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Original article

Medium- and long-term follow-up of transcatheter closure of ruptured sinus of Valsalva aneurysm in Central Europe population

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ABSTRACT

Background: We aimed to evaluate medium- and long-term outcomes of transcatheter closure (TC) of ruptured sinus of Valsalva aneurysm (RSVA), which is a rare and mostly congenital heart disease.
Methods: Retrospective analysis included 23 patients (14 males) aged 15–79 years (y; 39.9 ± 18.5) selected for TC of RSVA between 2007 and 2017 in two tertiary centers in Poland and Ukraine. Fifteen patients were in New York Heart Association (NYHA) class III or IV before TC; 5 patients had acquired RSVA after previous cardiac surgery. We applied 22 duct, 3 muscular, and 1 atrial septal Amplatzer or Amplatzer-like occluders by the anterograde venous approach after arterio-venous loop creation in all but 1 patient. Mean follow-up conducted in outpatient clinic was 5.5 ± 3.5 (1–11) y.
Results: The procedure was successful in 19/23 patients (82.6%). Four procedures were abandoned and the device percutaneously retrieved due to coronary artery compression (1 patient), transient increase of aortic regurgitation (AR; 1 patients) or embolization (2 patients). New onset of significant AR was noted in one of the latter patients after device removal. NYHA class improved in all treated patients but 2, in whom it remained stable ($p < 0.05$), with 10 patients in class I. Three patients needed percutaneous re-intervention during follow-up because of significant residual shunt in 1 and late recurrent RSVA in 2 patients. The follow-up of the remaining patients was uneventful. Neither erosion, embolization, new AR, nor death were observed.
Conclusions: The percutaneous closure of RSVA is a safe and effective method of treatment with good clinical outcome. However, although not described previously, recurrent shunts after TC of RSVA are possible and can be treated successfully with another transcatheter intervention.

Introduction

Sinus of Valsalva aneurysm (SVA) is an uncommon and mostly congenital cardiac anomaly which predominantly affects Asian males [1]. Congenital SVA is caused by deficiency of normal elastic tissue between aortic media and the annulus fibrosus (abnormal bulbus cordis development) [2]. Ventricular septal defect (VSD), aortic regurgitation (AR), and bicuspid aortic valve (BAV) are frequent concomitant lesions in this SVA type. Acquired SVA can result from previous cardiac surgery, endocarditis, syphilis, atherosclerosis, or chest injury [3]. SVA arises from the right sinus of Valsalva in 80–85% cases, from the non-coronary sinus in 5–15%, and rarely from the left sinus. Despite being generally asymptomatic, SVA can compress adjacent structures, resulting in acute

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myocardial ischemia, complete heart block, or right ventricle outflow tract obstruction, or can rupture into one of the heart's chambers, which results in aortocardiac shunting and leads to congestive heart failure with dyspnea, chest pain, bounding pulse, and 'machinery-type' murmur being the most frequent symptoms. Open-heart surgery with patch closure at both ends of the defect remains the mainstay therapy for ruptured sinus of Valsalva aneurysm (RSVA).

However, since the first report in 1992 by Hourihan et al. [4], successful RSVA transcatheter closures (TC) with different types of devices have been described, predominantly as single case reports and small series [5–13]. This method not only avoids sternotomy and extracorporeal circulation, especially in hemodynamically unstable patients, but allows also for shorter hospitalization with cost reduction [10]. In order to emphasize the percutaneous approach, its long-term observation is highly expected. To date, only a few such reports have been published [11,13]. We present our multicenter study with up to 11-year follow-up of TC of RSVA.

Methods

Patient characteristics

Retrospective analysis of in-hospital data, medium- and long-term follow-up of 23 elective Caucasian patients selected for percutaneous closure of RSVA between March 2007 and December 2017 in two tertiary centers in Poland and Ukraine was performed. There were 9 females and 14 males with a mean age of 39.9 ± 18.5 years (range 15–79 years) (Table 1).

