Percutaneous closure of perimembranous ventricular septal defects with Amplatzer occluders – a single centre experience

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Abstract

Background: Perimembranous ventricular septal defect (VSD) is the most common congenital heart defect. Percutaneous transcatheter closure of VSD is one of the greatest challenges in interventional cardiology.

Aim: Presentation of our experience in transcatheter closure of perimembranous VSD.

Methods: Eighteen patients were treated. Nine patients (group I) had VSD closed with implant Amplatzer Perimembranous VSD Occluder (PMVSDO) whereas the other nine had VSD closed with Muscular VSD Occluder (MVSDO). In the second group the presence of at least 4 mm rim from aortic valve was mandatory to undergo the procedure. Average patients age was 17.1 (3.2-40) years, defect diameter – 4.7 (4-8) mm and Qp/Qs ratio – 1.84 (1.5-4.6). Perimembranous interventricular septum aneurysm was noted in 5 cases. Only patients who had hemodynamically important defect (Qp/Qs ratio >1.5) were selected for interventional VSD closure. Patients with subarterial VSDs, pulmonary hypertension or/and aortic regurgitation were excluded. Ventricular septal defect closure was performed with standard techniques.

Results: Procedures were completed successfully in 16 of 18 patients. There was no early or late implant embolisation. After the procedure in every case complete closure or important reduction of the shunt was observed. In the group I there was a trend towards more frequent occurrence of rhythm disturbances (p=0,08), including two cases with severe arrhythmias occurring during VSD closure requiring abandoning of procedure. In other 2 cases (patients age 12 and 14 years) in the second week after PMVSDO placement complete atrio-ventricular block occurred. In one patient sinus rhythm was restored after steroid treatment whereas another patient required pacemaker implantation. In group II mild nonprogressive tricuspid regurgitation was noted in 3 patients.

Conclusions: Percutaneous perimembranous VSD closure is an interesting alternative to surgical treatment. In selected cases closure of the defect with muscular VSD implant is effective and safe.

Key words: perimembranous ventricular septal defects, transcatheter closure, interventional cardiology

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Introduction

Perimembranous ventricular septal defects (pmVSD) occur in the upper portion of the ventricular septum and are the most common form of this congenital malformation (approximately 70% of cases). They may extend into the inflow, outflow or apical part of the ventricular septum. Thus they are usually localised close to the tricuspid and aortic valves. These anatomical circumstances made it difficult to design an appropriate implant that would not cause any adverse results after VSD closure, including aortic insufficiency (AI). Introduction of special implantable devices dedicated to occlusion of ventricular defects such as the Amplatzer Perimembranous VSD Occluder (PMVSDO) [1] and Amplatzer Muscular VSD Occluder (MVSDO) at the beginning of this decade was a milestone in the invasive treatment of these malformations [2] (Figure 1 A, B). At first, interventional cardiologists showed great interest in using them in daily clinical practice [3]. Accumulating experience however tempered initial enthusiasm [4, 5].

The aim of this study was to present a single centre experience with transluminal percutaneous closure of pmVSD.

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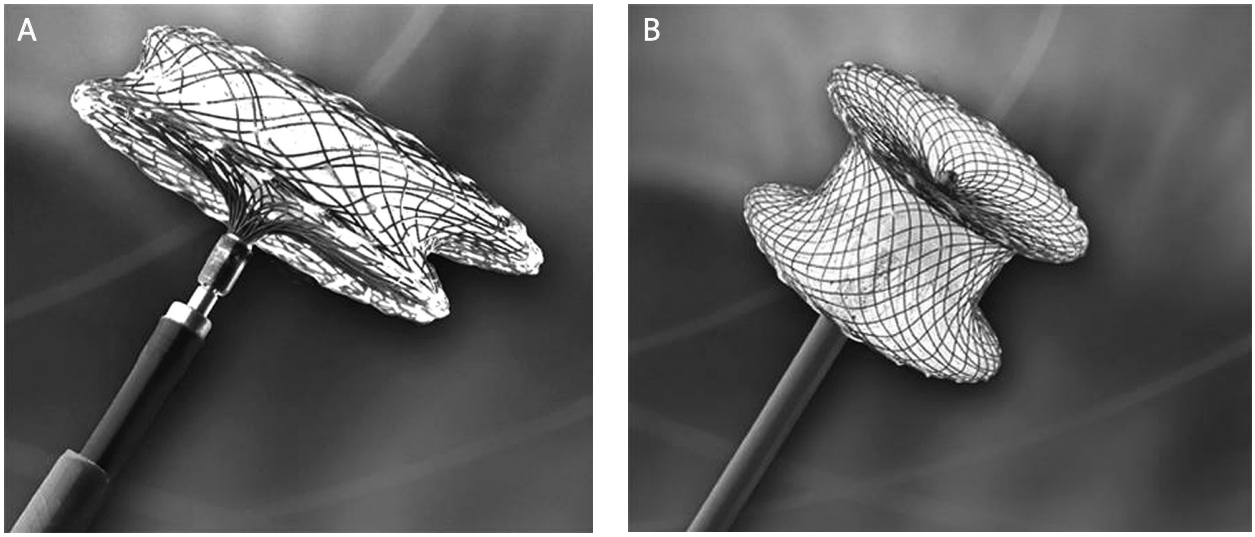

