Research article/Raziskovalni prispevek

PERCUTANEOUS CLOSURE OF SECUNDUM-TYPE ATRIAL SEPTAL DEFECTS USING AMPLATZER SEPTAL OCCLUDERS

PERKUTANO ZAPIRANJE DEFEKTOV INTERATRIJSKEGA SEPTUMA TIPA SEKUNDUM Z AMPLATZOVIMI SEPTALNIMI ZAPIRALI

Uroš Mazić[1], Pavle Berden[2], Tomaž Podnar[1]

[1] University Children's Hospital, Cardiology Unit, University Medical Center Ljubljana, Vrazov trg 1, 1525 Ljubljana
[2] Department of Radiology, University Medical Center Ljubljana, Zaloška 2, 1525 Ljubljana

Arrived 2001-07-27, accepted 2002-11-28; ZDRAV VESTN 2003; 72: 1–6

Key words: *atrial septal defect; Amplatzer septal occluder; percutaneous closure; surgery; echocardiography*

Ključne besede: *defekt interatrijskega septuma; Amplatzovo septalno zapiralo; perkutano zapiranje; kirurgija; ehokardiografija*

Abstract – Background. *Percutaneous closure of secundum-type atrial septal defect (ASD II.) is becoming an increasingly widespread alternative to surgical closure. We report our initial clinical experience with the percutaneous closure of ASD II. using Amplatzer Septal Occluders (ASO) in Slovenia.*

Patients and methods. *Fifty consecutive patients with ASD II. were evaluated for transcatheter closure with ASO using both transthoracic (TTE) and transesophageal echocardiography (TEE). Transcatheter closure was performed under general endotracheal anesthesia with simultaneous fluoroscopy and TEE guidance. The stretch defect diameter was measured using an Amplatzer sizing balloon catheter. The ASO having a 2–4 mm larger diameter than the stretched defect diameter was selected for defect closure. Follow-up was scheduled 10 min, 24 hours, 1 month, 3 months, 6 months, 1 year and then annually after the procedure.*

Results. *Eight patients (16%) with deficiency of the posterior, inferior anterior, or inferior posterior rim were not deemed suitable for transcatheter closure and were referred for surgery. Fourteen patients (28%) had centrally positioned defects, 23 patients (46%) defects with a deficient superior anterior rim, 3 patients had multiple defects, while 2 patients presented with atrial septal aneurysm: 1 associated with a single perforation and 1 with multiple perforations. So far, cardiac catheterization has been performed in 24 patients, while the remaining 12 patients are waiting cardiac catheterization. During cardiac catheterization, 1 additional patient was excluded from percutaneous closure due to an additional defect unsuitable for percutaneous closure. Therefore, percutaneous closure was attempted in 23 patients. In a single patient we retrieved an inadequately positioned occluder and referred the patient for elective surgical closure. A large Eustachian valve caused this single failure of occluder positioning in our series. In the remaining 22 patients successful implantation of ASO was achieved. The correct position of the occluder was achieved in 13 patients at the first attempt, while in 9 patients several attempts were necessary. The complete closure rate rose from 70% at the end of the procedure to 95% at the latest*

Izvleček – Izhodišča. *Defekt interatrijskega septuma tipa sekundum (ASD II.) je ena najpogostejših prirojenih srčnih napak. Klasično zdravljenje ASD II. je kirurško. Od leta 1974 dalje je bila preizkušana vrsta različnih tipov zapiral za perkutano zapiranje ASD II. Pri vseh zapiralih so bile ugotovljene pomembne pomanjkljivosti, zato se nobeno od zapiral ni uveljavilo v klinični praksi. Najpogosteje ugotovljene pomanjkljivosti zapiral so bile: zapleteni postopki vstavljanja zapiral, številni zapleti med in po posegu vključno s poznimi embolizacijami zapiral, zlomi oz. mehanskimi poškodbami zapiral ter visok delež rezidualnih šantov. Leta 1995 je bilo prvič klinično uporabljeno Amplatzovo septalno zapiralo (ASZ). Zapiralo je bilo zasnovano z namenom, da preseže pomanjkljivosti predhodnih zapiral in tako izboljša rezultate perkutanega zapiranja. V članku smo predstavili prve klinične izkušnje s perkutanim zapiranjem ASD II. z uporabo Amplatzovega septalnega zapirala v Sloveniji.*