Four patients were in New York Heart Association (NYHA) class IV, 11 patients in class III, and other patients in class II, all with continuous heart murmur in physical examination. Congenital RSVA was diagnosed in 18 patients; among whom was a patient with BAV who had undergone primary RSVA surgery one year before and was admitted with a defect recanalization (recurrent symptoms occurred after strenuous physical effort; No. 2). Five remaining patients had probably acquired RSVA after previous cardiac surgeries: tetralogy of Fallot complete repair (No. 3), mechanical aortic valve implantation (No. 11), left ventricular outflow tract obstruction relieve (LVOTO; No. 18), atrioventricular septal defect repair (No. 20), and coarctation of aorta repair with VSD closure (No. 22). Causative factor of SVA rupture was identified in five patients: strenuous physical effort in three, acute infection with high temperature in one, and chest trauma in another patient. The RSVA diagnosis was established after detailed clinical and echocardiographic examination, moreover, 13 patients had computed tomography performed before the procedure for better RSVA visualization, which is essential. Rupture of right- or non-coronary sinus into the right atrium in 17 patients and to the right ventricle in four patients as well as from the left coronary sinus to pulmonary artery in one patient and to the left atrium in another (No. 3, 20, respectively; both with acquired defects) were confirmed. None or trivial AR was present in all patients, but moderate in one patient (No. 18). All patients (or caregivers) were informed about both surgical and transcatheter treatment options and the latter method was preferred by all except patient 11, who was disqualified from surgery. The informed consent was obtained.

Procedure

The procedure was conducted under general anesthesia in 12 patients and under local anesthesia in 11 patients with two- or three-dimensional transesophageal echocardiography (TEE) and angiography guidance. After femoral vein and artery access completion (6–7 F sheath) intravenous heparin (50 IU/kg) and cefazolin were administered. Right and left heart pressures were measured and pulmonary to systemic flow ratio (Qp/Qs) calculated, followed by aortic root angiography. RSVA was measured at its aortic and rupture site in both TEE and angiography. The RSVA aortic orifice to coronary artery ostium distance was evaluated exclusively in TEE in 11 patients and in both TEE and coronary angiography in the remaining 12 patients. The distance was less than 5 mm only in one patient (No. 3). The defect was crossed with different types of catheters (mostly Judkins right coronary catheter) on a glide wire (Terumo Inc., Tokyo, Japan) and exchanged for a long 0.035″ standard guidewire. This wire was snared and exteriorized out of the femoral vein, which created an arteriovenous loop. Over such a loop, trans septal sheath was introduced from vein access through RSVA to the ascending aorta in order to enable the occluder deployment. However, retrograde arterial approach was used in one patient with acquired left coronary sinus to left atrium shunt (No. 20). Twenty one type I duct occluders were applied including nine Amplatzer (ADO I, AGA Medical Corp., Plymouth, MN, USA), five Cardi-O-Fix (Starway Medical Technology, Beijing, China), five HeartR (Lifetech Scientific, Shenzen, China), two MemoPart (Lepu Medical Technology, Shanghai, China) as well as one Nit-Occlud duct occluder (PFM Medical, Cologne, Germany). Moreover, two Amplatzer and one Lifetech muscular VSD occluders and one Amplatzer atrial septal occluder were applied. Overall 26 devices were used in 23 patients during a single primary session. Implants were selected according to RSVA morphology and deployed in the aortic RSVA orifice except four patients, in whom the device was deployed in the distal end of RSVA because of either RSVA anatomy or device displacement (No. 4, 15, 16, 23). Ductal occluders 1–7 mm larger than RVSA aortic orifice diameter were generally chosen. The balloon calibration was abandoned in all but two patients (No. 7, 15) in order to prevent further damage of fragile tissue around the RSVA. Angiography and TEE evaluation were repeated before and after releasing the device. Patient No. 21 had native coarctation of aorta stented during the same session.

