Review Article

The Use of Biological Heart Valves

Types of Prosthesis, Durability and Complications

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Summary

Background: Biological heart-valve prostheses have undergone continuous development up to the present, and technological advances have been made in catheter-assisted valve systems (transcatheter aortic valve implantation, TAVI) and minimally invasive routes of application. These parallel trends have led to major changes in therapeutic strategies, widening the spectrum of patients who are candidates for biological aortic valve implantation.

Methods: This review is based on pertinent publications retrieved by a systematic search in PubMed employing the search terms “conventional biological aortic prosthesis,” “rapid deployment prosthesis,” and “transcatheter aortic valve implantation/replacement.”

Results: Among biological heart-valve prostheses, a distinction is drawn between stented (conventional, rapid-deployment, and catheter-assisted) and non-stented types. The long-term durability of conventional, surgically implantable biological valve prostheses is by far the best documented: the reported 5-year reoperation rates range from 13.4% to 36.6%, and the pacemaker implantation rate is ca. 4%. Rapid-deployment prostheses combine the advantages of conventional and catheter-assisted techniques and facilitate minimally invasive approaches. The TAVI method is currently recommended for high- and intermediate-risk patients, while conventional valve replacement remains the method of choice for those at low risk. Rapid-deployment and TAVI prostheses is associated with a higher pacemaker implantation rate than conventional prostheses: these rates are 8.5–15.3% for TAVI and 6.0–8.8% for rapid-deployment valves. The intermediate-term durability of catheter-assisted and rapid-deployment prostheses appears promising, but their long-term durability is still unclear.

Conclusion: The further development of biological heart-valve prostheses in the form of improved conventional, transcatheter, and rapid-deployment prostheses now enables individualized treatment. Before any such procedure is performed, the cardiac team must assess the patient's risk profile and the advantages and disadvantages of each type of prosthesis to determine which is best.

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Rates of degenerative heart disease are rising, especially owing to increasing life expectancy. A needs assessment that considered the potential for progress in developing countries estimated a number of heart valve procedures worldwide of 800 000 for the year 2050 (1). In Germany, a total of 33 440 aortic valves were surgically replaced in 2016. Of these operations, 22 561 were conventionally performed by using a heart-lung machine/cardiopulmonary bypass—either as an isolated aortic valve replacement (n = 11 084) or as a combined procedure—and 10 879 were done by means of transcatheter aortic valve implantation (TAVI) (2).

For the treatment of aortic valve diseases, biological prosthetic valves are available, in addition to mechanical prostheses and reconstructive methods. The crucial advantage of using biological valves—compared with valve replacements using mechanical prostheses—is the fact that continuous anticoagulation is not required. Another advantage for many patients is also the fact that biological valves do not produce any sounds. The disadvantages of biological heart valves are a smaller valve orifice area (3) and the risk of structural valve degeneration (4), which may necessitate reoperation (*Table 1*).

Since the development and initial implantation of biological heart valves in the 1960s, the chemical treatment of biological material, the construction of the prostheses, and the possible surgical access routes to the aortic valve have undergone fundamental developments. The therapeutic recommendations are being continually adapted. The *Figure* shows the individual types of biological heart valves that can be implanted today; they are presented in this article together with their special characteristics, such as their durability. In principle, we will distinguish between stented valves with a so called stent frame and non-stented valves.

Method

For our review article, we searched the database PubMed, using the search terms “conventional biological aortic prosthesis”, “rapid deployment prosthesis”, and “transcatheter aortic valve implantation/replacement”. From the search results (6475 studies) we selected 41 studies that were relevant in terms of the advantages and disadvantages of the valve types.

