Evolving approach to aortic valve replacement in children and adolescents – a preliminary report

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Abstract

Background: Surgical treatment methods are still controversial in children with congenital or acquired aortic valve dysfunction.

Aim: To evaluate treatment results in children after mechanical or biological valve implantation.

Methods: We analysed a group of 55 children after mechanical valve implantation (group A) and a group of 8 children after Freestyle biological valve implantation (group B). We evaluated in both groups: patient's age, type of valve dysfunctions, severity of heart failure symptoms, and quality of life. The parameters of physiological left ventricular (LV) remodelling were examined on the basis of echocardiographical signs of LV contractibility (%SF) and anatomical changes: LV diastolic diameter (LVDd), LV posterior wall thickness (LVPW), thickness of intra-ventricle septum (IVS) and pressure gradient between LV and aorta (LV-Ao).

Results: There were no hospital deaths in either group. There were two late deaths in children from group A. Thromboembolic (2), nonspecific bleeding complications (2), and infections (2) occurred in group A. There were two re-operations in children after mechanical valve implantation. The early postoperative period was good in groups A and B. Furthermore, late postoperative period was good in group B. Physiological LV remodelling occurred in children in groups A and B. Quality of life was good in both groups.

Conclusions: Good clinical results, simplicity, repeatability and safety of surgical technique mean that mechanical valve implantation in the aortic position is still an attractive option for treatment in children and adults. However, absence of bleeding, thromboembolic and infection complications and improvement of durability mean that the Freestyle biological new generation valve could be a good option for future in children and adolescents who need aortic valve replacement.

Key words: aortic valve dysfunction, mechanical prosthesis, stentless biological prosthesis, children

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Introduction

Selection of the optimal therapy in children with congenital aortic valve disease remains controversial. Physiological growth of the aortic annulus and a risk of thromboembolic complications, requiring routine use of anticoagulation, mean that implantation of mechanical valves in the aortic position are not an accepted therapeutic option in children. Alternative methods of surgical management such as implantation of allografts, xenografts or pulmonary autograft implantation not uncommonly significantly increase the risk of possible complications and mortality in the perioperative period. Currently available stentless bioprostheses seem to have longer durability and preserve all haemodynamic characteristics of the biological prostheses. The cusps of stentless bioprostheses are coated with α-aminooleic acid to prevent their calcification and eventually to markedly improve durability of the valves.

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In this report we present the results of aortic valve replacement with mechanical prostheses and preliminary experience with the use of currently available bioprostheses. Recently a programme of implantation of the new generation stentless bioprostheses in children has been initiated at our department.

Methods

Between 1992 and 1999, 55 children hospitalised at the Department of Cardiac Surgery our Institute underwent aortic valve replacement with mechanical prostheses (group A). Between May 2004 and February 2006, in 8 patients Freestyle biological stentless prostheses were implanted using the subcoronary technique (group B).

All examined patients were contacted either by mail or phone; all are alive and feel well. A late follow-up examination was performed in 31 patients in group A, while 24 subjects declined to attend due to remote place of living and high costs of the trip. All patients of group B attended an early follow-up examination.

Mechanical aortic prostheses were implanted in patients at the age of between 8 and 18 years old (mean 12 years and 9 months). Five (16%) children in the examined group were less than 10 years of age at the time of prosthesis implantation, 15 (48.4%) between 11 and 15 years and the remaining 11 (35%) patients were older. Age of the patients in group B ranged from 6.9 to 15.4 years (mean 12 years and 2 months).

Follow-up in group A ranged between 5 and 13 years (mean 6 years and 5 months), in group B from 1 month to 2 years (mean 1.5 years). Age of the patients who underwent follow-up examination ranged from 13 to 27 years (mean 17 years and 7 months) in group A and from 7 to 16 months (mean 12 years and 8 months) in group B. The form of the aortic valve disease, its aetiology, comorbidities and defects, previous operations, type of implanted prosthesis and additional procedures performed at the time of aortic valve replacement as well as preoperative functional status in both groups are outlined in Table I.

On the echocardiographic examination carried out before surgery, after operation and at the final follow-up study, anatomy and function of the left ventricle (LV) and LV-aorta pressure gradient (LV-Ao) were evaluated.