Follow-up protocol

Follow-up data were collected during previously scheduled visits in out-patient clinic 1, 3, 6, 12 months after the procedure and annually thereafter [clinical examination, electrocardiogram (ECG), transthoracic echocardiography]. Aspirin 150 mg a day for 6 months was administered. Mean follow-up was 5.5 ± 3.5 years (range 1–11; in 10 patients >5 years).

Statistics

All continuous variables are expressed as mean values and standard deviation or median with range as appropriate, and discrete variables are presented as percentages. Univariate analysis was performed by the Student *t*-test. A *p*-value <0.05 was considered statistically significant. The data were analyzed with Statistica 13.3 software (StatSoft Inc.).

Results

In-hospital observation

Mean pulmonary artery pressure was 24.0 ± 7.9 mmHg (5–38 mmHg; in 8 patients >25 mmHg) and Qp/Qs ranged from 1.4 to 3.7 (median 2.2). The defect's mean aortic orifice diameter was 9.5 ± 3.3 mm (4–16 mm). Transcatheter closure of RSVA was successfully completed in 19/23 patients (82.6%) (Figs. 1 and 2).

In patient No. 3, with a 7 mm postsurgical left coronary sinus to pulmonary artery connection (after tetralogy of Fallot repair) and with the distance between left coronary artery orifice and

Table 1
Clinical in-hospital data, mid- and long-term outcome of patients in whom attempt of percutaneous closure of ruptured sinus of Valsalva aneurysm was performed.

Pt No.	Age [y]/sex	NYHA class before/at latest follow-up	Mean PA pressure [mmHg]	Qp/Qs	RSVA type	RSVA size [mm] aortic/rupture orifice	Device, size [mm]	Implantation success	Complications	Fluoroscopy duration [min]	Follow-up duration [y]	Follow-up
1	51/m	III/I	19	2.2	RCS-RVOT	10/12	ADO 14/12	+	Bigeminy, SVT	10	11	Uneventful
2	23/m	III/I	17	2	RCS-RA	5/5	ADO 10/8	+	-	16.4	10.9	Second RSVA closed with ADO 10/8 after 6 months, then 10 y observation uneventful
3	18/f	III/-	28	1.5	LCS-PA	7/3.8	ADO 8/6	–	Left coronary artery compression, occluder withdrawn, sent for surgery	34.9	-	-
4	41/m	II/I	22	2.2	RCS-RA	12/6	ADO 8/6 → ASO 6[a]	+	-	19	10.3	After 8 y recurrent RSVA closed with ADO 14/12, then 2 y observation uneventful
5	27/f	II/I	14	1.7	NCS-RA	4/4	ADO 8/6	+	-	17	10.6	After 4 y recurrent RSVA closed with ADO 10/8, then 6 y observation uneventful
6	15/m	II/I	20	1.6	RCS-RA	8/8	ADO 10/8	+	-	33	5	Uneventful
7	27/f	III/-	30	2.6	NCS-RA	13/8	ADO 14/12	+	-	10.6	/	Lost
8	39/m	II/I	30	1.9	NCS-RA	6/6	ADO 8/6 → ADO 12/10[b]	+	ADO 8/6 embolization[b]	35.2	7.5	Uneventful
9	49/m	III/I	37	2.3	NCS-RA	10/8	ADO 14/12	+	-	10	4	Uneventful
10	43/m	IV/III	21	2.2	RCS-RVOT	10/9	ADO 14/12	+	-	15	3	Uneventful, lost after 3 y (Crimea inhabitant)
11	72/f	IV/III	35	/	NCS-RV	15/7	ADO 16/14 + MVO 10[c]	+	Femoral AV fistula	48	7	Uneventful
12	59/m	III/I	31	3.7	NCS-RA	12/5.7	ADO 18/16	+	-	8.9	6.7	Uneventful
13	26/m	IV/II	/	/	NCS-RA	10/15	ADO 16/14	+	-	6.5	3.3	Uneventful
14	79/f	III/II	19	1.4	NCS-RA	10/7	ADO 12/10	+	Groin hematoma	9	6	Uneventful
15	63/m	III/-	20	2.1	NCS-RA	7/5	Nit-Occlud 11,5	–	Embolization, percutaneously removed, sent for surgery	31	-	-
16	56/f	III/III	19	2.3	NCS-RA	15/8	ADO 12/10	+	-	18	6	Uneventful
17	21/f	IV/I	34	3	NCS-RA	7/7	ADO 14/12	+	-	5	1	Uneventful
18	17/f	II/-	24	2.2	RCS-RA	8/6	ADO14/12	–	AR transient exacerbation, occluder withdrawn, sent for surgery	14	-	-
19	64/m	III/II	20	1.7	NCS-RA	8/5	ADO12/10	+	-	11	3	Uneventful
20	32/f	II/I	5	1.5	LCS-LA	4/3	MVO 4	+	-	13	1	Uneventful
21	28/m	II/II	25	3.7	RCS-RA	16/14	ADO 22/20	+	-	27	1	Uneventful
22	34/m	III/II	21	2.1	RCS-RV	10/10	MVO 14	+	-	10	1	Mild residual shunt
23	33/m	II/-	38	2.9	NCS-RA	10/8	ADO 14/12	–	Embolization, percutaneously removed, new onset of AR, sent for surgery	12	-	-

