

Individual approach in the treatment of aortic stenosis with contemporary TAVI valves

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Abstract

The treatment of severe, symptomatic, aortic stenosis has changed in recent years. A medical-technological breakthrough was presented by the development of the TAVI (transcatheter aortic valve implantation) concept. Namely, earlier therapy included conventional, surgical replacement of the aortic valve on the one hand and, on the other hand, conservative, relatively effective balloon valvuloplasty in high-risk patients. Today, it is possible to help once inoperable patients as well as high-risk patients with transcatheter aortic valve implantation. Thanks to the recent development of medicine and technology, there are more TAVI systems available. Taking into account the conventional and medicinal therapeutic approach, the decision on the method of treatment can best be carried out by the HEART team (cardiologist, cardiac surgeon, radiologist, anesthesiologist). By carefully considering the anatomical and clinical characteristics of each individual patient, we can decide which type of aortic prosthesis provides the patient with the maximum therapeutic benefit.

In the following text, the basic characteristics of the TAVI system, which, in accordance with the clinical results, are most often applied, as well as the characteristics of patients in whom TAVI is already indicated, will be listed.

Key words aortic stenosis, TAVI

Balloon-expanding TAVI system Sapien System (Edwards)

This model is made of bovine pericardium. It is a trileaflet aortic prosthesis and a prototype of a transcatheter aortic valve, which was used for the first time in humans, in 2002. The pericardium, from which the valve is made, was treated with a special procedure that prevents calcification, and the stent is covered with a sheath made of polyethylene terephthalate (PET). The valve of the newer generation Sapien Ultra contains a modified, thicker cover. The catheter of this valve is easily bendable, so it is easy to pass through the aortic arch. Sapien is currently the only TAVI system that has the possibility of anterograde and retrograde implantation, so it is also the only system for transapical access (TA - TAVI). The system includes conduits with an internal diameter of 14-16 francs and thus enables therapy in patients with blood vessels with a small or sclerotic lumen. Thanks to the high radial power of this balloon-expanding system, it is possible to treat aortic stenosis with very severe calcifications. The advantage is also the low height of the sheath, which lies intra-annular, which enables good accessibility to the coronary arteries. This must be taken into account in patients with coronary heart disease and in possibly younger patients. Also, further medical-technological de-

velopment implies in the future the application of the so-called VALVE's VALVE strategy, which would be simpler with this type of valve than with supraannular TAVI systems, which will be discussed in the following text. Severe calcifications in the outflow tract of the left ventricle or a narrow outflow tract represent an obstacle in the application of the Sapien system. In that case, subannular perforation or annulus rupture can occur, which in both cases could be fatal for the patient. The PARTNER study is certainly well known in the world of cardio medicine and as such deserves a specially written review/special article.

Self-expanding TAVI system CoreValve (Evolut R/Pro)

Medtronic models of self-expanding TAVI systems (Evolut R/Pro) are made from porcine pericardium. The trileaflet valve is attached to a nitinol sheath, the distal end of which extends to the sinotubular junction of the aorta. The newer generation of Evolut Pro differs from the previous one, because it is reinforced with pericardium on the proximal part, which would prevent the risk of paravalvular leakage (leakage). The guide has an internal diameter of 16 French. The ducts are flexible, which allows access to smaller and calcified blood vessels. The main characteristic of these prostheses is the

Features of TAVI in relation to anatomic characteristics of the patient			
	<i>Especially well suited</i>	<i>Moderate suited</i>	<i>Less suited</i>
Horisontally positioned aorta	ACURATE neo	Sapien	Evolut, Portico
Calcium in LV outflow tract, bicuspid valve, asymetric calcifications	-	Sapien, Evolut	Portico, ALLEGRA, ACURATE neo
Small aortic root	Evolut, ACURATE neo	Portico, ALLEGRA	Sapien
Possible intervention on coronary arteries	Sapien, ACURATE neo	-	Evolut, ALLEGRA
Valve in Valve	Evolut, ALLEGRA	Portico	Sapien 3
Aortic regurgitation without calcium	ACURETE neo	Sapien 3, Evolut	-
Difficult transfemoral access	Evolut	Sapien, Portico, ALLEGRA, ACURATE neo	-