Table I. Patients' characteristics

Parameter	Group A	Group B
Number	55	8
Type of aortic valve disease	6 – isolated AoR (19%) 7 – isolated AoS (23%) 18 – AoR + AoS (58%)	3 – isolated AoR (37.5%) 1 – isolated AoS (12.5%) 4 – AoR + AoS (50%)
Aetiology of aortic valve disease	54 – congenital dysfunction (98.1%) 1 – rheumatic disease (1.9%)	7 – congenital dysfunction (87.5%) 1 – IE (12.5%)
Concomitant defects and diseases	1 – VSD (1.8%) 4 – MvR (7.3%)	1 – MvR (12.5%) 1 – IE (12.5%)
Age [years]	8-18 (mean 12.8)	6.9-15.4 (mean 12.2)
Previous surgical interventions	3 – Ao commissurotomy (9.6%) 1 – CoA repair with Waldhasen's method (1.8%)	5 – Ao commissurotomy (62.5%)
Type of implanted prosthesis	Mechanical: – 53 St Jude (96.4%) – 1 Jork-Shiley (1.8%) – 1 Carbo-Medics (1.8%)	Biological (Medtronic Freestyle Stentless Bioprosthesis)
Size of implanted prosthesis	19-27 (mean 22)	19-27 (mean 21)
Additional procedures during Ao-v replacement	1 – VSD closure (1.8%) 4 – Mv repair (7.3%) 6 – enlargement of the ascending aorta with pericardial patch (10.9%)	1 – Mv repair (12.5%)
Preoperative functional NYHA class	12 – III°/IV° (21.8%) 24 – II°/III° (43.6%) 19 – I°/II° (34.5%)	1 – III°/IV° (12.5%) 3 – II°/III° (37.5%) 4 – I°/II° (50%)

Abbreviations: AoR – aortic valve regurgitation, AoS – aortic valve stenosis, MvR – mitral valve regurgitation, IE – infective endocarditis, VSD – ventricular septal defect, Mv – mitral valve, Ao-v – aortic valve, CoA – aortic coarctation

The following LV parameters were measured: diastolic cross-sectional LV diameter (LVDd), LV posterior wall (LVPW) and ventricular septum (IVS) thickness. Shortening fraction of LV (%SF) was calculated as a measure of systolic LV function.

In 6 patients, repair of the ascending aorta using a pericardial patch trimmed in a glutaraldehyde or polytetrafluoroethylene (PTFE) patch was performed in order to implant a prosthesis larger than the diameter of the native ascending aorta. In group B, in one case a prosthesis of 27 mm in diameter, in 3 cases 21 mm, and in one case 19 mm, were implanted. The choice of prosthesis was based on the size of both the aortic annulus and aortic root assessed during the preoperative transoesophageal echocardiography.

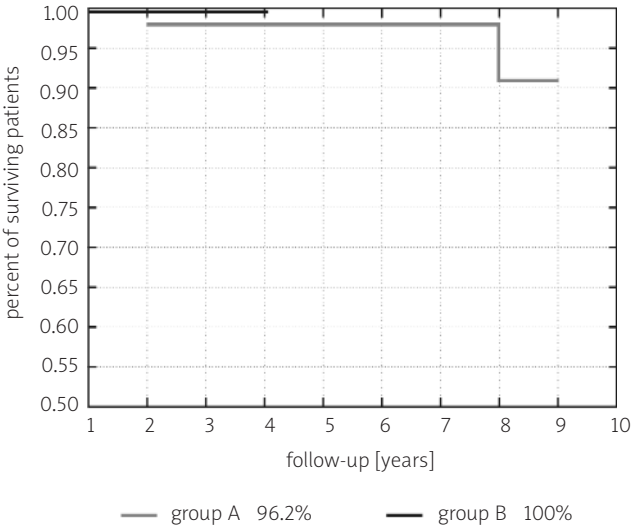

Figure 1. Probability of survival calculated using Kaplan-Meier method

In all group A patients, anticoagulation prophylaxis was initiated with low molecular weight heparin, and after cessation of bleeding and peristalsis recovery oral acenocoumarol therapy was introduced and titrated according to the INR value, with the aim of achieving the target range 2.5-3.5. In group B, acenocoumarol was not used as anticoagulation prophylaxis.

Quality of life was assessed based on patient-reported wellbeing, level of education reached, current occupation and family history.

