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Opinion

Surgical Aortic Valve Replacement Remains a Valid Option to Treat Aortic Valve Disease in the Era of Transcatheter Aortic Valve Implantation: An Opinion

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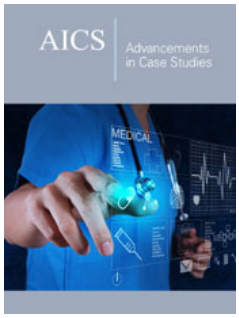

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Abstract

Transcatheter aortic valve implantation has become a major treatment for aortic valve disease in elderly high-risk patients and is expanding into a younger low-risk population. Concurrently, newer rapid deployment and highly durable bioprosthetic valves were developed for surgical implantation. At the same time, less invasive approach has become an option for many patients. These developments indicate that aortic valve surgery will remain an important option for the treatment of a highly lethal and invalidating aortic valve disease.

Keywords: Surgical aortic valve replacement; Rapid deployment valve; Transcatheter aortic valve implantation; Minimally invasive surgery; Durability

Introduction

Surgical aortic valve replacement (SAVR) has been the standard for the treatment of symptomatic aortic valve disease [1]. Replacement of the aortic valve by a mechanical valve offers the advantage of a life-long durability and avoidance of reoperation. The disadvantages are the risk for thromboembolic vents, with the need for life-long anticoagulation vitamin K antagonists, major bleeding, the need for dietary restrictions and of an active lifestyle [2]. In case of device failure, a valve-in-valve transcatheter aortic valve implantation (VIV-TAVI) is not possible. Replacement by a biological heart valve (BHV) prosthesis poses a problem of durability. Nevertheless, the implantation of BHV has increased during the last decades [3]. At the same time, TAVI has been applied with success for frail patients with a high-risk profile. The technique has been improved and has been expanded into a younger patient population with a lower risk profile [1]. This raises the question, which future does SAVR have in the treatment of aortic valve disease in the TAVI era? To address this question, the recent progress of the BHV prosthesis needs to be discussed, especially with respect to the internally mounted stented valves such as the Carpentier-Edwards valve. The device is highly durable, even in a relatively young patient population. Several improvements such as Carpentier-Edwards Magna Ease (CEME) were introduced. Its frame was used to construct newer BHV prostheses. Two tracks were followed. Parallel to these developments, the mode of surgical access also underwent modifications.

Main findings

The first track led to the INSPIRIS RESILIA, mounted on a CEME frame, with glycerolized tissue to allow the dry storage and handling. To facilitate possible future VIV-TAVI, the frame is made expandable by using a cobalt-chromium alloy band for valve sizes 19 to 25. During TAVI-VIV, a radial force can be applied by the new device, allowing a uniform, controlled and

predictable expansion. The perforated polyester band of the ISPIRIS RESILIA valve is able to expand at each of the three commissures, without the need to achieve a high-pressure BHV fracture. This reduces the risk for stroke and other procedural complications. The recently published COMMENCE trial showed promising results, with low 30-day mortality, adverse events reoperation rate and favorable hemodynamic profile. At 5 years these results were sustained [2].

The second track involves the development of rapid deployment valves, of which the INTUITY valve, is an example. It is also mounted on a CEME platform [4]. It needs only 3 guiding sutures and involves a balloon-expandable frame covered with cloth. This device can be mounted in the left ventricular outflow tract (LVOT), which is widened. The INTUITY ELITE, which is also mounted on the CEME platform combines the aspect of rapid deployment with dry handling of the valve. The device has a modified location of sealing cloth and double-crimped frame designed to enhance parachuting and anatomical seating [4]. The use of these rapid deployment devices results, according to reviews, [5] metanalyses [1], PSM studies [6] and single arm series [4] in

A. A high technical success rate, but still somewhat lower to sutured valves [1].

B. A low transvalvular gradient (TVG) for all sizes, especially the smaller ones [1,5,7] and absence of valve prosthesis mismatch or VPM [8].

C. Less turbulence because of the absence of pledgets and of expansion of the LVOT [4,7].

D. A reduced aorta cross-clamp (ACC) and cardiopulmonary bypass (CPB) time [4,9,10].

E. A low 30-day mortality, myocardial infarction, stroke rate, comparable to sutured valves [1,5] even in patients needing concomitant CABG [7].

F. A need for permanent pacemaker (PPM) implant, comparable to TAVI but higher compared to sutured valves [1,5,8].

G. An increased need for reintervention for paravalvular leak (PVL), which varied according to the included series in the review. An annular purse-string suture was proposed as solution [1]. Other authors reported a comparable rate for PVL [5].

H. A five-year outcome such as survival and thromboembolism, comparable to CEME [10].

I. A five-year hemodynamic outcome, comparable to CEME [10].

J. Comparable and low reoperation rate for SVD or for prosthetic valve endocarditis [4].

Another rapid deployment valve, the PERCEVAL device, has bovine pericardial leaflets mounted on a self-expanding nitinol stent with a "memory" [9]. Two rings and nine connecting struts support and secure the position of the valve after implantation. The advantages of this device are somehow comparable to the INTUITY valves according to one review [11] and a very large PSM [6].

a) A favorable hemodynamic profile because of the thin stents, the freely moving leaflets and the absence of pledgets [12,13].

b) A shorter ACC and CPB times [11,13].

c) A comparable mortality as for sutured valves [9,13] or as for TAVI [11].

d) An increased stroke rate, but only in the early era of valve implant [11].

e) A similar mild-to-moderate PVL [9], comparable to that after TAVI [11].

f) A need for PPM implantation comparable to sutured valves [13], to TAVI [11], and in one report a higher need [9].

g) A long-term survival, comparable to sutured valves [13].