possibility of repositioning, which enables their precise placement. The supraannular position of the valve gives it an advantage in asymmetric, heavily calcified annuli, as well as in bicuspid valves where the calcification extends all the way to the left ventricular outflow tract. A properly placed prosthesis implies free ostiums of the coronary arteries. In clinical practice, the incidence of Trilevel bovine valve, with a long nitinol stent. This self-expanding prosthesis is characterized by small diameter guides (14 French), which enables its retrograde application in more complex anatomies. The intraannular position and structure of the valve enables good access to the coronary arteries, which should be taken into account in younger patients. Disadvantages are the high postoperative incidence of pacemaker implantation (19%), as well as the more frequent occurrence of para-valvular leakage. The multicenter PORTICO 1 study confirmed a high rate of pacemaker implantation after one year of patient follow-up. postoperative AV block is more frequent than in other TAVI models, so pacemaker implantation is unfortunately unavoidable in 10-15% of cases. In addition to the Sapien Edwards prosthesis mentioned above, the Evolut TAVI system offers through the Evolut - Low - Risk - Trial a really good record of data on the application of this valve.

Acurate Neo (Boston Scientific, Marlborough, MA, USA)

Acurate Neo is a self-expanding prosthesis made from porcine pericardium. This model is characterized by its crown-like appearance. Namely, the valve consists of two "crowns" of nitinol ring. The position of the valve is supraannular, which reduces the transvalvular gradient and makes the system suitable for small annuluses. Furthermore, due to the low radial strength of the stent, the prosthesis is primarily indicated for stenoses that are medium and symmetrical. In case of bicuspid, asymmetric and narrow stenoses, this valve is not recommended. Postoperatively, the incidence of AV block is lower compared to other TAVI systems (supraannular position). SCOPE I is a randomized study comparing the intraannular Sapien 3 prosthesis and the supraannular Acurate Neo system.

Allegra (NVT, Hechingen, Germany)

Allegra is a self-expanding, supraannular prosthesis with a short nitinol stent. The trilevel valve is made from bovine pericardium. Implantation is planned retrograde, but application through the subclavian/axillary artery (TAX TAVI) is possible. So far, it has shown good results in VALVE in VALVE procedures, especially with biological prostheses of smaller diameter. Also, implantation of pacemakers is lower than with the others. The Nautilus - Pilot - Study is a small prospective study that included 27 high-risk patients. In them, the procedure was successfully performed in 96% with a transfemoral approach, with an incidence of pacemaker implantation of 8%.

Portico (Abbott, Chicago, USA)

Trilevel bovine valve, with a long nitinol stent. This self-expanding prosthesis is characterized by small diameter guides (14 French), which enables its retrograde application in more complex anatomies. The intraannular position and structure of the valve enables good access to the coronary arteries, which should be taken into account in younger patients. Disadvantages are the high postoperative incidence of pacemaker implantation (19%), as well as the more frequent occurrence of para-valvular leakage. The multicenter PORTICO 1 study confirmed a high rate of pacemaker implantation after one year of patient follow-up.

Clinical/anatomical characteristics of patients

For the precise performance of the operation and the prevention of periprocedural complications (more on that in one of the following texts), it is very important to properly perform diagnostics using well-established algorithms. Planning includes echocardiography, coronary angiography, CT scanner and, of course, evaluation by the HEART team.

Echocardiography is the basic non-invasive method for diagnosing aortic stenosis. It confirms the very existence of the disease, enables the visualization of the morphology of the valve, then the assessment of the condition of the outflow tract of the left ventricle and the

The role of the HEART team in evaluation of patients with aortic stenosis		
<i>Patients clinical characteristics</i>	<i>Anatomical and technical aspects</i>	<i>Co-morbidities</i>
Frailty	Porcelan aorta	Disease of other valves (no improvement following treatment of aortic stenosis)
Deformity of the chest or radiation	Neadekvatna velicina aortnog anulusa (< 18 mm, > 29 mm)	Thromb in left ventricle
Cirrosis hepatis	Presence of aneurism or thrombus in aorta	Endocarditis
Previous cardiac surgery	Increased risk of the obstruction of coronary ostia	Decreased ejection fraction
Social aspects (activity, family circumstances, need for a special care...)	Existence of asymmetric calcium, bicuspid valve	Hipertrophy of the septum

native valve. The height of the orifice of the coronary arteries and their position (with bicuspid valves there are anatomical variations), as well as the height of the sinus of Valsalva, represent a diagnostic imperative. Coronary angiography is also a therapeutic procedure, because there is no doubt that the TAVI trend is increasingly applied to younger patients. In this regard, the technology in the hybrid halls will certainly enable the appearance of new catheters (guides) which, depending on the TAVI model, will be selectively applied. Assessment of the size of the aortic root and the ascending aorta belongs to the routine examination.