Metode. *V prospektivno študijo smo vključili 50 zaporednih bolnikov z ASD II. Pri vseh bolnikih smo opravili transtorakalni (TTE) in transezofagealni (TEE) ehokardiogram. Za perkutano zapiranje smo izbrali bolnike, ki so izpolnjevali naslednje kriterije: 1. s TEE izmerjen največji premer defekta < 30 mm; 2. dolžina robov defekta ≥ 5 mm, razen zgornjega sprednjega roba; 3. interatrijski septum daljši od premera levega diska ASZ. Perkutano zapiranje smo pri vseh bolnikih izvedli v splošni anesteziji s sočasnim diaskopskim in TEE nadzorom. Zapiralo smo vstavili preko desne femoralne vene. Velikost zapirala smo izbrali na osnovi meritve razteznega premera defekta. Meritev smo izvedli z Amplatzovim merilnim balonskim katetrom. Za zapiranje smo izbrali 2–4 mm večje zapiralo od izmerjenega razteznega premera defekta. Amplatzovo septalno zapiralo je zgrajeno iz nitinolne mreže, ki je oblikovana v dva diska, med seboj povezana s telesom zapirala v obliki valja. Premer telesa zapirala predstavlja označeno velikost zapirala. Izbrano zapiralo smo preko dolgega implantacijskega uvajala vstavili v defekt. Telo zapirala je zaprlo defekt interatrijskega septuma. Diska sta bila razprta vsak v svojem atriju in sta tako stabilizirala zapiralo v defektu. Pred uvedbo merilnega balonskega katetra je vsak bolnik pre-*

follow-up. Regression of right ventricular M-mode echocardiographic dimension was evident from 26.4 ± 3.1 mm before closure to 21.7 ± 4.2 mm at 1 month (p < 0.05), and to 19.1 ± 3.2 mm (p < 0.05) at 3 months follow-up. Late complications were not detected during a 12-month follow-up.

Conclusions. *Percutaneous closure of ASD II. using ASO is a safe and effective alternative to surgical closure. Up to 80% of ASD II. are amenable to percutaneous closure using ASO. Careful patient selection, precise stretch defect diameter measurement, selection of proper occluder size and precise positioning of the occluder are crucial for successful defect closure. Additional clinical experience in a larger number of patients and long-term follow-up results are required to further support our statements.*

jel heparin (100 E/kg TT i. v., največ 5000 E). Po posegu je vsak bolnik prejel dalteparin (50 E/kg TT s. c., največ 2500 E). Nadaljnjih 6 mesecev je vsak bolnik prejemal aspirin 3–5 mg/kg TT/dan. Pri vseh bolnikih smo dan po posegu opravili klinični pregled, EKG, RTG prsnih organov in TTE. Klinični pregled in TTE smo predvideli 1, 3, 6 in 12 mesecev po posegu ter nato na 1 leto. Pri kontrolah smo bili posebno pozorni na morebitne poškodbe zapirala, delovanje atrioventrikularnih zaklopk, rezidualne šante preko interatrijskega septuma in velikost srčnih votlin.

Rezultati. *Pri 14 bolnikih (28%) smo ugotovili defekt v centralnem delu interatrijskega septuma (področje fose ovalis). Pri ostalih 36 bolnikih smo ugotovili različne morfološke različice ASD II.: pri 23 bolnikih (46%) defekt ni imel zgornjega sprednjega roba, pri 8 bolnikih (16%) je bil defekt bodisi brez zadnjega, spodnjega zadnjega ali spodnjega sprednjega roba. Pri 3 bolnikih (6%) smo odkrili 2 ali več defektov, pri 2 bolnikih (4%) pa je bil defekt v anevrizmi interatrijskega septuma. S TTE smo ugotovili, da kriterijev za perkutano zapiranje ne izpolnjuje 5 bolnikov (10%). Dodatne 4 bolnike (8%) smo izključili s TEE. Doslej smo kateterizacijo srca opravili pri 24 bolnikih. Ob kateterizaciji srca smo ugotovili, da dodatna 2 bolnika nista primerna za perkutano zapiranje. Pri prvem bolniku smo ugotovili dodaten defekt interatrijskega septuma brez zadnjega roba. Pri drugem bolniku nam je velika Eustahijeva zaklopka preprečila popolno odprtje desnega diska zapirala in s tem ustrezen položaj zapirala v defektu. Zato smo zapiralo odstranili iz telesa. Oba bolnika smo napotili na programirano kirurško zaprtje. Pri 22 bolnikih smo zapiralo uspešno vstavili: pri 13 bolnikih ob prvem poizkusu, pri 9 bolnikih po dveh ali več poizkusih. Deset minut po vstavitvi zapirala smo ugotovili popolno zaprtje defekta pri 15/22 bolnikov (68%), po 24 urah pri 18/22 bolnikov (81%) in 6 mesecev po posegu pri 16/17 bolnikov (94%). V tem času smo ugotovili zmanjšanje velikosti desnega prekata, ki je pred zaprtjem meril 26,4 ± 3,1 mm, 1 mesec po posegu 21,7 ± 4,2 mm (p < 0,05) in 3 mesece po posegu 19,1 ± 3,2 mm (p < 0,05). V 12 mesecih spremljanja po posegu poznih zapletov nismo ugotovili.*