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TABLE 1

Factors that contribute to favoring a specific type of prosthesis in patients stenosis of the aortic valve (+) or that militate against using a particular type of prosthesis (-)

Factor	Mechanical prosthesis	Biological prosthesis		
		Conventional	"Rapid deployment"	Transcatheter (TAVI)
Age <60 years	+	-	-	-
Age 60–65 years	No unequivocal treatment recommendation currently			
Age 65–75 years	-	+	+	-
Age >75 years	-	+	+	+
STS score >4%	-	-	+	+
Life expectancy <10 years	-	+	+	+
Already requires anticoagulation ^{*1}	+	- ^{*1}	- ^{*1}	- ^{*1}
On hemodialysis	-	+	+	+
Endocarditis	+	+	-	-
Contraindication for phenprocoumon ^{*2}	-	+	+	+
Bicuspid aortic valve	+	+	+ ^{*3}	- ^{*4}
Porcelain aorta	-	-	-	+
Patient has had previous bypass surgery; at risk of bypass injury from reoperation	-	(+)	-	+

^{*1} In some clinical scenarios (for example, anticoagulation for atrial fibrillation) it may make sense in spite of existing anticoagulation to implant a biological prosthesis.

^{*2} For example, limited compliance, women wishing to become pregnant, high risk of hemorrhage, etc.; ^{*3} Classification according to Sievers: 1 & 2; ^{*4} Classification according to Sievers: possibly 1;
STS, Society of Thoracic Surgeons; TAVI, „transcatheter aortic valve implantation“

Results for stented biological prosthetic valves

The biological semilunar valve material used to make stented prostheses is mounted on a frame that consists, for example, in the case of a valve of the Perimount Magna type, of a polyester-coated cobalt-chrome alloy. The material used for the semilunar valves is either bovine pericardium or porcine aortic valves. These are chemically treated in order to prevent a rejection reaction and to prolong the durability of the prostheses. The frame may be collapsible, such as is the case for transcatheter valves or “rapid deployment” valves of the Perceval type, or it can be rigid, as is the case for conventional biological prostheses or rapid deployment valves of the Intuity type.

Conventional bioprostheses

Definition

“Conventional bioprosthesis” is the term used to describe prostheses with a rigid, non-folding stent frame. The surgeon ties the replacement valve—after removing the diseased native valve—to the aortic valve annulus with 12–18 sutures. The implantation of such biological valve prostheses is done with the patient on cardiopulmonary bypass, and the patient’s heart is stopped briefly.

Materials and evidence of durability

The semilunar valves of conventional bioprostheses consist of either bovine pericardium (for example, in

case of the Perimount and Trifecta types) or native semilunar valves from pigs (for example, the Mosaic, Hancock II, and Epic types). In small prospective randomized trials with short follow-up periods, prostheses made from bovine pericardium had better hemodynamic results than porcine prostheses, with smaller transvalvular gradients and larger aortic valve orifice areas (5–7).

A large study reported by Hickey et al in 2015 included almost 40 000 patients and retrospectively analyzed data from national registries. The researchers adjusted for confounding variables. The study showed that 10 year survival rates of patients with implanted bovine valves and those with implanted porcine valves were almost identical (49.0% versus 50.3%) (8). These findings were confirmed by additional smaller retrospective and prospective studies (9, 10). The comparison of the study results is made difficult by the fact that different types of prostheses were used and study design, follow-up periods, and characteristics of the patient populations differed (11).

The assumption is that valves made from bovine pericardium are superior to those made from porcine valves because of their improved hemodynamic characteristics; newer bioprostheses are mostly made from bovine pericardium (11). In smaller studies, such valves from bovine pericardium, such as the Trifecta valve, were again found to have better

FIGURE

Types of biological heart valve prostheses—an overview (adapted from Puri et al. [e2])

hemodynamic characteristics, with lower gradients and larger valve orifice areas (12–14).

The speed at which conventional bioprostheses are subject to calcific degeneration depends, among other factors, on the patient's age. *Box 1* lists risk factors that contribute to valve degeneration. A study by McClure investigated how long patients were free from reoperation because of structural valve degeneration. 15 years after implantation of a bioprosthesis of either the Perimount or the Perimount Magna type, the rate of freedom from reoperation in the patient group aged less than 65 years was 35%, in the age group 65–75 it was 90% and in the group of patients older than 75 years it reached 99.5% (4). Because of structural valve degeneration, reoperations in patients with biological valves prostheses are about eight times more common in 60 year old patients (25% versus 3%) than for mechanical valve prostheses (15). The risk of reoperation after implantation of a conventional biological aortic valve is about 45% for patients aged 50, 25% for patients aged 60, and 10% for patients aged 70 (15).

