Sutureless aortic valve bioprothesis '3F/ATS Enable' – 4.5 years of a single-centre experience

Jerzy Sadowski, Bogusław Kapelak, Roman Pfitzner, Krzysztof Bartuś

Department of Cardiovascular Surgery and Transplantology, Jagiellonian University *Collegium Medicum*, The John Paul II Hospital, Krakow, Poland

Abstract

Background: Management of patients with acquired heart malformations, including aortic valve disease, is still challenging. Due to ageing of population, patients undergoing valve surgery are older than in the past. The 3F Therapeutics, conducting a programme of construction of heart valves for transarterial or transapical implatation, prepared the 'Enable' bioprosthetic valve for sutureless insertion in the aortic position. The first world implantation was performed in our Department on 13 January 2005.

Aim: To present our experience, qualification criteria and methods of implantation of sutureless bioprosthesis of aortic valve – 'Enable'.

Methods: The 'Enable' valve is a tubular structure, tailored and sutured of equine pericardium, treated with glutaraldehyde, and mounted on an openwork Nitinol[™] alloy stent. It consists of two distal rings connected with three vertical sticks. The characteristic property of nitinol is thermoplaticity: due to refrigeration it becomes elastic and easy to bend, after rewarming returns to the initial dimensions and shape, remaining stable at the body temperature. Distension of the nitinol ring make possible strong mounting of the valve in aortic annulus. The examined group consised of 27 patients (16 males, 11 females), aged 60-78 years (average 69.5), with advanced aortic valve disease, left ventricular hypertrophy, and aortic gradient up to 102 mmHg. Exclusion criteria were: severe annular deformations or bicuspid aortic valve, other valves' malformations, coronary disease, severe other comorbidities or no agreement for 'Enable' valve implantation. The patients were operated using extracorporeal circulation, general moderate hypothermia and cold crystalloid cardioplegia. Care was taked to remove calcifications, estimate of aortic annulus geometry, valve size selection, and orientation of the valve toward coronary ostia. The mounting time was approximately one min, and the aorta cross-clamp time was reduced to 26-56 min, mean 30 min.

Results: There was no mortality in the perioperative period, and during 3 months to 4.5 years of follow-up. No severe complications were present after surgery. One patient needed reoperation on post operative day 4 due to severe perivalvular leak. One other patient presented discrete leak with no need for intervention. The clinical improvement of one to three NYHA classes was observed. Echocardiographic and MSCT examinations confirmed adequate position of the valves, no structural deteriorations, normal movement and coaptation of the leaflets. The average maximal transvalvular gradient was 11.6 mmHg and the mean gradient – 6.8 mmHg, which remained stable during the follow-up period. No thromboembolic or infective complications were present.

Conclusions: 1. The 'Enable' aortic bioprosthetic valve has very good hemodynamic properties. 2. Self-expanding thermoplastic nitinol-made ring allows permanent stable mounting. 3. The quick fixation (about 1 min) significantly shortens the operation time. 4. The 'Enable' valve seems to be suitable for patients with increased periopertive risk.

Key words: 'Enable' aortic bioprosthetic valve, equine pericardium, nitinol, sutureless implantation

Kardiol Pol 2009; 67: 956-963

Introduction

Acquired valvular heart disease is still one of the most significant clinical problems. According to the National Cardiac Surgery Registry, it accounts for 27% of heart surgeries [1]. Twenty percent of valvular surgery in Poland and 1% of valvular surgery in the European Union are performed in the Department of Cardiovascular Surgery and Transplantology, *Collegium Medicum*, Jagiellonian University. Each year ca. 300-350 patients undergo aortic valve surgery [1, 2].

Available for the implantation are: mechanical valves, most commonly used for this procedure, bioprostheses

Address for correspondence:

Prof. Jerzy Sadowski Md, PhD, Klinika Chirurgii Serca, Naczyń i Transplantologii, Uniwersytet Jagielloński *Collegium Medicum*, Krakowski Szpital Specjalistyczny im. Jana Pawła II, ul. Prądnicka 80, 31-202 Kraków, tel.: +48 12 614 30 75, fax: +48 12 423 39 00, e-mail: jsadowski@szpitaljp2.krakow.pl harvested from animal tissue and becoming more and more popular, and biovital, humanified aortic valves which are significantly less accessible. Despite technological progress including the use of pirolite for the construction of artificial valves, patients after artificial valve replacement have to remain on lifelong coumarin-derived anticoagulants therapy requiring frequent INR monitoring and therefore creating a number of inconveniences for the patients. Biological valves, despite having some important advantages, have limited durability, the average being several years. It is expected that modification in tissue sample preservation techniques will enable to prolong this period of time [3].