Comparison between the INTUITY and the PERCEVAL devices showed that the latter had lower ACC and CPB times and allowed more right anterior mini-thoracotomy (RAMT), but the INTUITY valve had a significantly better hemodynamic profile with lower mean TVG and a lower rate of PVL. Safety (stroke, mortality) and SVD rate were comparable in a large PSM analysis, but long-term data were also absent [6]. In a meta-analysis [5], long-term outcome of implantation with PERCEVAL was compared to that for INTUITY valve. Mortality, PVL, endocarditis, thromboembolism, and SVD were low and comparable. Mean effective orifice area after 5 years was between 1.6 and 1.8 cm^2. In one meta-analysis [12], it was established that the PERCEVAL and INTUITY valves were complementary. The PERCEVAL device was associated with increased mean and peak TVG. This could paradoxically be due to oversizing (with folding) and more PVL. The balloon expanded INTUITY valve skirt could result in larger LVOT and better flow, which seems more suitable for small annuli. However, long-term data, especially with respect to increased TVG, are lacking, as well as data for major cardiac adverse events. The INTUITY device carried the risk of an increased need for PPM implant, but less than the PERCEVAL [4]. Although a meta-analysis [14] confirmed the clinical findings for PERCEVAL devices, it contrasted the need of PPM implantation, which was 2.50-fold higher for this device. Increase in experience and improvement in surgical technique may alleviate the higher need for PPM implantation. The need for PPM implant should be a reason for concern, since this not a benign event. Annular calcification was identified as a risk factor for this event [9]. Adequate decalcification and balloon pressure in case of INTUITY valves, avoidance of oversizing and exclusion of patients with prior conduction defects might improve this complication rate [6], especially if this concerns right bundle branch block [8]. The postoperative conduction defects could be reversible [8]. The timing for implanting a PPM could be postponed for 5 to 7 days [4].

The development of minimal access aortic valve replacement (MI-AVR) ran somewhat parallel with the introduction of these

newer valves. Partial sternotomy (PS) and RAMT were the main options. Implantation through MI-AVR for the rapid deployment valves was considered as a good alternative for TAVI, with the potential to overcome challenging anatomical issues [1,5,9,11,13]. There was a success rate of 98.6% for MI-AVR in one series, with a good outcome for safety and efficacy [15]. Implantation of the INTUITY valve through RAMT was considered as safe, feasible, and reproducible. Although RAMT was considered as less invasive, the technical challenges were higher compared to a sternotomy. The CPB and ACC times were higher compared to PS and full sternotomy, for the INTUITY valve as well as for the PERCEVAL devices [6]. Contraindications for RAMT were, and still are chest deformity, endocarditis with suspected root abscess or a calcified ascending aorta. This approach seems underused in the surgical community. With the more modern valves, RAMT might become more acceptable, but this approach requires standardization. With growing expertise, cannulation thought the femoral vessels could be replaced by a more difficult cannulation through the chest incision, thereby avoiding complications in the groin [8].

The durability of any BHV prosthesis makes SAVR a good option in the TAVI era. This would be the definite solution for most elderly patients. Even with a good durability of any biologic prosthesis, there remains a possibility for SVD and the need for reintervention in younger counterparts. In these cases, the choice will be between redo-SAVR or a valve-in-valve TAVI (VIV-TAVI). Since these patients will have become older and possibly have developed more comorbid conditions, VIV-TAVI might be the preferred option. The UNTUITY device has been designed to allow a predictable and controlled expansion of the stent. One PSM analysis showed a higher early mortality rate after a redo-SAVR but six-year survival was comparable between both groups. Early outcome of VIV-TAVI for SVD was better in elderly, while the mid-term survival was comparable. Aortic regurgitation and higher TVG after VIV-TAVI was a concern [16]. This analysis, however, did not include a prior implanted INTUITY or RESILIA valve. A meta-analysis [17] confirmed these findings. The potential for coronary obstruction in TAVI-VAV was a reason for concern. A difficult anatomy of the aortic root, valve prosthesis dehiscence, endocarditis, and younger age favored redo-SAVR. The 30-day benefit of VIV-TAVI was lost after one year follow-up [17].

A TAVI-VIV procedure seemed preferrable in older and frail patients with a shorter life expectancy. A redo-SAVR was better in the long run, especially in younger patients with small annuli. The INSPIRIS RESILIA valve with Vfit technology has been designed to accommodate for a TAVI-approach, thereby avoiding the need for fracturing of the previously implanted valve ring. The system allowed implantation of a second valve thereby decreasing the risk for VPM and concurrently high gradients, which in itself is a risk factor for early SVD and mortality. The issue of opting for SAVR in the era of TAVI cannot be restricted to isolated SAVR, since an important portion of patients with aortic valve disease also suffer from CAD [18]. Often, this is a multivessel disease. The strategy to associate a percutaneous coronary intervention with TAVI is fraught with technical difficulties, while associating CABG to a SAVR is common practice. Furthermore, functional mitral or tricuspid valve regurgitation associated with aortic valve disease is often left untreated with TAVI. These associated conditions resolve only in part of the patients, and morphologic mitral or tricuspid valve abnormalities do not regress at all. These considerations make TAVI less attractive in patients with combined heart diseases.

Conclusion

The recent developments with respect to durability and ease of implantation of the newer valves indicate that SAVR still has a future in the treatment for aortic valve disease, especially when VIV-TAVI in a later stage of the life of the patient is anticipated. The INSPIRIS RESILA device was developed with this in mind. Currently, only short and mid-term results are available, which is the main limitation of this opinion. The long-term results of the involved devices and the success rate of VIV-TAVI will determine the future place of SAVR in the therapeutic armamentarium. Current results indicate this will be probably the case.

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