The risk of reoperation to exchange a prosthetic valve is only slightly higher than for the initial procedure. A prospective observational study documented for selected patients without endocarditis an

in-hospital death rate of 0.9% (16). If the patient's risk profile makes the exchange impossible transcatheter procedures are an alternative. Transcatheter aortic valve implantation (TAVI) into a conventional biological prosthesis can be undertaken with a high degree of safety (case fatality rate at 30 days: 2.7%) and good functional results. However, the long term durability is unknown. The procedure in which a TAVI prosthesis is implanted into a bioprosthesis that is mostly affected by degenerative changes (17) is known as the "valve in valve" procedure. Because of the technical feasibility of valve in valve treatment, conventional biological types of prostheses have been developed in the meantime that are particularly suitable for the valve in valve approach. The Inspiris valve (*Figure*) has a stent frame that is particularly visible on a radiograph; this frame is expanded during the valve in valve procedure and is intended to aid the implantation of larger catheter valves. Currently, however, no studies exist of this valve type in combination with a valve in valve procedure.

In the mitral valve position, the prosthesis will degenerate faster than in the aortic valve position (18). For this reason, a higher age limit for biological—rather than mechanical—valve replacement has been recommended (>75 years) (18).

BOX 1

Factors that affect the durability of bioprostheses (39, e3, e4)

- Construction and overall height—mechanical stress on the free edges of the leaflets
- Type and preparation of the semilunar valve material—denaturation, preventing recalcification
- Age at the time of implantation (“biological stress”)
- Comorbidities (renal failure, diabetes mellitus, dyslipidemia, etc)
- Smoking
- Overweight
- “Patient-prosthesis mismatch”
- Persistent left ventricular hypertrophy

A meta-analysis showed that in patients requiring dialysis, using biological heart valves does not affect mortality compared with mechanical heart valves (19). Furthermore, bleeding complications are significantly less common (6.9% versus 19.6%) and structural valve degeneration occurs in very few cases (0.6% of patients after biological valve implantation) (19). The explanation is that survival is notably reduced in patients required dialysis. For this reason, the recommendation is to implant biological prostheses into such patients.

Advantages and disadvantages

Among all biological valve types, long term durability is best confirmed for conventional biological valve prostheses; 10 years post-implantation, 99.5% of patients older than 75 were free from reoperation for valve degeneration (4) (*Table 2*). Furthermore, conventional valve prostheses are characterized by the lowest risk of paravalvular leakage, a low stroke risk (ca. 1%), and the lowest rates of pacemaker implantation (ca. 4%) (20). The patient is put on cardiopulmonary bypass for a brief period only (50–70 min). Surgical access is usually through a complete or partial median sternotomy. This usually heals well and causes little postoperative pain. Minimally invasive access through right anterior thoracotomy between the ribs is possible, but requires a strict selection of patients. To shorten the period of cardioplegic cardiac arrest, enable minimally invasive access, and maintain the advantages of conventional prostheses, “rapid deployment” prostheses were developed.

“Rapid deployment” prostheses

Definition

As with conventional valves, rapid deployment prostheses are implanted while the patient is on cardio-

pulmonary bypass (21). Two types of valves are available: a sutureless, self-expanding bioprosthesis (Perceval and Perceval Plus) and a conventional bioprosthesis that is combined with a subvalvular balloon expandable stent frame and is anchored in the aortic annulus with three fixing sutures (Intuity).