Zaključki. *Amplatzovo septalno zapiralo je varno in učinkovito zapiralo za perkutano zapiranje ASD II. Z ASZ je mogoče zapreti do 80% vseh ASD II., kar je bistveno več kot z doslej preizkušanimi zapirali. ASZ omogoča zaprtje defektov, ki jih z doslej uporabljanimi zapirali ni bilo mogoče zapreti. Z ASZ lahko zapiramo defekte, katerih največji premer meri do 36 mm. Edino od zapiral omogoča zapiranje najpogostejše morfološke različice ASD II. – defektov brez zgornjega sprednjega roba. Za uspešno vstavitev ASZ je ključen ustrezen izbor bolnikov, natančna določitev raztezne velikosti defekta, ustrezna izbira velikosti zapirala in natančna vstavitev zapirala. Učinkovitost zapirala smo potrdili s popolnim zaprtjem defekta pri 21 od 22 bolnikov (95%) ob zadnji opravljeni kontroli. Zapletov med posegom, neposredno po posegu in kasnih zapletov nismo ugotovili, kar potrjuje varnost perkutanega zapiranja ASD II. z uporabo ASZ. ASZ je trenutno najobetavnejše zapiralo za perkutano zapiranje ASD II. Za dokončno oceno ASZ so potrebne izkušnje pri večjem številu bolnikov in daljše obdobje spremljanja bolnikov.*

Introduction

The secundum-type atrial septal defect (ASD II.) is one of the most common congenital heart defects, with an estimated prevalence of 1/1500 live births (1). A left to right shunt across the defect causes right heart volume overload. Predominantly in adult patients, ASD II. causes right heart failure, cardiac arrhythmias, pulmonary artery hypertension and early death (1, 2).

Surgical closure is an established method of treatment of ASD II. and is associated with rare, but significant, complications. Nowadays, the perioperative mortality of surgical treatment is less than 1%. However, residual shunts have been reported in 7% to 30% of patients and late atrial arrhythmias in 15% to

50% of patients in large surgical series (3–5). Therefore, percutaneous closure of ASD II. is becoming an increasingly popular alternative to surgery. The first clinical attempts to close ASD II. percutaneously were reported by King and Mills in 1974 (6). Several devices were subsequently evaluated with important drawbacks being found in all of them. The most important drawbacks were the large size of the devices and the high incidence of complications such as device embolisation, device fractures, heart perforation and a high rate of residual shunts (7–13).

In 1995, the initial experience in percutaneous closure of ASD II. using a new, self-expanding, self-centering Amplatzer Septal Occluder was reported in humans (14). The Amplatzer Septal Occluder (ASO) was designed to overcome the drawbacks of previously evaluated devices, in particular, to increase the rate of complete defect closure, both in children and adults. According to reported results, percutaneous closure of ASD II. using ASO is safe and effective, even in patients not suitable for closure with other devices (14–16). The purpose of the present study is to report our initial clinical experience in the transcatheter closure of ASD II. using ASO in Slovenia.

Methods

Between November 1998 and June 2001, 50 consecutive patients with ASD II. were evaluated for transcatheter closure using ASO. Transthoracic echocardiography (TTE) was performed in all patients with the Hewlett-Packard Sonos 1000 imaging system, using standard subxyphoid, apical, parasternal and suprasternal views. Prior to cardiac catheterization, transesophageal echocardiography (TEE) was performed in patients, who were deemed suitable candidates for percutaneous closure after TTE. TEE was performed with the Hewlett-Packard Sonos 1000 imaging system using a 7.5/5.0 MHz pediatric biplane probe. TEE was used for accurate determination of the defect size and morphology. In addition, partial anomalous pulmonary venous drainage was excluded with TEE. The maximal longitudinal diameter of the defect was measured in the longitudinal view. Either the plane of the caval veins or the plane of the ascending aorta was used for maximal longitudinal defect size measurement. The maximal horizontal defect diameter was obtained in the four-chamber view or in the plane of the central interatrial septum using slight anterior or posterior flexion of the transducer to obtain the maximal diameter of the defect. The maximal measured value in either the longitudinal or transverse plane was stated as the maximal diameter of the defect.