Statistical analysis was performed using STATISTICA for Windows software. Mean and standard deviation were calculated for the selected parameters. Rates of thromboembolic complications, haemorrhagic events and reoperations were assessed. Survival probability was estimated using the Kaplan-Meier method.

Results

Mortality (Figure 1, Table II): In-hospital mortality was 0% both in group A and B. No late deaths occurred in group B. Two patients (3.6%) died in group A during follow-up. One death was attributed to CNS bleeding 2 years after reoperation performed due to gradual increase of LV-Ao pressure gradient. A second child died suddenly from unknown cause 8 years after surgery.

Thromboembolic and haemorrhagic complications (Figure 2, Table II): In one group A patient, periprosthetic thrombus formation was observed 7 days after valve implantation and treated with Actylise. One patient died 2 years after surgery as a result of ischaemic stroke. In

Table II. Postoperative complications

		Group A	Group B
Follow-up duration [years]		5-13 (mean 6.5)	0.1-4 (mean 2.1)
Early complications	In-hospital death	0	0
	Thromboembolic events	1 (1.8%)	0
	Haemorrhagic events	0	0
	Infections	1 (1.8%)	0
	Reoperations	0	0
Mid- and long-term complications	In-hospital death	2 (3.6%)	0
	Thromboembolic events	1 (1.8%)	0
	Haemorrhagic events	Excessive bleeding – 0 Bleeding episodes – 2 (3.6%)	0
	Infections	1 (1.8%)	0
	Reoperations	1 (1.8%)	0
Postoperative functional NYHA class at the final follow-up examination		I° – 52 (94.5%) II° – 1 (1.8%)	I° – 8 (100%)

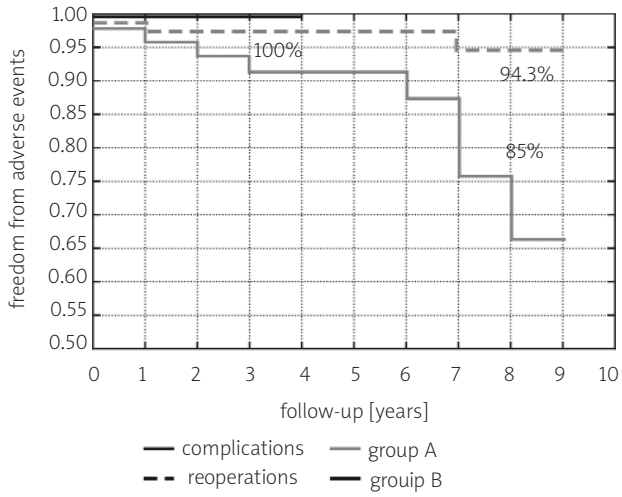

Figure 2. Postoperative complications and reoperations

group A, 3.6% thromboembolic complications were noted. No early or mid-term thromboembolic complications were observed in group B.

Episodes of epistaxis were observed in 2 children in group A. Additionally, one case of minor gastrointestinal bleeding was noted. The remaining 53 (96%) patients were free from any haemorrhagic complications. No haemorrhagic events were observed in the patients from group B.

Infectious complications (Figure 2, Table II): In group A, in 2 cases bacterial endocarditis was detected and treated successfully with antibiotics. In one patient, perivalvular abscess was diagnosed and treated medically. One patient developed a fistula between the mediastinum and skin. It made us replace the previously implanted mechanical valve with a homograft. Fifty-two (94.5%) patients were free from any infectious complications. No early or mid-term infectious events were found in group B.

Reoperations (Figure 2, Table II): In group A, one patient required replacement of the mechanical valve with a homograft due to infectious complication. The remaining 54 (98%) patients were free from repeat surgery during follow-up. No patients in group B required any surgical reintervention.

Echocardiographic assessment of LV function and anatomy (Figures 3 and 4): In 4 children in group A, shortening fraction (%SF) evaluated in the preoperative period was below 28%. No impairment of myocardial contractility was noted before the operation in children in group B. All examined patients in the follow-up echocardiographic examination had a %SF value exceeding 30%.