Due to demographic and epidemiological changes there has been an increase in the age of the patients requiring heart valve surgery; currently, the average age for such surgery is around 75 years, with a few percent of the patients undergoing operation over the age of 80. In this group of patients extracorporeal circulation may not be well tolerated, inducing microcirculation disorder and inflammatory reaction. Moreover, advanced age of the patients and associated comorbidities are responsible for a greater surgical risk [4, 5].

Research on new technological solutions and surgical methods is therefore being conducted aimed at limiting the invasive procedures and improving the comfort of postsurgery life. One of the results of the mentioned research is a unique bioprosthesis of aortic valve '3F/ATS Enable' constructed for sutureless implantation. The '3F/ATS Enable' valve was implanted for the first time in the world on 13 January 2005 in our Department [2, 6-8].

The aim of this study is to present qualification criteria and methods of implantation of sutureless bioprosthesis of aortic valve 'Enable', as well as to review early and long--term clinical results.

Methods

Patients

Between 2005 and 2009, the bioprosthesis 'Enable' was implanted in 27 patients (16 men, 11 women) aged 60-78 (mean 69.5 years), for severe isolated aortic valve dysfunction with aortic stenosis (AS) in most cases. Preoperative echocardiography (TTE) revealed left ventricular hypertrophy, severe aortic valve disease, especially calcification and transvalvular gradient: maximal range 70-102 mmHg with average gradient 40-60 mmHg.

An approval from the Bioethics Committee for performing the innovative procedures was obtained.

The exclusion criteria were as follows: 1. severe deformations of aortic ostium, especially bicuspid

- aortic valve, 2. low ejection fraction of the left ventricle < 35%,
- 3. disease of any other heart valve,
- 4. pathological changes in the ascending aorta: significant dilatation/aneurysm,

- 5. systemic connective tissue disease, e.g. Marfan's syndrome,
- 6. accompanying coronary heart disease (diagnosed by means of coronary angiography performed in every patient),
- 7. severe illness of any other organ (such as COPD, advanced renal failure, neoplastic disease, stroke with significant neurological deficiency etc.),
- 8. lack of patient consent for the implantation of the 'Enable' valve.

Valve characteristics

Bioprosthesis 'Enable' was constructed and introduced in the Department by 3F Therapeutics and is currently produced by ATS Medical Inc. Bioprosthesis is designed for sutureless implantation in aortic ostium with the compression of the metal ring to the human tissue. Available diameter sizes range from 19 mm up to 29 mm (in 2 mm steps). It is tubular-shaped and fixed on scaffold stent. Bioprosthesis is derived from equine pericardium, preserved with low glutaraldehyde concentration buffer. Using the laser technique, three identical pieces of proper size are cut out and put together with marginal sutures to form a tube with three commisura. The height of the valve corresponds to its diameter. The supportive part consists of a frame fabricated from a single piece of alloy (NiTinol[™]). It is an open-work structure made of profiled rods: corrugated rings - a single lower ring enabling fixation to the aortic ostium and a double upper ring for stabilisation. The rings are connected by three vertical elements with a plate-like dilation near the upper ring allowing for commisura fixation in this part (with the usage of plastic patches from the outside for reinforcement). The bottom of the valvular tube is sutured to the polyester cuff fixed to the lower ring of the stent. Such construction allows undisturbed mobility of free margines of any of the leaflets and guarantees wide opening and tight closure of the valves (Figure 1).

One specific characteristic of the nitinol, composed of nickel and titan, is its thermoplasticity. In low temperatures, the structure (stent) becomes soft and flexible enabling deformation, bending and coiling (Figure 2). When warmed up, stent undergoes self-decompression with shape-memory characteristic preserved and becomes stiff at a core body temperature (Figures 3, 4).