The rims of the defect were measured using standard TEE views. The superior anterior rim was measured in the horizontal plane as the minimal distance between the anterior defect margin and the aorta. The posterior rim represents the minimal distance from the posterior defect margin to the posterior atrial wall. The inferior anterior rim was measured in the four-chamber view as the minimal distance from the defect to the atrio-ventricular valves. The longitudinal planes were used to determine the superior posterior rim as the minimal distance from the defect to the opening of the superior vena cava and the inferior posterior rim as the minimal distance from the defect to the opening of the inferior vena cava. The total interatrial septal length was obtained using either the four-chamber view or the plane of the caval veins.

Patient selection

Criteria for transcatheter closure were: 1) ASD II. with maximal TEE defect diameter < 30 mm; 2) defect rims, except the superior anterior rim, of at least 5 mm in diameter and 3) the total length of the interatrial septum greater than the diameter of the left atrial disk of the chosen device.

Informed written consent was obtained from patients or their parents prior to both the TEE and cardiac catheterization. The study was part of a clinical trial approved by an authorized Slovenian ethics committee.

Device and procedure

The ASO (AGA Medical Corporation, Golden Valley, MN, USA) is a self-expandable, self-centering device that has been previously described in detail (14). It is made of super-elastic nitinol wire woven into two disks, which are connected by a cylindrical waist (Fig. 1). The device is filled with polyester foam to facilitate thrombosis and occlusion. The diameter of the waist represents the size of the device (4–36 mm) and corresponds to the stretch defect diameter. The left atrial disk is 10 mm and the right atrial disk is 8 mm larger than the waist in smaller devices (4–10 mm). In larger devices the left atrial disk is 14 mm and the right atrial disk is 10 mm larger than the connecting waist.

Fig. 1. *Amplatzer Septal Occluder.*
Sl. 1. *Amplatzovo septalno zapiralo.*

Vascular access was obtained through the right femoral vein. The stretched diameter of the defect was determined using an Amplatzer sizing balloon catheter (Fig. 2). The balloon was positioned across the defect and slowly inflated with diluted contrast until the waist appeared. The diameter of the waist was measured and corrected for magnification using the radiopaque markers on the balloon catheter. Thus, the stretch defect diameter was obtained and used for selection of the proper size of the device. The device was fixed to the delivery wire with a microscrew and introduced through the loader into the delivery sheath. Under simultaneous TEE and fluoroscopic guidance the left atrial disk and the waist were deployed in the left atrium. The whole system was then pulled back against the interatrial septum resulting in self-centering of the device in the defect. The right atrial disk was then deployed in the right atrium and pushed against the right atrial aspect of the interatrial septum. Adequate device position was confirmed using TEE by demonstrating unobstructed flow from the coronary sinus, right pulmonary veins and superior and inferior caval veins. In particular, normal function of both atrioventricular valves was confirmed. All patients received heparin 100 I.U./kg i. v. (max. 5000 E) before insertion of the sizing balloon catheter, followed by dalteparin 50 I.U./kg s.c. (max. 2500 E) after the procedure. Aspirin was prescribed for 6 months (3–5 mg/kg) in all patients.

The role of TEE

TEE was used for final patient selection, because it allowed superb visualization of the defect size and morphology. This was particularly important in patients with large defects, multiple defects and patients with atrial septal aneurysm.

During the procedure TEE was used for: 1) guidance for correct sizing balloon catheter placement, 2) guidance for correct delivery sheath placement, 3) guidance for correct device

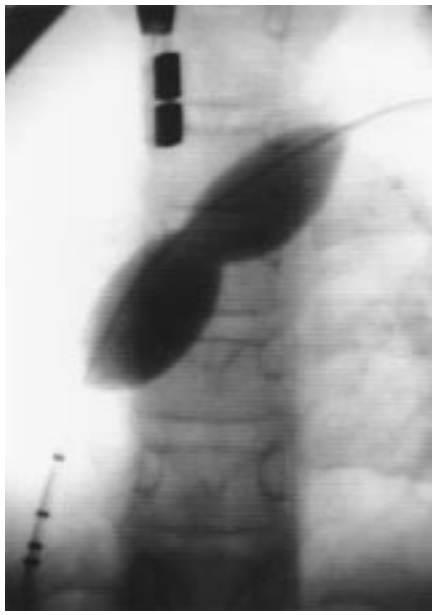

Fig. 2. *Amplatzer sizing balloon catheter. The Amplatzer® Sizing Balloon is a 7 Fr double lumen balloon catheter made from radiopaque nylon. Radiopaque markers at 10, 5 and 2 mm intervals allow for radiographic measurement.*

Sl. 2. *Amplatzov merilni balonski kateter.*

placement, 4) controlling the position and stability of the device, 5) guidance for the release of the device and 6) assessment of residual leaks immediately after implantation.