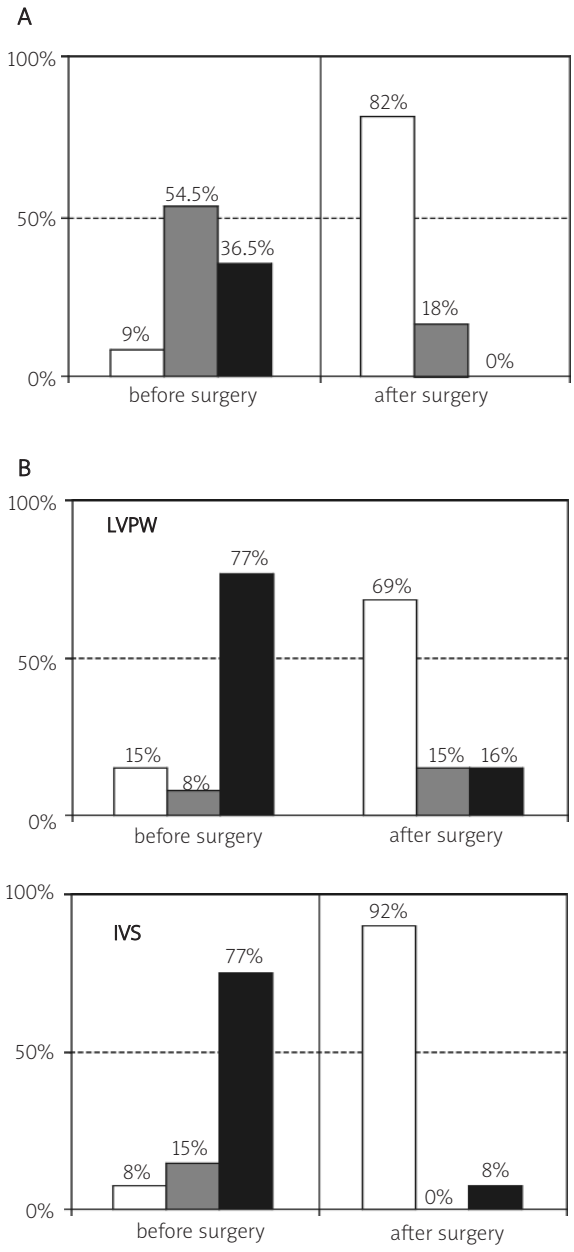

Figure 3. Echocardiographic assessment of LV remodelling in patients after aortic valve replacement with mechanical prostheses. **A** – postoperative assessment of LV diastolic diameter (LVDd) change in patients with preoperative diagnosis of aortic valve regurgitation (AoR). **B** – postoperative assessment of LV posterior wall (LVPW) and ventricular septum (IVS) thickness changes in patients with preoperative diagnosis of aortic valve stenosis (AoS)

White bars – proportion of patients with normal results, grey bars – proportion of patients with abnormal results not exceeding 150%, black bars – proportion of patients with abnormal results exceeding 150% of the normal values

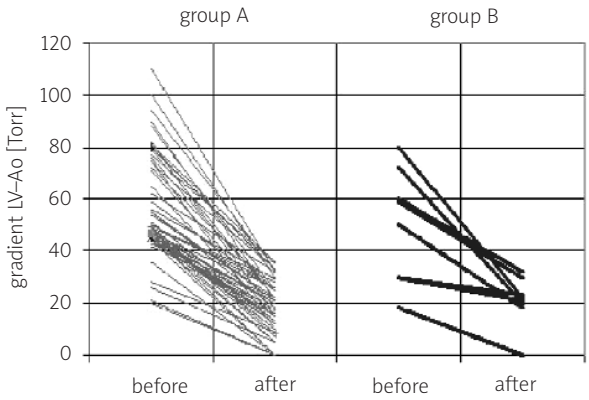

Figure 4. Assessment of left ventricle-aorta (LV-Ao) pressure gradient before and after surgery in the examined patient groups

In group A, LV-Ao pressure gradient above 50 Torr was noted in 23 (75%) children in the preoperative echocardiography, but at the final follow-up study only in 2 (6.5%) patients. In group B, LV-Ao pressure gradient in the preoperative period ranged from 26 to 79 Torr (mean 51±20.4 Torr) while after surgery it was between 0 and 33 Torr (mean 21.8±10 Torr).

In group A at the last follow-up examination, normal LVDd was noted in 84% of the examined children. The IVS thickness exceeding the upper limit of normal before surgery was revealed in 45% of patients, and after surgery – only in 23%. Thickening of LVPW myocardium noted in 42% of patients prior to surgery and was still present after operation in 26% of them.