ADO, Amplatzer or Amplatzer-like type I duct occluder; AR, aortic regurgitation; ASO, Amplatzer septal occluder; AV, arteriovenous; f, female; LA, left atrium; LCS, left coronary sinus; m, male; MVO, muscular VSD occluder; NCS, noncoronary sinus; Nit-Occlud, Nit-Occlud duct occluder; PA, pulmonary artery; Qp/Qs, systemic to pulmonary flow ratio; NYHA, New York Heart Association; RA, right atrium; RCS, right coronary sinus; RSVA, ruptured sinus of Valsalva aneurysm; RV, right ventricle; RVOT, right ventricle outflow tract; SVT, supraventricular tachycardia; y, years; / - no data.

[a] ADO 8/6 unstable, retrieved on delivery cable, ASO 6 effective.

[b] ADO 8/6 embolized, percutaneously retrieved, ADO 12/10 effective.

[c] Both devices used simultaneously to close entrance and RSVA exit, respectively.

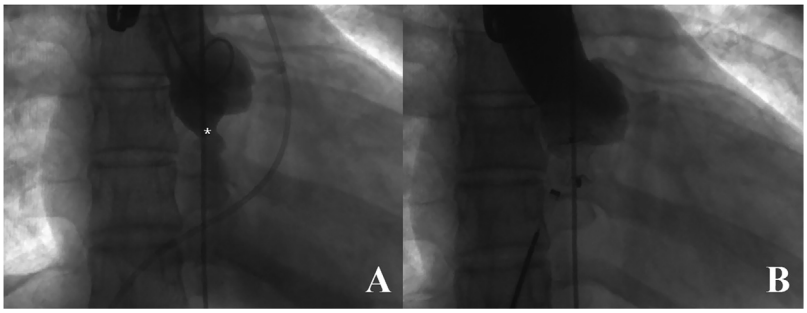

Fig. 1. Aortography. (A) Noncoronary sinus to right atrium ruptured sinus of Valsalva aneurysm (asterisk). (B) Defect closed with 14/12 HeartR duct occluder – no residual shunt (No. 17).