CT has a very important role in periprocedural planning. The scanner with contrast enables selection of access and visualization of the geometry/dimensions of the valve and aortic root. The approach can be transfemoral, transapical, transaxillary (subclavian), transaortic. The approach itself and its selection represent a very complex topic that requires a separate article, so only a few basic features will be listed here. Transfemoral is the most frequently applied and involves the inner diameter of the blood vessel a. Femoralis/ Iliacae of at least 5.5 mm. The transapical approach is an alternative and is used in patients with marked atherosclerosis in the femoral/iliac blood vessels in whom the transfemoral approach is contraindicated, as well as in the case of kinking of the blood vessels of the pelvis. TAVI implantation through the subclavian artery is a very elegant method that can only be used in centers of high expertise. The transaortic approach is a rarity and does not represent a daily standard in hybrid interventions. By measuring the size of the aortic annulus, we obtain data on the size of the diameter of the prosthesis. This radiological method also accurately determines the height between the coronary ostium and the annulus, as well as the calcifications that extend into the outflow tract of the left ventricle (most often on the front cusp of the mitral valve).

The role of the HEART team in the treatment of this valvular disease is the basis and all diagnostic methods would not be useful if there was not a team of doctors who look at the entire clinical picture of a patient in whom TAVI per se is already indicated. Namely, in addition to scores that make it easier for us to set an operative indication, there are other conditions that provide information about the patient. The table will list certain

general, anatomical and clinical characteristics as auxiliary guidelines in operative therapy.

Conclusion

Cardio - medicine today has several TAVI systems available in the treatment of aortic stenosis. The basic characteristics of modern models are listed in the text. The approach to the treatment of aortic stenosis requires the expertise of the entire team of doctors. Considering the well-known growth trend of this procedure and the emergence of an increasing number of centers, careful selection of patients is of primary importance. Absolute commitment to its performance is imperative in order to maintain procedural results and thereby prevent uncontrolled commercialization of this technique. Good knowledge of the patient himself and the possibilities available to us oblige us to know the differences between TAVI "providers". Today's systems differ in the postoperative incidence of pacemaker implantation, paravalvular disease (PVL) as well as the implantation approach depending on the anatomy of the patient and the characteristics of the prosthesis itself, further, eventual intervention on coronary blood vessels, hemodynamics, etc. There are currently no studies covering these complex issues, so valve selection remains subjective and should therefore always be considered by an interdisciplinary TAVI team.

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Sažetak

Individualni pristup terapiji aortne stenoze pomocu savremenih TAVI proteza

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Terapija teške, simptomske, aortne stenoze se proteklih godina promenila. Medicinsko - tehnološki pomak se predstavio razvojem TAVI (transcatheter aortic valve implantation) koncepta. Naime, ranija terapija je podrazumevala konvencionalnu, hiruršku zamenu aortne valvule sa jedne i sa druge strane konzervativnu, relativno efikasnu balon-valvuloplastiku kod pacijenata sa visokim rizikom. Danas postoji mogućnost da nekada inoperabilnim pacijentima kao i pacijentima visokog rizika možemo pomoći transkateterskom implantacijom aortnog zaliska. Zahvaljujući uporedom razvoju medicine i tehnologije, postoji više TAVI sistema na raspolaganju. Uzimajući u obzir konvencionalni i medikamentozni terapijski pristup, odluka o načinu lečenja najbolje može biti sprovedena od strane HEART tima (kardiolog, kardiohirurg, radiolog, anesteziolog). Pažljivo razmatrajući anatomske i kliničke karakteristike svakog pacijenta ponaosob, možemo odlučiti koji tip aortne proteze omogućava pacijentu maksimalni terapijski benefit.

U daljem tekstu ce biti navedene osnovne karakteristike TAVI sistema koji se, u skladu sa kliničkim rezultatima najčešće primenjuju, kao i osobine pacijenata u kojih je TAVI već indikovano.

Ključne reči: aortna stenoza, TAVI