Functional status according to NYHA classification and quality of life (Tables I and II): Before the operation, 12 (21.8%) patients in group A were found in functional NYHA class III or IV while 43 were in class I or II. In group B all patients prior to surgery were in NYHA class II or II/III. All patients evaluated during the final follow-up examination were classified as NYHA class I patients. All reported feeling well and estimated their physical activity to be similar to that of healthy children at the same age. The vast majority of patients were found to be above the 95th percentile of age-adjusted height and body weight.

Currently, all patients in group A and 3 in group B are at primary or grammar schools, 12 at secondary school, 9 are students and 4 work (as a watch-maker, a graphic artist, a car electrician, a confectioner). Two patients receive disability payment. One of the female patients has been a happy mother of a healthy child for 3 years now, not working. One patient is a rally driver.

Discussion

Due to the lack of possibility to repair the aortic valve, the choice of optimal valvular prosthesis in children operated on for aortic valve disease remains controversial. This is especially true for small children in whom many limitations exist, namely anatomical and physiological factors, such as the size of the aortic annulus, diameter of the ascending aorta, intense metabolism and specific calcium-phosphate balance. Typical and physiological for children is high mobility, high level of physical activity and often interest in sports. A rigid and non-compliant ring of a mechanical prosthesis during an accident may cause obstruction of prosthetic discs and lead to acute heart failure. Due to the necessity of anticoagulation and its possible complications, implantation of mechanical prostheses significantly limits activity of children and has a negative impact on the quality of their life.

In 96% of our patients after mechanical prosthesis implantation during the follow-up lasting over ten years, no such complications were noted. Our results are similar to the findings published by others [1-4]. Similar complications were noted in 7% of patients during 20-year follow-up in the observational study reported by Alexiou et al. [1]. Such events were found by Mazzitelli et al, in 7.8% and 1.2% of children in 20-year and 8-year follow-up, respectively [2].

One patient 5 years after the operation experienced fatal ischaemic stroke. In another patient who was admitted to a prison hospital, too high dose of acenocoumarol resulted in gastrointestinal bleeding. In current clinical practice, the most problematic is to ensure adequate acenocumarol dosing to maintain the recommended target INR [5, 6]. In almost all children, acenocumarol dosing and INR evaluation are left to the discretion of their parents. Throughout puberty, changes of the drug dose and frequency of its administration are necessary; thus oral anticoagulation requires more careful control. Unfortunately in real life INR values are often found beyond the accepted target range. Difficulties in providing adequate anticoagulation represent one of the key disadvantages of mechanical valves, leading to development of other alternative solutions, such as the use of allografts and bioprostheses.

Many surgeons however stress the simplicity, repeatability and safety of mechanical valve implantation in the aortic position, and so such treatment is still being used [1, 7]. In the report of Alexiou et al. the youngest patient with an implanted prosthesis in the aortic position was a child only one year old. Employment of the Nicks technique (patch aortoplasty), described in 1970, enables implantation of

a prosthesis larger than the aortic diameter [8]. This technique was used successfully in 6 patients in our group.

In many reports in-hospital mortality ranged from 0 to 5% [2, 9]. This is supported by our findings, as we observed no deaths during hospitalisation. Late survival in a group of patients with implanted mechanical valves was reported to reach 91% and 71% during the 10-year and 20-year postoperative follow-up respectively [2, 9, 10]. In our group, a 10-year survival was 96%.

A mechanical prosthesis implanted in the young growing body will certainly need reoperation and replacement. In the presented study group of children after mechanical prosthesis implantation in the aortic position, 94% are still free from reoperation.

Echocardiographic assessment of LV cardiac function and anatomy performed ten years after mechanical prosthesis implantation confirmed the efficacy of such treatment in children with aortic valve disease. In all patients who underwent echocardiographic follow-up, normal LV function and contractility were documented, which might indicate proper physiological myocardial remodelling. It must be stressed that quality of life of patients who underwent follow-up examination was similar to that of healthy children at the same age. High survival rate, low percentage of complications, normal cardiac performance and physiological myocardial remodelling following mechanical prosthesis implantation in the aortic position as well as high quality of life confirm that the method represents a real therapeutic alternative and in some centres remains to be used as an effective strategy in the management of aortic valve disease even in paediatric patients [1-4, 7, 10].