Surgery technique

All the patients were operated under general anesthesia, following the standard protocol. The longitudinal sternotomy was the surgical approach. The extracorporeal circulation was performed in a classical way (aortic cannulation – ascending aorta, venous cannulation through the auricle of the right atrium). Moderate hypothermy of 20-30°C and cold crystaloid cardioplegia (4°C) of potassium concentration of ca. 8 mEq/l, volume



Figure 1. 'Enable' valve. A - the lateral view: valvular tube, fixing ring, commisura fixation area, upper ring of the nitinol stent. B - top view: upper ring of the stent, commisura fixation area, loosely mobile free leaflets' margins



Figure 2. 'Enable' valve bent and coiled after being cooled down to 0-5°C



Figure 3. 'Enable' valve inside delivery tool during implantation. Transverse opening in ascending aorta, initial aortic valve removed. Three commisura oriented sutures present

1000-1500 ml, administered directly into coronary arteries ostia, were used. After performing surgery, warming up, reperfusion, weaning off extracorporeal circulation and achieving hemostasis, suction drain was introduced into the pericardial sac and mediastinum. Sternum was stabilised with metal sutures, and the layers with catguts.

The ascending aorta was accessed by transverse incision within the distance from the ring slightly longer than the height of the valve (Figures 3, 4). After aortic valve removal and thorough debridement of the ring from calcifications, the geometry of commisura, as well as coronary ostia and valvular ring and its size were assessed. The ultimate qualification for 'Enable' valve implantation was based on this evaluation. After selecting the valve of a proper size, 3 provisional directional sutures were applied in the commisura area to facilitate establishing location (Figure 3). The valve was then cooled down with physiological saline at 0-5°C. Next the valve was bend and transfered into a plastic delivery tool (Figure 2.). After fixing the valve in aortic ostium as it was warming up from the surrounding tissues and additionally from warm saline (37°C) that was poured on it, it returned to its original shape and its ring was compressed to the surrounding tissues. Stability of the fixation and adjustment in relation

to coronary ostia were monitored. The alignment of the valve could be easily corrected through warming it up or cooling it down. Fixing the valve lasted around 1 min. Clamping time of aorta depended on pathology severity and surgeon's experience and ranged from 26 up to 58 min, mostly around half an hour.

Valve assessment and monitoring

Echocardiography was crucial for the study. The patients were selected on the basis of the results of preoperative TEE. Those with severe ring deformations, especially with bicuspid aortic valve, were excluded from the study.

In all participants intraoperative TEE was performed – before starting and after stopping the extracorporeal circulation. The ultrasound was performed in intraesophageal projections: atrioventricular longitudinal axis (120-160°), short-axis (30-60°), quadrilocular (0-20°), and apical transgastric longitudinal axis. The assessment of 'Enable' valve included its alignment, function, mobility, valve opening degree, valve sufficiency and presence of possible perivalvular leak.

The follow-up ranged from 3 months to 4.5 years. Each 3-6 months the patients were routinely examined and underwent echocardiography (TTE). In some cases, the multi-slice computed tomography (MSCT) was performed.

During the first 3 months following the operation oral anticoagulant therapy was used to maintain INR within the target range 2.5-3.0.

Results

In three cases, not included in the study group, due to a significant aortal ring deformation, the decision concerning 'Enable' valve implantation was changed and mechanical valve was implanted with the classical usage of sutures. In a few initial cases reposition of the valve due to stent collision with coronary ostia (area of commisura fixing) was necessary. Re-cooling the valve followed then by its warming up allowed within just few minutes to fix it in stable alignment.

No perioperative deaths were reported. In early postoperative period inotropic support was administered. No major postoperative complications were observed, neither excessive haemorrhage nor relative heart muscle ischemia. Echocardiography (Figure 5) and MSCT (Figure 6) monitoring showed correct valve alignment with optimal commisura position without interference with the coronary ostia and coronary blood inflow. No structural damage of the implant, especially stent deformation, was detected. The mobility of the leaflets was correct and the valvular apparatus was fully sufficient (Figures 5, 6). In one patient a small, hemodynamically irrelevant perivalvular leak was detected. The average maximal transvalvular pressure gradient was 11.6 mmHg, whilst the mean transvalvular



Figure 4. Sutureless valve 'Enable' fixed in aortic ostium. Proper orientation in relation to the native commisura and coronary ostia



Figure 5. 'Enable' valve properly located in aortic ostium seen in echocardiography in longitudinal axis of transesophageal projection. Correct leaflet coaptation and valve sufficiency

pressure gradient – 6.8 mmHg. In four patients the gradients were only 6 and 2 mmHg respectively.