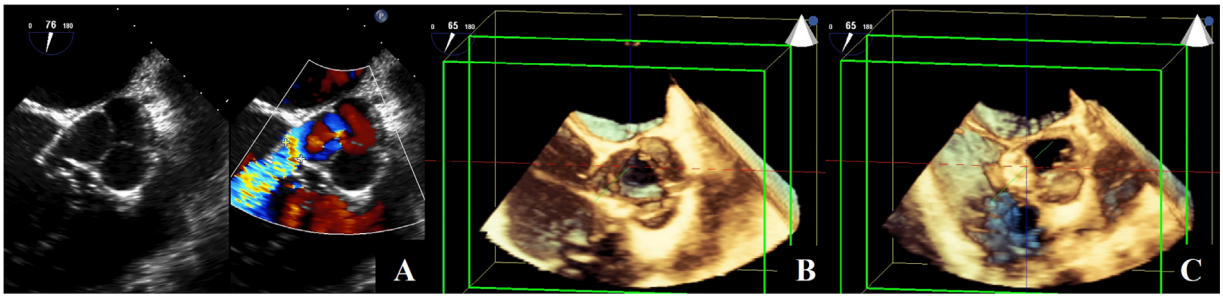

Fig. 2. Transesophageal echocardiography. (A) Noncoronary sinus to right atrium ruptured sinus of Valsalva aneurysm (RSVA). (B) Three-dimensional reconstruction, guidewire through RSVA. (C) RSVA closed with 14/12 Cardi-O-Fix duct occluder (No. 9).

RSVA opening of less than 5 mm in TEE, ST segment depression in ECG occurred immediately after only 1 mm oversized Amplatzer 8/6 duct occluder implantation (undoubtedly due to left coronary artery compression) and the device was withdrawn with ECG change resolution. In patient No. 18 after previous LVOTO surgery with moderate AR before the intervention, after HeartR 14/12 duct occluder deployment, an increase of AR was observed and the procedure was abandoned with AR regression (Fig. 3). Occluders' embolization occurred in 3 patients and in all of them it was possible to retrieve the implant percutaneously. In patient No. 8, an undersized Amplatzer 8/6 duct occluder which embolized to the pulmonary artery immediately after its release was retrieved with 6F bioptome and a bigger Cardi-O-Fix 12/10 duct occluder device was successfully implanted. In patients No. 23 and 15 (in whom previous balloon calibration was performed) MemoPart 14/12 duct occluder and NitOcclud 11.5 mm, respectively, embolized to pulmonary artery and were removed with lasso. In both of these patients, the device was implanted in the RSVA exit. Furthermore, in patient No. 23, the new onset of severe AR was observed after the device removal. Presumably due to the RSVA enlargement, the non-coronary aortic cusp was sucked into the RSVA mouth and eventually immobilized (during following RSVA surgery the aortic valve proved to be intact) (Fig. 4). All four patients with unsuccessful attempts at TC of RSVA were scheduled for elective cardiac surgery, which was successful in all of them.

In patient No. 4 Amplatzer 8/6 duct occluder was initially implanted in the distal RSVA orifice (6 mm), but it migrated through RSVA over the delivery cable to the right atrium, another attempt with Amplatzer 6 atrial septal occluder in the same position was successful. In a 72-year-old woman with iatrogenic RSVA (No. 11; after aortic valve replacement; with chronic aortic wall dissection and multiple comorbidities), Cardi-O-Fix 16/14 duct occluder was deployed in the aortic RSVA orifice; however, because of a significant residual leak on the edge of the device, the procedure was supplemented by Amplatzer 10 muscular VSD occluder implantation in the distal RSVA orifice, which finally resulted in the disappearance of the shunt. Muscular VSD occluder, which has symmetrical discs, was chosen in order to prevent its embolization.

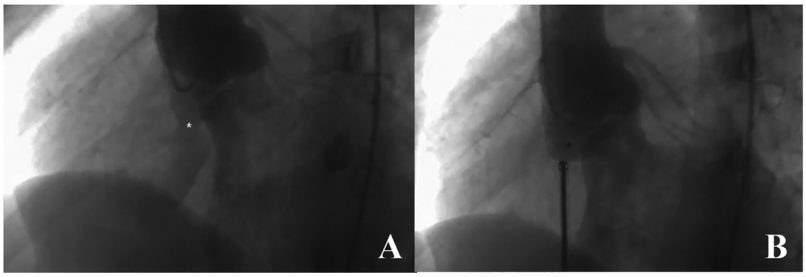

Fig. 3. Aortography. Right coronary sinus to right atrium ruptured sinus of Valsalva aneurysm (asterisk), mild aortic regurgitation. (B) Severe aortic regurgitation after 14/12 HeartR duct occluder deployment, the procedure was abandoned (No. 18).