However, problems associated with mechanical valve implantation in children stimulated the search for better alternatives in this particular group of patients. Together with development of tissue banking (in our Institute we organised our own allograft bank), better availability of aortic and pulmonary allografts as well as with the introduction of new technologies in bioprosthesis manufacture, mechanical valves are slowly becoming history and are being replaced both in adult and paediatric patients [6, 11-14]. Many surgeons implant aortic allografts as the first choice prostheses in the aortic position [15]. The major reported disadvantage of this technique is the relatively early onset of calcification of the implanted graft [16]. It leads to valve degeneration that results in increased degree of prosthesis regurgitation or stenosis that eventually requires its replacement. In the published reports, early postoperative mortality in patients after aortic valve replacement with a homograft was approximately 10%, and only 68% of patients were free from reoperation during 15-year follow-up [15]. Thus, it cannot be viewed as an ideal therapy, especially in children, putting them at risk of relatively early reoperation. Moreover, an aortic allograft of adequate size is not always available. In our centre in some cases we were forced to reduce larger homograft size to fit the individual needs of patients. Employing such a technique, early outcome of operation is good, but it remains unknown whether a homograft of reduced diameter will be durable, and what kind of future problems might occur when it comes to its replacement. Many authors judge that the Ross operation using a pulmonary autograft is an ideal method for the youngest children [17, 18]. The key advantage of this Ross procedure seems to be physiological growth of the implanted pulmonary autograft because living tissue does not induce an immunological response and practically does not become calcified [6]. Very beneficial haemodynamic characteristics and no need for anticoagulation are undoubted advantages of using the autografting method [6]. However, the operation is complex and difficult [6]. Almost always such patients require replacement of a homograft implanted into right ventricular outflow tract in the future [6]. Employing the Ross operation in fact means exchanging left ventricle outflow tract disease with left and right ostia defects. Due to its complexity and potential risk of complications this method is also not widely used.

In this situation third generation biological prostheses (e.g. Freestyle) seem to be a promising solution for children and adolescents. The cutting edge technology used in the manufacture of these prostheses holds the promise that their durability may be comparable with mechanical valves [13] while retaining all known advantages of biological valves [14, 19, 20]. Due to coating of the bioprosthetic leaflets with α-aminooleic acid they theoretically do not undergo calcification [11]. They feature ideal haemodynamic characteristics that practically do not produce a LV-Ao pressure gradient [14, 20]. They have a soft, pliable and compliant annulus [14, 16, 20]. The aforementioned features mean that stentless biological prostheses produce quick LV myocardial remodelling and improve cardiac performance. Jasiński et al. documented that LV myocardial mass index significantly improved in comparison with a group of patients after implantation of mechanical prostheses [12]. Moreover, the pressure gradient across the stentless bioprosthesis was significantly lower than across the mechanical prosthesis. In view of these facts we initiated in 2004 in our centre a programme of stentless bioprosthesis implantation in children. Our preliminary experience

and results are very satisfying. No fatal events or thromboembolic or infectious complications occurred which may sugegest that these valves may represent an optimal solution for children and adolescents requiring aortic valve replacement. However, we must wait a few years to get to know the results of final assessment of the performance, durability and risk of complications associated with implantation of this new generation of stentless bioprostheses. So far, our department is the only paediatric centre in Poland to have started implanting such prostheses. Very promising results of their use in adults have been presented from another centre [12].

Due to the dynamic advances in biotechnology, an evolving approach to aortic valve replacement in children and adolescents has become a fact. Currently, stentless biological prostheses are not widely used in Poland, mainly because of the limited experience with this technique, particularly in children. They deserve special interest and more common use also in paediatric patients, since the results of their implantation are promising.

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Zmiana podejścia do sposobu wymiany zastawki aortalnej u dzieci i młodzieży – doniesienie wstępne

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Streszczenie

Wstęp: Wybór metody leczenia chirurgicznego u dzieci z wrodzoną i nabytą dysfunkcją zastawki aortalnej jest tematem kontrowersyjnym. Fizjologiczny wzrost pierścienia aortalnego oraz ryzyko wystąpienia powikłań zatorowo-zakrzepowych i krwotocznych sprawiają, że implantacja zastawek mechanicznych w pozycji aortalnej nie jest metodą jednoznaczną u dzieci. W świetle obserwacji dokonanych głównie na pacjentach dorosłych wydaje się, że bezstentowe zastawki biologiczne mogą być dobrą opcją leczniczą dla dzieci i młodzieży wymagających wymiany zastawki aortalnej.