In one patient reoperation on postoperative day 4 was required as a consequence of a significant perivalvular leak caused by small implant displacement (tilting). In further follow-up (up to 4.5 years) no deaths were reported. In the rest of the patients the 'Enable' valve showed no signs of instability. A small perivalvular leak was detected postoperatively in one of the patients. However, no increase of the leak was detected, thus no corrective surgery was necessary. In all the examined patients clinical improvement was observed (by one to three classes in NYHA scale). No endocarditis or thromboembolic complications were observed. Echocardiography (TEE) showed no relevant structural damage of the valve. Both maximal and mean transvalvular pressure gradient remained on the level similar to the initial value, with a non-significant tendency to decrease (Table I).

patches in commisura area. Modernised tissue preservation technique was adapted with the usage of low concentration of glutaraldehyde solution. Once preserved the excess of the solution was removed in order to prolong durability of the tissue. A multicentre study, with important participation of our centre which is very experienced in valve surgery, showed clinical usefulness of the valve bioprosthesis produced by ATS [9].

This led to the second stage of the project – the construction of innovative sutureless valve. The previously examined valve 3F/ATS was fixed on a thermoplastic stent, the essential component of the construction made of nitinol alloy. This feature enables to properly shape the cooled valve making the implantation possible. The stent being warmed up, the prosthesis may be fixed and stabilised as the self-decompressing ring of the stent presses down the bioprosthesis to the surrounding tissues [2, 10-13]. As it was previously assumed, the duration of the operation, especially aorta clamping time, was reduced even by 2 to 3 times. In our department a surgeon needs around 1 min to fix the valve prosthesis and aorta clamping time is reduced down to around 30 min while in many other centres it lasts around 40-65 min [12].

Experience gained with the 'Enable' valve [2, 11-13] gives a reason to recommend its usage in elderly patients with numerous accompanying illnesses. Clinical experience shows that advanced age of the patient – over 80 years, is a substantial challenge when it comes to reducing surgery risk, often many times higher than the one observed in younger patients, and therefore a reason for questioning advisability of the procedure [4, 5, 11].

The idea of minimising surgery invasiveness through reducing duration of heart muscle ischemia has been brought up before. In 1963, Magovern used sutureless mechanical valve that was fixed in a very short period of time with several needles-staples simultaneously stuck out from a rotative device and embedded in the surrounding tissues. [14]. Among new technical solutions there is an aortic valve Trilogy, fixed with staples to the artificial ring permanently located in aortic ostium. If the implanted valve degenerates, its replacement is simple and quick – the old valve is removed and the new one is introduced using the same procedure as initially [15].

Having proved that the 'Enable' valve can be successfully tightly coiled after cooling down and subsequently stably located due to self-decompression triggered by warming it

Table I. Echocardiography monitoring of mean transvalvular gradient values with 'Enable' valve in the postoperative period

	On discharge	6 months	1 year	2 years	3 years	4 years
Max gradient [mmHg]	11.6	11.4	11.3	11.3	11.3	10.1
Mean gradient [mmHg]	6.8	6.1	6.0	6.0	6.0	5.2

Figure 6. 'Enable' valve in MSCT scanning. A – closed valve, B – opened valve

Discussion

The pursuit of optimal construction of valvular prosthesis and introduction of possibly least invasive implantation techniques constitute important research goals of contemporary cardiosurgery.

A decade ago 3F Therapeutics company set a goal to create an innovative aortic valve bioprosthesis. In the first stage a stentless valve derived from equine pericardium was produced. This bioprosthesis did not contain metal or plastic frame for leaflet fixation. It was equipped only with sutural ring made of material along with reinforcement



up, in the third stage of the project the implantation technique was developed: first, in Sapien modification (next to CoValve valve), without extracorporeal circulation, on beating heart, with usage of catheter technique and femoral access, or, in case of present contraindications (e.g. obliterative atherosclerosis), through minitoracotomy with left auricular access. First transauricular (25 November 2008) and second transartery implantation in Poland were performed in our department. The presented technique can be applied in selected group of patients who otherwise could not undergo successfully a classical type surgery [16-18].