Follow-up

Follow-up examinations were scheduled 24 hours, 1 month, 3 months, 6 months, 1 year and then annually after the procedure. Clinical examination and TTE were performed at each follow-up visit, with particular attention being focused on residual shunts, right ventricular diameters and late complications. Residual shunts after transcatheter closures were studied according to the following classification (10): trivial (< 1 mm), small (1–2 mm), moderate (3–4 mm), and large (> 4 mm in diameter).

Results

Fifty patients with ASD II. were detected between November 1998 and June 2001. After TTE, 5 patients (10%) were excluded from attempted percutaneous closure (Tab. 1). Forty-five patients underwent TEE examination. Based on the TEE findings, an additional 4 patients (8%) did not meet the criteria for transcatheter closure (Fig. 3).

Fourteen patients (28%) had centrally positioned defects (in the region of the fossa ovalis). The remaining 36 patients (72%) had various morphological variations of ASD II.: 23 patients (46%) had defects with deficient superior anterior rim (Fig. 4A), and 8 patients (16%) had partial or total deficiency of the posterior, inferior anterior or inferior posterior rim. Three patients had multiple defects, while 2 patients presented with an atrial septal aneurysm: with a single perforation in 1 patient and with multiple perforations in another patient.

Cardiac catheterization was performed in 24 patients, while 17 are still awaiting the procedure. During cardiac catheterization, a single patient was excluded from attempted percutaneous closure, since an additional defect, not suitable for device closure, was revealed during cardiac catheterization, the patient therefore being referred for elective surgery. In another patient, we retrieved an ASO already positioned in the defect. A large Eustachian valve prevented proper device positioning in this patient and therefore, she was referred for elective surgical closure. Successful implantation of ASO was achieved in the remaining 22 patients. The procedural time range from 40 to 115 min. (mean 65 min.) and the mean fluoroscopy time was 12.7 minutes (range 5.1 to 21.4 min.).

The age of patients who underwent transcatheter closure with ASO ranged from 27 months to 22 years (median 11.7 years) and their weight ranged from 13 to 69 kg (median 47 kg).

The diameter of ASD II. measured by TEE ranged from 8 to 21 mm (mean 14.4 ± 2.6 mm) and the stretched defect diameter ranged from 10 to 25 mm (mean 18.2 ± 3.1 mm). The ran-

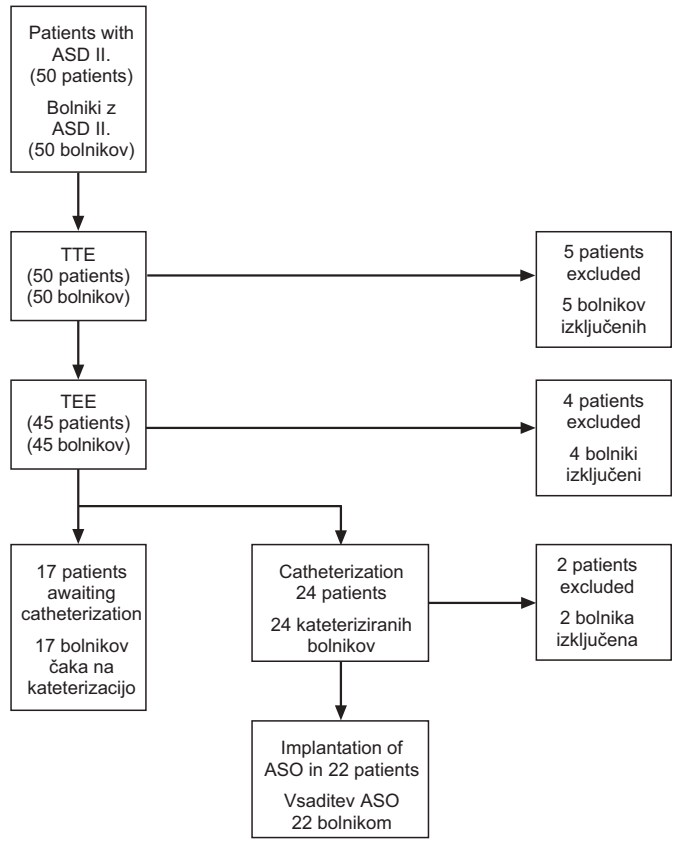

Fig. 3. *Selection of patients for percutaneous closure of ASD II. using ASO.*

Sl. 3. *Izbor bolnikov za transkatetersko zapiranje interatrijskega septuma tipa sekundum z ASO.*