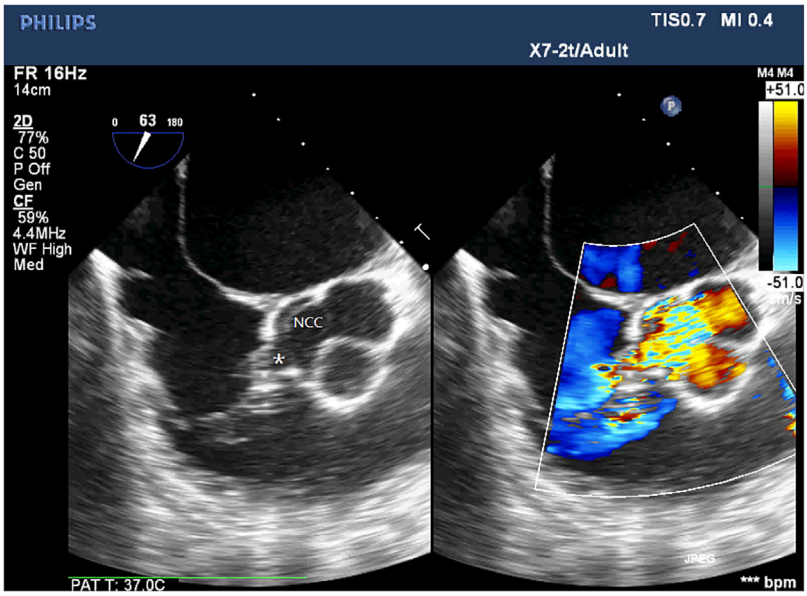

Fig. 4. Transesophageal echocardiography. Noncoronary sinus to right atrium ruptured sinus of Valsalva aneurysm (RSVA) (asterisk). Severe aortic regurgitation persisted after withdrawal of 14/12 MemoPart duct occluder. Noncoronary cusp (NCC) sucked into the RSVA and immobilized presumably because of the defect enlargement (No. 23).

Mean fluoroscopy and procedure time were 18.0 ± 11.0 (5–48) min and 103.0 ± 44.6 (35–195) min, respectively.

There was one patient with new onset of AR (unsuccessful case, No. 23) and no new AR or AR progression among successfully closed RSVA. Trivial in 5 patients, mild in one patient (No. 22), and significant in another one (No. 2), residual shunts were diagnosed with echocardiography in the post-procedural period. In the latter patient, a second RSVA was revealed after the primary procedure. All patients with trivial residual leak had complete RSVA closure confirmed at the one-month observation. One major complication occurred, femoral arteriovenous fistula, which required urgent vascular surgery (No. 11). Ventricular bigeminy and supraventricular tachycardia were found in one patient (No. 1) during in-hospital observations and after amiodarone administration they have yielded.