Strict adherence to the inclusion and exclusion criteria in patients undergoing first surgeries of this type worldwide allowed to assess clinical usefulness of the 'Enable' valve eliminating the potential influence of any other determinants and performed procedures on the study results. Introduction of the 'Enable' valve into clinical practice will allow to treat some patients who have contraindications to standard valve implantation, and this trend is already seen in some centres [11]. This is the case mainly with the patients with accompanying dysfunctions of the other valves or coronary heart disease. In the latter cases hybrid procedures should be taken into consideration, e.g. PCI of the coronary arteries will allow the patient to benefit from significantly reduced operation time. Adding to the list of indications for surgery the patients with low ejection fraction, if caused by significant left ventricle hypertrophy, will also be possible. For it has been proven that in these cases it is not an independent risk factor and may even improve in postoperative period [19]. Aneurysmatic aorta excludes the use of sutureless technique, while in patients with severe kidney failure, especially requiring dialysis, bioprosthesis implantation is contraindicated. Severe illnesses with less than 1 year survival prognosis make surgery treatment pointless.

The aortic valve ring pathology, especially its deformation, requires a detailed inspection. What should be born in mind is that 'Enable' valve is composed of a circular fixing ring that remains of a particular size and stable shape once decompressed. Thus, only corresponding circular aortic ring with no irregularities resulting from, e.g. calcifications infiltrating the tissues, and with no postinflammatory deformations, e.g. post-abscess cavity, guarantees permanent and stable prosthesis fixation. Disregarding that rule as well as failing to assess correctly the valve size can cause instability and lead to the most serious complication which is valve migration, requiring urgent reoperation as it occurred in 3.7% of our patients. Similar results were obtained in other studies; however, those that included small groups of patients showed even up to dozen of valve migration occurrence [11-13]. Our study showed that small perivalvular leak, which is hemodynamically irrelevant, did not increase during the follow-up [11]. Preoperative echocardiography is a suitable qualification test for sutureless valve implantation.

Nonetheless, in some cases full assessment of ring deformation is possible only after the removal of a damaged valve. At this stage withdrawal from the 'Enable' valve implantation surgery may be required [11]. In our study this was the case in 10% of the patients.

Despite numerous accompanying illnesses no early or late deaths in the studied group occurred. None of the patients reported major complications except for one case where the valve migration was diagnosed. Other clinical centers report mortality rate of up to dozen, as calculated with the risk scale [11].

A few years of follow-up have demonstrated transvalvular pressure gradients remaining low and good functioning of the valve apparatus [11-13]. These observations are coherent with the results of our study based on 4.5-year follow-up.

Conclusions

- 1. Aortic valve bioprosthesis 3F/ATS shows very good hemodynamic parameters.
- 2. The time of valve fixation is very short (about 1 min), which is an undoubtable advantage.
- 3. Self-decompressing thermoplastic Nitinol ring enables stable, permanent fixation of a sutureless valve prosthesis.
- 4. Aortic valve 3F/ATS proved to be useful in patients with an increased surgical risk.

References

- 1. Raport Krajowego Rejestru Operacji Kardiochirurgicznych, KROK-Polkard, Kardiochirurgia Polska 2008. Klub Kardiochirurgów Polskich.
- Sadowski J, Wierzbicki K, Cieśla-Dul M. Nowe technologie, niewydolność serca – znane i poznawane wyzwania w leczeniu operacyjnym wad lewego ujścia tętniczego. *Kardiologia po Dyplomie* 2008; 1: 30-9.
- Sadowski J, Kapelak B, Wróbel K. Techniki chirurgicznego leczenia wad zastawki aortalnej i patologii aorty wstępującej. In: Tracz W, Podolec P, Hoffman P. (eds.). Echokardiografia praktyczna. *Medycyna Praktyczna*, Kraków 2005; II: 277-89.
- 4. Varadarajan P, Kapoor N, Bansal RC, et al. Survival of elderly patients with severe aortic stenosis is dramatically improved by aortic valve replacement. Results from a cohort of 277 patients aged > or = 80 years. *Eur J Cardiothorac Surg* 2006; 30: 722.
- 5. Kuduvalli M, Grayson AD, Au J, et al. A multi-center additive and logistic risk model for in-hospital mortality following aortic valve replacement. *Eur J Cardiothorac Surg* 2007; 31: 607-13.
- 6. Bartuś K, Sadowski J, Kapelak B, et al. Pierwsze użycie bezszwowej zastawki Enable u ludzi. Obserwacja roczna. *Kardiochir i Torakochir Pol* 2006; 3 (Supl. 1.): 45-6.
- 7. Sadowski J, Kapelak B, Bartuś K, et al. First human use of the Enable aortic valve bioprosthesis: sutureless implantation of a stented pericardial valve. 3rd Biennial Meeting of the Society for Heart Valve Diseases, Vancouver 2005. Abstract P175.
- Trybowski G, Olejniczak P, Sadowski J. Bezszwowa biologiczna zastawka aortalna 3F. In: Podolec P, Tracz W, Hoffman P, et al. (eds.). Echokardiografia praktyczna. *Medycyna Praktyczna*, Kraków 2006; IV: 289-92.