Tab. 1. *Patients referred for surgical closure.*

Razpr. 1. *Bolniki, napoteni na programirano kirurško zaprtje.*

Investigation Vrsta preiskave	Defects with deficient rims Defekti s pomanjkljivimi robovi	Multiple defects Multipli defekti	Associated malformations Pridružene napake	Defect diameter > 30 mm Velikost defekta > 30 mm
TTE	3	0	1	1
TEE	2	1	0	1
CATH	0	1	1	0

CATH – cardiac catheterization, PAPVR – partial anomalous pulmonary venous return, TEE – transesophageal echocardiography, TTE – transthoracic echocardiography

CATH – srčna kateterizacija, PAVPR – parcialni anomalni venski priliv, TEE – transezofagealni ultrazvok srca, TTE – transtorakalni ultrazvok srca

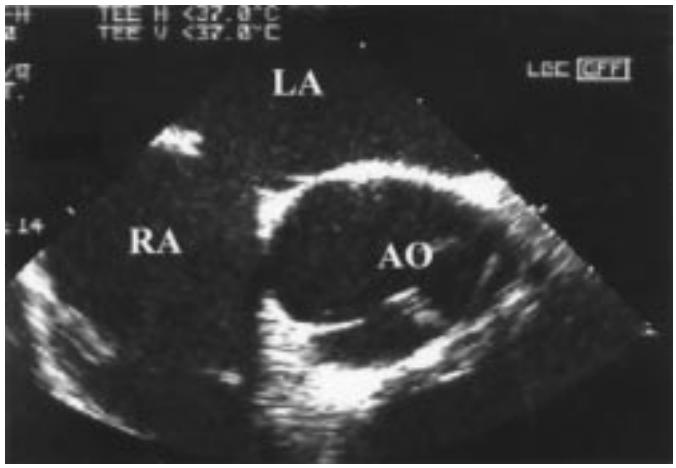

Fig. 4A. *Secundum-type atrial septal defect with deficient superior anterior rim.*

Sl. 4A. *Defekt interatrijskega septuma tipa sekundum brez zgornjega sprednjega roba.*

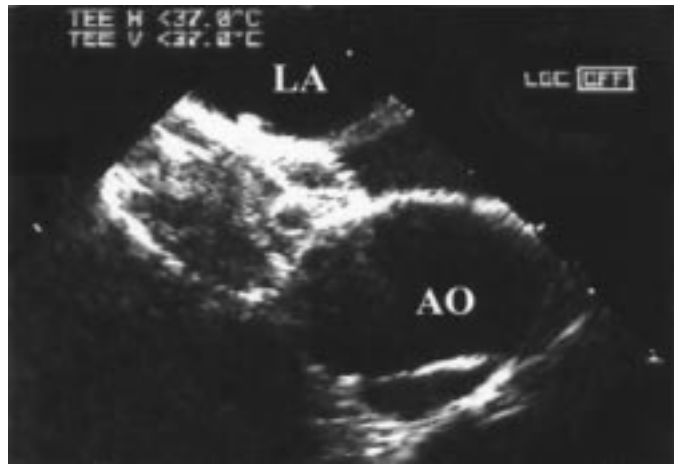

Fig. 4B. *Amplatzer Septal Occluder closing secundum-type atrial septal defect with deficient superior anterior rim.*

Sl. 4B. *Amplatzovo septalno zapiralo zapira defekt interatrijskega septuma tipa sekundum brez zgornjega sprednjega roba.*

ges of implanted ASO were between 12 and 28 mm (average 20 mm). Correct placement of the device was achieved in 13 of 23 patients at the first attempt. In 9 patients redeployment of the ASO was necessary.

In all patients, the TEE appearance of the occluder was clear and characteristic, allowing precise assessment of its position in relation to the surrounding structures (both atrioventricular valves, coronary sinus, right pulmonary veins, superior and inferior caval vein). At the end of the procedure the position of the ASO was correct and stable in all 22 patients.

Residual shunts were studied by TEE 10 min. after release of the ASO and at 24 h., 1, 3, 6 and 12 months after transcatheter closure with TTE. The results of closure are presented in Table 2.

Tab. 2. *Results of percutaneous closure.*

Razpr. 2. *Rezultati transkateterskega zapiranja.*

Residual shunt / Ostanek šanta	Follow-up / Spremljanje					
	10 min. (22 patients) / 10 min. (22 bolnikov)	24 h. (22 patients) / 24 ur (22 bolnikov)	1 month (22 patients) / 1 mesec (22 bolnikov)	3 months (20 patients) / 3 mesece (20 bolnikov)	6 month (17 patients) / 6 mesecev (17 bolnikov)	12 month (9 patients) / 12 mesecev (9 bolnikov)
None / Brez	15 (68%)	18 (81%)	19 (86%)	19 (95%)	16 (94%)	8 (89%)
Trivial / Neznaten	6 (27%)	3 (14%)	2 (9%)	1 (5%)	1 (6%)	1 (11%)
Small / Majhen	1 (5%)	1 (5%)	1 (5%)	0	0	0
Moderate / Zmeren	0	0	0	0	0	0

During follow-up regression of right ventricular dilatation was observed. The average right ventricular dimension before closure was 26.4 ± 3.1 mm, 21.7 ± 4.2 mm at 1-month ($p < 0.05$), and 19.1 ± 3.2 mm ($p < 0.05$) at 3-month-follow-up.