Follow-up

NYHA class had improved in all but two patients at the latest check-up, with most patients (10) in NYHA I class ($p < 0.05$) (Fig. 5). During the medium- and long-term observation, three patients needed percutaneous re-intervention because of another RSVA. In patient No. 2 (BAV, after previous RSVA surgery) a significant 5.6 mm residual shunt (second RSVA) was closed with another Amplatzer 10/8 duct occluder after 6 months, then the 10-year observation was uneventful. In a young woman (No. 5), subsequent de novo 5 mm non-coronary sinus to the right atrium shunt revealed itself in pregnancy during the fourth year of follow-up. After successful delivery by cesarean section (NYHA II class) it was electively closed during another session with Cardi-O-Fix 10/8 duct occluder without any problems (Fig. 6). During the following 6 years she was pregnant once again, but it was uneventful at that time. Augmented cardiac output as well as hormonal changes during pregnancy are considered to be a risk factor for RSVA [13]. In a man with arterial hypertension (No. 4), in whom the preceding device had been deployed in distal RSVA orifice, recurrent 6 mm right coronary sinus to right atrium leak (next to the previous one) was revealed after 8 years and was electively closed with the HeartR 14/12 duct occluder. Further observation of the other 15 patients was uneventful, mild residual shunt persisted in one patient (No. 22). Patient No. 7 was lost from observation. Neither erosion, late embolization, endocarditis, stroke, new AR, complete heart block, nor death have been observed during follow-up.

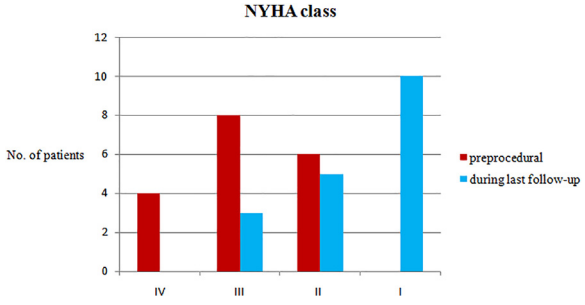

Fig. 5. New York Heart Association (NYHA) class: preprocedural and during last follow-up.

Discussion

RSVA was first described by Hope in 1839 [15] and although it usually occurs in adulthood, it was even described in a neonate [16]. SVA is more prevalent in Asians, hence all series of percutaneous closure of RSVA come from the Far East [5,6,8–13], despite our previous short-term observations [7]. To the best of our knowledge, this multicenter report is the only long-term follow-up of TC of RSVA among the European population.

Five of our patients (5/23, 21.7%) probably had an acquired SVA after previous cardiac surgeries. SVA rupture can occur spontaneously, after exertion, chest trauma, or even heart catheterization. Severe infection with high temperature (1 patient), strenuous effort (3 patients), chest trauma (1 patient), and pregnancy (1 patient) are suspected to be the causes of SVA rupture in this report.

Since 1957, urgent open-heart surgery under cardiopulmonary bypass remains the first method of RSVA treatment [17]. It carries low mortality, an up to 95% survival rate after 20 years and there was no fistula recurrence in patients in whom patch closure at both defects' ends was performed [3,18]. The first transcatheter closure of an acquired RSVA was accomplished by Hourihan with a double

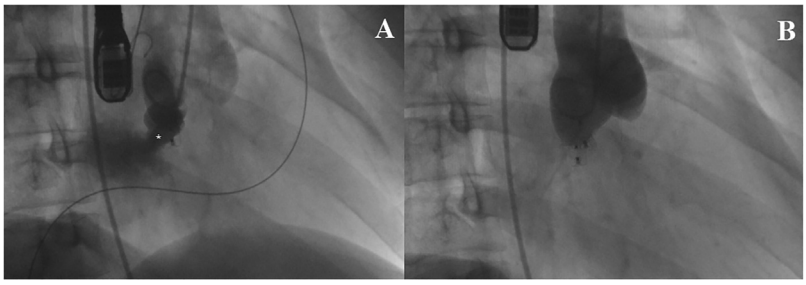

Fig. 6. Aortography. (A) Recurrent noncoronary sinus to right atrium ruptured sinus of Valsalva aneurysm (RSVA) (asterisk) 4 years after primary transcatheter closure with 8/6 Amplatzer Duct Occluder I. (B) Defect closed with 10/8 Cardi-O-Fix duct occluder (No. 5). Recurrent RSVA occurred during pregnancy and was closed after delivery with cesarean section.

umbrella device in 1992 [4]. Since then, more than 200 procedures of TC of RSVA have been reported in the literature, mostly with type I duct occluders [19].