- 9. Sadowski J, Kapelak B, Bartuś K, et al. Stentless 3F Therapeutics Aortic Bioprosthesis – a new alternative to aortic replacement. *Acta Cardiol* 2004; 59: 231-2.
- Cox H, Ad N, Myers K, et al. Tubular heart valves: a new tissue design – preclinical eveluation of the 3F aortic bioprosthesis. *J Thorac Cardiovasc Surg* 2005; 130: 520-7.
- 11. Martens S, Ploss A, Sirat S, et al. Sutureless aortic valve replacement with the 3F Enable aortic bioprosthesis. *Ann Thorac Surg* 2009; 87: 1914-8.
- 12. Wendt D, Thielmann M, Buck T, et al. First clinical experiences and 1-year follow-up with the sutureless 3F-Enable aortic valve prosthesis. *Eur J Cardiothorac Surg* 2008; 33: 542-7.
- 13. Leyh R, Yildirim C, Buck T, et al. Early single-center experience with 3F-Enable aortic valve bioprosthesis. *Herz* 2006; 31: 423-8.
- 14. Magovern JJr. Invited commentary (to: 11). Ann Thorac Surg 2009; 87: 1917-8.
- 15. Harringer W, Schmitz C, Sadowski J, et al. The trilogy sutureless aortic valve system: early experience with a modular, tri-lobal

bovine pericardium valve technology. *Das Magazin zur 36. Jahrestagung der Deutschen Gesellschaft fur Thorax-Herz und Gefasschirurgie,* Hamburg 2007; 16.

- 16. Wilczek K, Chodór P, Przybylski R, et al. Przezcewnikowe implantacje zastawek w objawowej stenozie aortalnej u chorych niebędących kandydatami do leczenia operacyjnego – wspólne zabiegi kardiologów i kardiochirurgów. *Kardiochir i Torakochir Pol* 2008; 5: 386-96.
- Walther T, Simon P, Dewey T, et al. Transapical minimally invasive aortic valve implantation: multicenter experience. *Circulation* 2007; 116 (Suppl. 11): 1240-5.
- Wendt D, Eggebrecht H, Kahlert P, et al. Successful transapical aortic valve implantation four weeks before 97th birthday. Interact *Cardiovasc Thorac Surg* 2009; 8: 684-6.
- 19. Cieśla-Dul M, Pfitzner R, Drwiła R, et al. Low ejection fraction as risk factor after aortic valve replacement. *Przegl Lek* 2004; 61: 579-84.

Bezszwowa bioproteza zastawki aortalnej 3F/ATS Enable – 4,5-letnie własne doświadczenie kliniczne

Jerzy Sadowski, Bogusław Kapelak, Roman Pfitzner, Krzysztof Bartuś

Klinika Chirurgii Serca, Naczyń i Transplantologii, Uniwersytet Jagielloński *Collegium Medicum*, Krakowski Szpital Specjalistyczny im. Jana Pawła II

Streszczenie

Wstęp: Nabyte wady serca, w tym wady zastawki aortalnej, wciąż należą do istotnych problemów klinicznych. Przemiany demograficzne i epidemiologiczne powodują, iż wzrasta liczba chorych w starszym wieku, także ponad 80-letnich, wymagających leczenia operacyjnego. W ramach programu badań prowadzonego przez 3F Therapeutics, docelowo zakładającego wytworzenie zastawek nadających się do wszczepiania drogą przeztętniczą lub przez koniuszek lewej komory, bez krążenia pozaustrojowego, opracowano zastawkę Enable do wszczepiania klasycznego, lecz bez użycia szwów. Pierwsze na świecie jej wszczepienie miało miejsce w Klinice Chirurgii Serca, Naczyń i Transplantologii UJ CM 13 stycznia 2005 r.