Materials and evidence of durability

The valve prostheses of the Intuity and Perceval types are made from bovine pericardium. The durability of the Intuity valve after 5 years was described as very good in a prospective study of patients with a mean age of 75 years. A degeneration of the valve was seen in four patients (0.4% per patient year [ppy]). The effective valve orifice area—determined echocardiographically by means of continuity equation—was 1.7 cm² at discharge from hospital and 1.6 cm² five years later (22). A prospective pilot study of the Perceval valve confirmed the good hemodynamic results: the effective valve orifice area was 1.55 cm² after one year and 1.69 cm² after five years. A further prospective study including more than 700 patients showed very good hemodynamic results after five years and no cases of valve degeneration (23). Large randomized prospective trials are currently being conducted to investigate the long term results of rapid deployment valves. A prospective study started in 2016 (the PERSIST Trial) is comparing the Perceval valve with conventional biological valve prostheses. The primary study endpoints are rates of death, myocardial infarction, valve related reoperations, and occurrence of a stroke a year after implantation. Patients are being followed-up for five years. Such prospective randomized trials are essential in order to be able to draw more valid conclusions about the durability and the advantages and disadvantages of rapid deployment prostheses.

Advantages and disadvantages

Rapid deployment prostheses allow for shorter operation and implantation times and facilitate minimally invasive approaches (thoracotomy or mini-sternotomy). These prostheses are intended to combine the advantages of conventional surgery—the controlled, complete removal of the degenerated native valve, the safety and the control of possible complications, and the long durability of the prostheses made from bovine pericardium—and of transcatheter techniques (fast implantation, less invasive access). Hemodynamics are generally rated better thanks to the smaller stent frame (24). Rapid deployment prostheses were initially recommended as therapeutic alternatives to conventional bioprostheses (25). A retrospective study from 2018, however, documented for rapid deployment prostheses a greater need for postoperative pacemaker implantation than for conventional bioprostheses (3.7% versus 8.8%, $P < 0.001$) and no effect on in-hospital mortality (20). Compared with conventional bioprostheses, only one meta-analysis has confirmed the superiority of the Perceval valve with regard to the occurrence of postoperative renal failure, the

TABLE 2

Selection of biological (tissue) prostheses with confirmed long term results^{*1}

Bioprosthesis	Number of patients	Average age of patients	Length of follow-up; up to:	Rates of patients without reoperation after 10 years or SVD ^{*2}	Rates of patients without reoperation after 15 years or SVD ^{*2}	Rates of patients without reoperation after 20 years or SVD ^{*2}
Perimount (e5)	2659	70.7 ± 10.4	24 years	93.2 ± 0.8	81.5 ± 1.9	51.5 ± 4.6
Mitroflow (e6)	1516	75.6 (16–92)	19 years	79.2 ± 2.4	63.4 ± 5.3	Not available
Hancock II (e7)	1134	67 ± 11	25 years	97.6 ± 0.6 ^{*2}	86.6 ± 1.8 ^{*2}	63.4 ± 4.2 ^{*2}
Biocor (e8)	1518	70.8 ± 10.9	20 years	Not available	Not available	61.1 ± 8.5
Freestyle (e9)	725	71.7 ± 7.9	18 years	92.3 ± 1.8	80.7 ± 5.0	Not available
Mosaic (e10)	1005	74.7 ± 6.8	18 years	97.9 ± 0.6 ^{*2}	86.3 ± 3.9 ^{*2}	Not available

^{*1} The selection shows only some of the available bioprostheses and the available literature; other articles have reported different results for the long term durability of bioprostheses. The hemodynamic characteristics in the form of gradients are not evaluated in this table. ^{*2} SVD, structural valve deterioration.

intraoperative need for blood products, and the post-operative transvalvular gradient (26).

Because of its individual construction, the Intuity valve is the preferred option in combined procedures using aortocoronary bypass grafting, since, in case of the Perceval valve, the aortotomy has to be placed higher up because of the frame height of the Perceval valve, which restricts the space for the grafts to be connected to the aorta.

The frame of the Perceval valve is collapsible. This makes it particularly useful in operations with minimally invasive access, where space and visibility are restricted. Furthermore the flexibility of the frame lowers the risk of abrasions during implantation, especially if calcifications of the aortic wall are extensive. The prosthesis is collapsed and not “crimped,” as is the case with valves during TAVI. Damage to the collagen fibers of the pericardial valve, which is associated with collapsing the prosthesis, was not seen in a histological study using the scanning electron microscope—in contrast to TAVI valves after crimping (27).