During the 12-month-follow-up, late complications were not detected.

Discussion

Since 1974, several devices have been evaluated for the transcatheter closure of ASD II. and important drawbacks have been found in all of them (8–12). The main problems with buttoned or double umbrella/patch devices were relatively difficult implantation techniques, large delivery systems, and a high rate of complications including air embolism, late device failure (fracture, unbuttoning, device embolisation, heart perforation), and high rate of residual leaks (10–13). In addition, the retrievability of devices in case of malpositioning was difficult, or even impossible, if the device had completely opened in the heart, resulting in the frequent need for urgent surgical retrieval (13).

The ideal device for transcatheter closure should allow easy implantation, including the possibility of complete retraction and repositioning in case of malpositioning. The ASO is elastic and self-expandable, which makes deployment of the left atrial disk and the waist in the left atrium easy. Furthermore, self-centering of the device is crucial for its adequate positioning, resulting in stenting of the defect with the waist of the occluder and complete defect closure. Positioning of the ASO should be monitoring both by TEE and fluoroscopy, making the implantation procedure more precise, easier and more user-friendly than with other existing devices. The high elasticity also allows easy and complete retrievability of the device in the event of malpositioning. Retrievability was demonstrated in our nine patients, in whom devices were incorrectly implanted or their positions unstable. Therefore, urgent surgical retrieval of malpositioned devices was not necessary in our series.

In addition, the ASO proved to be resistant to damage. Despite several attempts at device positioning during the closure procedure, there were no signs of wire fractures or device damage and deformity. Late device fractures in buttoned and patch devices caused unstable positioning of the devices, leading to a high incidence of residual leaks or even late device embolisations (13). Our experience confirmed that ASO is very stable, due to its damage resistance, waist stenting of the defect and concomitant fixation of the occluder with the left and right atrial disks. So far, device instability or even late embolisation has not been encountered in our experience. Furthermore, the incidence of residual leaks is much lower than in other devices. Immediate complete closure was achieved in 70% of patients and at the latest follow-up, complete closure was found in 95% of patients in our study. Only a single patient with the trivial residual shunt was observed. We believe that stenting of the defect with the waist of the ASO contributes to

immediate closure results. Trombogenicity of the device due to polyester foam inside the device and epithelisation of the implanted device contribute to the high rate of late complete closure.

In comparison with other devices, the ASO also proved to be superior regarding the feasibility of closing various morphological variations of ASD II. Using the patch and buttoned devices approximately 50% of defects are amenable to transcatheter closure (8, 9, 12, 17). In contrast, closure using the ASO is feasible in up to 80% of patients having ASD II. Centrally positioned defects in the region of the fossa ovalis up to 20 mm in diameter are suitable for percutaneous closure using the majority of available devices (8, 9, 12, 17). Using the ASO, it is possible to close defects up to 36 mm in diameter (14–16). In our study we successfully closed defects in 7 patients with a stretch defect diameter larger than 20 mm. In addition, the ASO allows closure of defects with deficient superior anterior rim, the most common morphological variation of ASD II. In contrast, deficiency of the superior anterior rim is considered a risk factor for unsuccessful closure and a significant predictor of residual leakage using the Cardioseal device (17). In our series, all defects with deficient superior anterior rim were successfully closed using ASO, without any residual leakage. Both TEE and fluoroscopy demonstrated that the round and flexible disks embraced the aortic root from behind, while the waist of the device stented the defect itself (Fig. 4B). In all patients in our series the size of the implanted ASO was 2–4 mm larger than the measured stretched defect diameter.

The rate of successful device implantation is also higher using ASO compared to other available devices. We successfully implanted ASO in 22 of 23 patients. The high successful implantation rate is due to careful patient selection, precise measurement of the stretch defect diameter, proper selection of the device size, and precise implantation of the ASO under both TEE and fluoroscopy guidance. TEE is crucial for patient selection, allowing precise delineation of defect morphology. Recognition of defect morphology is essential for avoiding complications of closure such as device embolisation, residual shunting and valve incompetence.

However, ASO is not the ideal device for closure of all morphological variations of ASD II. Multiple small fenestrations in the oval fossa are probably better managed with the Cardioseal device (17). In our study we have not yet encountered any patient with multiple small fenestrations.