Procedure

Three-dimensional TEE guidance with color Doppler, which we used during the 12 procedures, provides excellent RSVA morphology and the assessment of AR progression or a residual shunt. However, computed tomography can be vital [20], providing operators with essential information about defect anatomy as well as giving opportunity for novel three-dimensional image fusion during the procedure. Two-dimensional TEE can effectively evaluate coronary arteries to RSVA opening proximity – we used this method exclusively in 11 patients. In one of them, with a rare left coronary sinus to pulmonary artery rupture (after tetralogy of Fallot surgery), the procedure was abandoned because of ECG changes presumably due to the left coronary artery compression with only slightly oversized Amplatzer duct occluder. It suggests that even avoiding oversized duct occluders in patients with proximity of coronary artery to RSVA opening, coronary compression is a possible and unpredictable risk. Although balloon RSVA calibration is helpful in selecting the proper device [5], we avoided it in all but two patients. We believe that this can cause further damage to a fragile tissue around the defect. Such a mechanism could have happened in one of our patients – even though we used the balloon calibration, the NitOcclud duct occluder turned out to be undersized and embolized to pulmonary artery.

Different types of occluders were used in previous reports, with duct and ventricular septal occluders being applied most commonly. Rashkind double umbrella [4,5,21], coils [6,22,23], atrial septal [5,7,24], and patent foramen ovale [25] occluders as well as vascular plugs [26,27] were also reported. We used 26 devices in 23 patients overall during a single session: 22 duct, 3 muscular VSD, and 1 atrial septal occluder. The size of the duct devices was chosen due to RSVA shape. The idea was to implant the device in the aortic RSVA orifice rather than in its tunnel in order to prevent embolization. In cone-shaped defects, the duct occluders were generally chosen to be more oversized than aortic RSVA orifice in comparison to tunnel-shaped ones. In one patient with 16 mm RSVA, we successfully used a 22/20 duct occluder, which is in contradiction to the study by Zhang et al. [28]; that such big RSVA is not applicable for TC.

Our TC of the RSVA success rate was 82.6% (19/23) but even a 100% success rate was described by Sivadasanpillai et al. (in 7 patients) [9]. From our point of view, the most important points are to avoid the new onset of AR or AR progression and to carefully select the device in order to avoid embolization. In our opinion patients with RSVA and moderate or severe AR should not be treated percutaneously.

Follow-up

According to Kuriakose et al. [29] recurrent RSVAs were described after surgical closure, but never after TC. However, data on long-term outcomes of TC approach are limited. In our material during up to 11-year observation we had two cases of late recurrent RSVA – 4 and 8 years after first intervention (2/19 patients; 10.5%). The second percutaneous RSVA closure was effective in both patients.

Among the four patients in whom we closed the RSVA exit, one needed re-intervention because of a recurrent shunt, in another two patients the device embolized, and only in one patient both the intervention and long-term observation was uneventful. It confirms the thesis of Chang et al. [6] stating that the retention disc should be deployed in the SVA aortic orifice and not in the aneurysm itself to avoid progressive RSVA dilatation or defect recurrence.

No new AR nor AR progressions after successful TC of RSVA were observed in our group. This specific result is in common with other reports [19] and underlines the superiority of RSVA TC over surgery.

Our study confirms the high utility of original ADO I and other type I duct occluders in the percutaneous closure of RSVA. The incidence of RSVA in Central and Eastern European populations remains unclear.

Study limitations

This is a multicenter, retrospective, but non-randomized study and the device selection depended on the operator's choice.

Conclusions

Percutaneous closure of RSVA is a safe and effective method of treatment with good clinical outcome. However, recurrent shunts after TC of RSVA are possible and can be treated successfully with another transcatheter intervention. Cautious follow-up is mandatory. In appropriately selected patients, percutaneous approach could replace surgery and become the method of choice.

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None.

Conflict of interest

None.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.jjcc.2019.03.012.

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