicuspid aortic valve that favors TAVI, the sizing of the valve and the best prosthesis for TAVI in bicuspid aortic valves. We need more data on the durability of TAVI in bicuspid aortic valves, on patient selection and on the sizing of the prosthesis. However, we know that TAVI in patients with severe and asymmetric leaflets and left ventricular outflow calcifications, with raphe calcifications, with a more elliptical aortic annulus or with a dilated ascending aorta >45 mm, can result in suboptimal prostheses expansions, and are associated with worse outcomes [36][37].

9. TAVI in Aortic Regurgitation

Aortic regurgitation also poses several challenges to the performance of TAVI, which are related to the larger annulus dimensions, the often-asymmetric annuli with a higher risk of PVL and the absence of valve calcifications, which are the landmark and the substrate for anchoring the prosthesis. Little evidence exists that shows good results in non-operable patients with pure aortic regurgitation and, according to the guidelines, TAVI may be considered in selected, non-operable patients with severe AR [22]. Newer valves have been developed specifically for patients with aortic regurgitation, such as the JenaValve (JenaValve Technology GmbH, Munich, Germany), which has a clip-based fixation over the native aortic leaflets. The ALIGN AR study is assessing the efficacy and the safety of the JenaValve system in patients with symptomatic severe aortic regurgitation who are at high surgical risk.

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