The hemodynamic benefit of defect closure was proved during follow-up. In our group of patients we found a statistically significant reduction of right ventricular dilatation in the first months after closure due to cessation of left to right shunting at the atrial level.

During follow-up, late complications such as cardiac arrhythmias, device malfunctioning, and thrombembolic events have not as yet been detected.

Conclusions

The percutaneous closure of secundum-type atrial septal defects is becoming an increasingly popular alternative to surgical closure. The ASO is currently the most promising device available for transcatheter closure of ASD II. The ASO has proved to be user friendly, with the highest feasibility rate and complete closure rate and the lowest complication rate among all evaluated devices. Up to 80% of ASD II. are amenable to closure using the ASO. High closure rates are achieved by careful patient selection using TEE and by precise measurement of the stretch defect diameter during cardiac catheterisation. However, further clinical experience in a larger number of patients, using larger devices and long-term follow-up results are required to further support our statements.

References

1. Šamánek M. Children with congenital heart disease: probability of natural survival. Pediatr Cardiol 1992; 13: 152–8.
2. Cheitlin DM, Rapaport E. Interatrial septal defect in the adult. In: Chatterjee K, Cheitlin DM, Karliner J, Parmley WW, Rapaport E, Scheinman M. Cardiology: an illustrated text/reference. Philadelphia: J. B. Lippincott company, 1991: 1143–51.
3. Murphy JG, Gersh BJ, McGoon MD et al. Long-term outcome after surgical repair of isolated atrial septal defect. N Eng J Med 1990; 323: 1645–50.
4. Bradenburg RO Jr., Holmes DR Jr., Bradenburg RO et al. Clinical follow-up of paroxysmal supraventricular tachyarrhytmias after operative repair of a secundum type atrial septal defect in adults. Am J Cardiol 1983; 51: 273–3.
5. Ward C. Secundum atrial septal defect: routine surgical treatment is not of proven benefit. Br Heart J 1994; 71: 219–23.
6. King TD, Mills NL. Nonoperative closure of atrial septal defects. Surgery 1974; 75: 383–8.
7. Sideris EB, Sideris SE, Thanapoulos BD et al. Transvenous atrial septal defect occlusion by the buttoned device. Am J Cardiol 1990; 66: 1524–6.
8. Justo RN, Nykanen DG, Boutlin C et al. Clinical impact of transcatheter closure of secundum atrial septal defects with the double umbrella device. Am J Cardiol 1996; 77: 889–92.
9. Latson L, Benson L, Hellenbrand W et al. Transcatheter closure of ASD – Early results of multicenter trial of the bard clemsheel septal occluder. Circulation 1991; 84: Suppl II: 544–4.
10. Rao PS, Sideris EB, Hausdorf G et al. International experience with secundum atrial septal defect occlusion by buttoned device. Am Heart J 1994; 128: 1022–35.
11. Das GS, Shrivastava S, O'Laughlin MP et al. Intermediate term follow up of patients after percutaneous closure of atrial septal defects with the Das Angelwings devices. Circulation 1996: 94: Suppl 1: I-56–I-66.
12. Lloyd TR, Rao PS, Beekman III RH, Mendelsohn AM, Sideris EB. Atrial septal defect occlusion with buttoned device (a multi-institutional U. S. trial). Am J Cardiol 1994; 73: 289–91.
13. Agarwal SK, Ghosh PK, Mittal PK. Failure of devices used for closure of atrial septal defects: Mechanisms and management. J Thorac Cardiovasc Surg 1996; 112: 21–6.
14. Masura J, Gavora P, Formanek A et al. Transcatheter closure of secundum atrial septal defects using new self-centering Amplatzer Septal Occluder: Initial human experience. Cathet Cardiovasc Diag 1997; 42: 388–93.
15. Thanopoulos BD, Laskari CV, Tsaousis GS, Zarayelyan A, Vekiou A, Papadopoulos GS. Closure of atrial septal defects with the Amplatzer occlusion device: preliminary results. J Am Coll Cardiol 1998; 31: 1110–6.
16. Chan KC, Godman MJ, Walsh K, Wilson N, Redington A, Gibbs JL. Transcatheter closure of atrial septal defect and interatrial communications with a new self-expanding nitinol double disc device (Amplatzer septal occluder): multicentre UK experience. Heart 1999; 82: 300–6.
17. Momenah TS, McElhimney DB, Brook MM, Moore P, Silverman NH. Transesophageal echocardiographic predictors for successful transcatheter closure of the defect within the oval fossa using CardioSEAL septal occlusion device. Cardiol Young 2000; 10: 510–8.