Since rapid deployment valves are made from the same material as conventional bioprostheses, their durability is well predictable. In our hospital, the use of these types of prostheses has proven to be of value, especially in complex combined procedures and in a setting of extensive annular calcifications, such as in degenerated stentless bioprostheses or homografts, and in minimally invasive procedures. On the basis of the current data, further large randomized trials are needed—such as the PERSIST Trial—for a general treatment recommendation.

Transcatheter valves (TAVI valves)

Definition

The leaflets of the TAVI valves are mounted on a collapsible frame. They are implanted in a folded, crimped state, usually through the arterial vessels in the groin, more rarely through the apex of the heart or other access routes. The native aortic valve is not removed

during implantation but displaced by the prosthesis. Self-expanding prostheses are distinct from balloon expanding prostheses.

Materials and evidence of durability

TAVI prostheses are made from different materials (*Figure*). The Sapien 3 and Sapien XT types are made from calf pericardium, and the Evolute Pro, Evolute R, and die Acurate neo from porcine pericardium. This material is thinner than that used for conventional or rapid deployment prostheses, so as to minimize the implantation diameter of the valve system. It is not clear whether the type and thickness of material, as well as the crimping, affect long term durability.

Different studies have reported that valves used in TAVI are non-inferior, or even superior, to conventional prostheses in patients with an intermediate or high surgical risk profile (28–30). The TAVI procedure was initially only recommended in older patients with a high risk profile (STS score >8%). In the meantime, however, lower complication rates, a lower degree of invasiveness, and a shorter postoperative recovery time have resulted in the recommendation of TAVI even in patients with an intermediate risk profile (age >75 years, STS score 4–8%) (31). In patients with a low risk profile—which on average equals the notably younger patient population—a higher life expectancy can be assumed. This fact has to be taken into consideration with regard to the durability of the valve that is to be used. Initial meta-analyses of six studies published in 2018 showed comparable results for TAVI and surgical aortic valve replacement in patients in the “low risk” range (STS score <4%) in the time period immediately after the intervention. But in the longer term, the mortality of patients with TAVI seems higher, for no apparent reason (32). For this group of patients, surgical aortic valve replacement therefore remains the method of choice.

The good results of valve in valve procedures have also resulted in an important treatment alternative in

BOX 2

Paravalvular leakage after aortic valve replacement

Paravalvular leakage is a possible complication when replacing aortic valves, which occurs with different degrees of severity—especially a mild degree, occasionally after a surgical and often after interventional aortic valve replacement (TAVI (e11, e12). A moderate to severe form of paravalvular leakage occurs after about 0.9% of conventional procedures and in 6.4% of TAVI procedures (e13). Several studies reported that especially in moderate and severe leakages, one-year-mortality may double and even reach 12-fold (e4–e16).

patients with conventional biological valve replacements (33, 34). Especially in the group of patients aged 60–65, this therapeutic option can change the treatment decision in favor of a biological prosthesis. However, a longer term follow-up of the valve in valve method exists only for smaller groups of patients (35). It has to be borne in mind that the already implanted conventional biological prostheses may not be large enough to allow for implanting a TAVI valve with a sufficiently large orifice area (“prosthesis-patient mismatch”) (36). Such a discrepancy is not rare and has been described as severe in 25% of patients (37). In order to avoid the difference in size, the Edwards Inspiris bioprosthesis was developed, whose valve ring can be expanded with a TAVI valve in case a valve in valve procedure is required.

Advantages and disadvantages

TAVI valves have a larger effective orifice area than conventional bioprostheses. Their implantation does not require use of the heart-lung machine/cardiopulmonary bypass, stopping the heart, and sternotomy. TAVI can now be undertaken under local anesthesia in selected patients (38). The operation takes less time than conventional procedures, and recovery is quicker.