Cel: Ocena wyników leczenia dzieci po wszczepieniu protezy mechanicznej oraz wstępna ocena wyników leczenia po implantacji protezy biologicznej.

Metodyka: Analizie poddano grupę 55 dzieci z wszczepioną protezą mechaniczną (grupa A) oraz grupę 8 dzieci z wszczepioną bezstentową protezą biologiczną (grupa B). Oceniono wiek pacjentów, typ dysfunkcji zastawki, stopień wydolności układu krążenia oraz komfort życia po wszczepieniu protezy zastawki aortalnej. Średni wiek w dniu implantacji protezy mechanicznej wynosił 12 lat i 9 mies. (8–18 lat), podczas gdy implantację protezy biologicznej wykonano średnio w wieku 12 lat i 2 mies. (od 6 lat i 9 mies. do 15 lat i 4 mies.). Okres obserwacji pooperacyjnej wynosił średnio 6 lat i 5 mies. dla dzieci z grupy A (5–13 lat) oraz 1 rok i 5 mies. dla dzieci z grupy B (od 1 mies. do 2 lat). Główną przyczyną dysfunkcji w obu grupach badanych była niedomykalność współistniejąca ze zwężeniem zastawki aortalnej (58% – grupa A, 55% – grupa B). Jedynie u 1 dziecka z grupy A oraz 1 z grupy B przyczyną zmian w aparacie zastawkowym była zmiana nabyta. W obu grupach rozmiar implantowanej protezy aortalnej wnosił średnio 22 mm. U 6 pacjentów z grupy A wykonano plastykę aorty wstępującej w celu implantacji zastawki większej niż średnica aorty wstępującej. Jako parametry oceniające fizjologiczną przebudowę mięśnia lewej komory po wszczepieniu protezy zbadano echokardiograficznie funkcję skurczową lewej komory na podstawie procentu skracania (%SF) i zmiany anatomiczne zachodzące w ścianie lewej komory: wymiar poprzeczny lewej komory serca w rozkurczu (LVDd), grubość tylnej ściany lewej komory serca (LVPW), grubość przegrody międzykomorowej (IVS) oraz gradient ciśnień lewa komora-aorta (LV-Ao).

Wyniki: Nie było zgonów szpitalnych w obu ocenianych grupach. Wystąpiły 2 odległe zgony u dzieci z grupy A. Jedno dziecko zmarło z powodu powikłań krwotocznych, drugie z przyczyn nieznanych. Ponadto u dzieci z grupy A wystąpiły powikłania: zatorowo-zakrzepowe (2), nieistotne powikłania krwotoczne (2), infekcyjne (2). Wykonano dwie reoperacje u dzieci po wymianie zastawki aortalnej na protezę mechaniczną. W okresie 2-letniej obserwacji dzieci po wszczepieniu biologicznej zastawki bezstentowej nie wymagały reoperacji. Stwierdzono dobry wczesny wynik leczenia operacyjnego wady – w grupie A i B, oraz dobry wynik średnio odległy i odległy w grupie B. Fizjologiczna przebudowa ściany lewej komory wystąpiła u dzieci zarówno z grupy A, jak i z grupy B. W obu grupach subiektywny i obiektywny komfort życia był dobry.

Wnioski: Dobre wyniki kliniczne, prosta technika, powtarzalność i bezpieczeństwo techniki operacyjnej wszczepiania zastawki mechanicznej w pozycji aortalnej sprawiają, że metoda ta jest wciąż atrakcyjną opcją leczenia wad zastawkowych zarówno u dzieci, jak i dorosłych. Jednakże brak powikłań zatorowo-zakrzepowych, krwotocznych i infekcyjnych oraz poprawa trwałości powodują, że rozwiązaniem na przyszłość dla dzieci i młodzieży wymagających wymiany zastawki aortalnej mogą być bezstentowe zastawki biologiczne nowej generacji.

Słowa kluczowe: dysfunkcja zastawki aortalnej, proteza mechaniczna, bezstentowa proteza biologiczna, dzieci

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