Cel: Przedstawienie zasad kwalifikacji i wszczepiania bezszwowych bioprotez zastawki aortalnej Enable oraz analiza wczesnych i średnio odległych wyników klinicznych.

Metody: Zastawka Enable jest tubularną bioprotezą wykonaną z końskiego osierdzia, konserwowanego glutaraldehydem wg unowocześnionej technologii i zamontowaną na ażurowym metalowym stencie z nitinolu (główne składniki to nikiel i tytan), składającego się z pierścieni na dwóch poziomach, połączonych pionowymi elementami. Charakterystyczną właściwością nitinolu jest termoplastyczność. Pod wpływem zimna staje się podatny i elastyczny – stent można zginać i zwijać, natomiast ogrzewany powraca do wyjściowych rozmiarów i kształtu, jest stabilny w temperaturze ciała. Rozprężenie pierścienia zastawki powoduje jej umocowanie w ujściu aortalnym. Grupa badana obejmuje 27 chorych (16 mężczyzn i 11 kobiet) w wieku 60–78 lat, średnio 69,5 roku, z zaawansowaną izolowaną wadą aortalną, przerostem lewej komory serca, gradientem przezzastawkowym do 100 mmHg. Z tej wdrożeniowej grupy wykluczono osoby ze znacznymi deformacjami lewego ujścia tętniczego, w tym dwupłatkową zastawką, jak również z innymi wadami serca, chorobą wieńcową, ciężkimi schorzeniami innych narządów, aby wyeliminować ich wpływ na ocenę samej zastawki, oraz osoby niezgadzające się na wszczepienie zastawki Enable. Operacje przeprowadzono w krążeniu pozaustrojowym, umiarkowanej hipotermii, z zastosowaniem kardiopleginy krystaloidowej. Zwracano uwagę na staranne usunięcie zwapnień, geometrię lewego ujścia tętniczego, dobór rozmiaru zastawki, orientację stentu względem ujść wieńcowych. Czas montażu zastawki wynosił średnio ok. 1 min, a czas zakleszczenia aorty 26–56 min, średnio ok. pół godziny.

Wyniki: Nie było zgonów okołooperacyjnych ani w okresie obserwacji od 3 miesięcy do 4,5 roku. Nie zanotowano poważnych wczesnych powikłań pooperacyjnych. Jeden chory wymagał po 4 dniach od wszczepienia zastawki reoperacji z powodu dużego przecieku okołozastawkowego. Inny chory z niewielkim przeciekiem, nieistotnym hemodynamicznie, nie wymagał interwencji. Uzyskano poprawę kliniczną o 1–3 klas wg NYHA. Badanie echokardiograficzne i MSCT wykazało prawidłowe położenie zastawek, brak zmian strukturalnych, prawidłową ruchomość i domykalność płatków. Maksymalny gradient przezzastawkowy wynosił średnio do 11,6 mmHg, a średni do 6,8 mmHg i utrzymywał się na tym poziomie przez cały czas obserwacji. Nie stwierdzono powikłań zakrzepowo-zatorowych ani zapalenia wsierdzia.

Wnioski: 1. Bioproteza zastawki aortalnej Enable charakteryzuje się bardzo dobrymi parametrami hemodynamicznymi. 2. Samorozprężalny termoplastyczny pierścień nitinolowy pozwala na stabilne, trwałe zamocowanie zastawki w ujściu aortalnym bez użycia szwów. 3. Czas montażu jest bardzo krotki (ok. 1 min), co pozwala skrócić czas zakleszczenia aorty do ok. pół godziny i czyni operację istotnie mniej inwazyjną. 4. Zastawka może więc być przydatna dla chorych o zwiększonym ryzyku.

Słowa kluczowe: bioproteza zastawki aortalnej Enable, osierdzie końskie, nitinol, bezszwowa technika wszczepiania

Kardiol Pol 2009; 67: 956-963

Adres do korespondencji:

prof. dr hab. n. med. Jerzy Sadowski, Klinika Chirurgii Serca, Naczyń i Transplantologii, Uniwersytet Jagielloński *Collegium Medicum*, Krakowski Szpital Specjalistyczny im. Jana Pawła II, ul. Prądnicka 80, 31-202 Kraków, tel.: +48 12 614 30 75, faks: +48 12 423 39 00, e-mail: jsadowski@szpitaljp2.krakow.pl