The effects of material type, thickness, and crimping on the valve’s durability is currently not known. Because the native valve is not excised but displaced, special risks arise. These include a higher rate of paravalvular leakage (Box 2), displacement/occlusion of the coronary ostia, annular rupture, the need for pacemaker implantation, or the risk of cerebral embolism. The latter risk can be reduced by means of protection systems. Furthermore, a topic under discussion is the possibly limited durability of the prosthesis if the valve frame unfolds incompletely or asymmetrically, which may lead to additional mechanical stress (39). For conventional prostheses placed in the aorta, medication with acetylsalicylic acid for three months is sufficient, whereas in TAVI patients—because of the stent frame of the TAVI valve and an increased occur-

rence of mostly asymptomatic thromboses affecting the prosthesis (up to 23%) (40)—platelet inhibition using acetylsalicylic acid and clopidogrel for six months is recommended.

The use of non-stented biological prostheses to treat aortic valve disorders has fallen noticeably for various reasons (eBox 1). An advantage over other conventional prostheses in patients with endocarditis could not be found (eBox 2).

To improve patient safety, the German Aortic Valve Registry (GARY) was founded in 2010. The registry is a unique project in the international context, and joint responsibility lies with the German Society for Thoracic and Cardiovascular Surgery (*Deutsche Gesellschaft für Thorax-, Herz- und Gefäßchirurgie*, DGTHG), and the German Cardiac Society—Cardiovascular Research (*Deutsche Gesellschaft für Kardiologie – Herz- und Kreislaufforschung*, DGK). The data in the registry open up the possibility to evaluate the benefits and risks of the available procedures and to develop clear criteria for using the difference treatment methods (20, 38, e1).

Conflict of interest statement

Sami Kueri was reimbursed for travel expenses and conference delegate fees by LivaNova.

Prof Sievers holds shares and patents, which are related to the subject of this article, in Tribio GmbH.

The remaining authors declare that no conflict of interest exists.

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Key messages

- The long term durability of conventional biological valve prostheses is well documented and has the best evidence. They entail the lowest risk of paravalvular leakage and the lowest rate of pacemaker implantations.
- “Rapid deployment” prostheses are implanted surgically, under direct vision, by using a valve holder. This enables faster, less invasive implantation.
- The TAVI procedure (TAVI, “transcatheter aortic valve implantation”) is currently recommended for patients with a moderate to high risk profile (age >75 years, STS score >4%), whereas conventional surgery is the method of choice for patients with a lower risk profile and an STS score <4%.
- Rapid deployment and TAVI prostheses are associated with a higher rate of pacemaker implantations than conventional prostheses. Their durability over the long term is currently not known.
- More recent data are available for patients who need a mitral valve replacement, which suggest a higher age limit for a biological (rather than mechanical) valve replacement (>75 years).

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► **Supplementary material**

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CLINICAL SNAPSHOT

Transvenous Migration of a Puncture Needle into the Pulmonary Trunk

Intraoperative view with a puncture needle in the pulmonary trunk

A 44-year-old man known to be an intravenous drug user was admitted after several days of dyspnea and respiration-related thoracic pain with the initial diagnosis of tachyarrhythmia absoluta (atrial fibrillation >100 bpm). There were no further underlying cardiac morbidities. During self-mobilization on an ordinary ward the patient unexpectedly suffered a syncope. A hemorrhagic pericardial effusion diagnosed by transthoracic echocardiography with echocardiographic demonstration of its hemodynamic relevance in the presence of stable circulatory conditions was decompressed by pericardial drainage. Subsequent computed tomography showed a slender intra-cardiac foreign body and a persistent pericardial effusion. Intraoperatively we found a 4-cm-long

puncture needle that had perforated the pulmonary trunk (arrow) and was continuously leaking blood. In the absence of a thoracic entry site, the needle most probably broke off after intravenous drug injection and migrated transvenously through the right heart into the pulmonary trunk. The needle was successfully removed and the patient's postoperative recovery was free of complications. He was transferred to an inpatient drug withdrawal unit in good general condition.

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The Use of Biological Heart Valves—Types of Prosthesis, Durability and Complications

by Sami Kueri, Fabian A. Kari, Rafael Ayala Fuentes, Hans-Hinrich Sievers, Friedhelm Beyersdorf, and Wolfgang Bothe

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