Figure 1. A – Amplatzer Perimembranous VSD Occluder, **B** – Amplatzer Muscular VSD Occluder

Methods

Data on treated patients are outlined in Tables I and II. Procedures were performed between 2002 and 2007.

In 9 patients (group I – see Table I) PMVSDO were implanted to occlude pmVSD. Group II included 9 patients with pmVSD closed with an MVSDO device – see Table II. Initially, pmVSD were occluded using MVSDO devices as no asymmetric implants were commercially available. Only patients with preserved aortic rim, defined as a distance between the upper border of a given defect and the aortic valve of at least 4 mm, were selected for MVSDO implantation. The mean age of patients in groups I and II was 15.9±13.3 (3.2-38) years and 18.5±13.6 (7-40) years, respectively. In group I, mean diameter of the defect was 5.0±0.8 (4-6) mm, Qp/Qs 2.0±1.0 (1.5-4.6), aortic rim size 4.7±1.0 (2-9) mm, fluoroscopy time 26±11, while in group II the mean VSD size was 5.0±0.7 (4-8) mm, Qp/Qs 1.63±0.1 (1.5-1.8), aortic rim 6.6±2.5 (4-12) mm and fluoroscopy time 24±12, respectively. In both groups, in 5 patients aneurysm of the perimembranous ventricular septum was revealed. The implant size was selected to be equal to or higher by 2 to 4 mm than pmVSD diameter calculated in 2D and colour doppler echocardiography.

Only patients with significant defects (pulmonary to systemic flow ratio Qp/Qs exceeding 1.5) were qualified for

Table I. Detailed demographic, clinical and procedural characteristics of patients who underwent PMVSDO implantation

Pt no.	Age [years]	Body mass [kg]	VSD diameter [mm]	Qp/Qs	Distance to aortic valve [mm]	Aneu-rysm	PMVSDO [mm]	Fluoro-scopy time [min]	Efficacy of implan-tation	Follow-up [years]	Remarks
1	23	51	4	1.8	2	+	12	42	yes	4.8	TI
2	7	29	4	1.5	8	+	–	37	no	4.8	complete AV block (sheath)
3	10	45	6	1.8	9	+	10	22	yes	4.6	AV block, pacemaker
4	5	19	5.5	1.7	5	0	8	14	yes	4.6	
5	7	19	6	1.8	6	0	8	31	no	4.5	VF after implantation, implant withdrawal
6	36	57	5	1.9	4	0	8	8	yes	3.6	
7	14	50	5	1.8	3	0	8	23	yes	3.3	AV block steroids/effective
8	38	101	5	1.5	2	+	8	22	yes	2.7	AI
9	3.2	14	4	4.6	4	+	6	22	yes	4.8	

Abbreviations: PMVSDO – Amplatzer Perimembranous VSD Occluder, VSD diameter – diameter of VSD calculated in TEE, TI – tricuspid valve regurgitation, AI – aortic valve regurgitation, aneurysm – ventricular septum aneurysm: + present 0 – absent, yes – successful implantation, no – failed implantation, AV – atrioventricular , VF – ventricular fibrillation

Table II. Detailed demographic, clinical and procedural characteristics of patients who underwent MVSDO implantation

Pt no.	Age [years]	Body mass [kg]	VSD diameter [mm]	Qp/Qs	Distance to aortic valve [mm]	Aneu-rysm	MVSDO [mm]	Fluoro-scopy time [min]	Efficacy of implan-tation	Follow-up [years]	Remarks
1	9.3	30	4	1.7	5	0	6	23	yes	5.3	TI
2	7	29	4	1.8	6	+	6	29	yes	5.2	–
3	8	22	4.5	1.6	8	0	6	49	yes	4.6	TI
4	20	48	5	1.6	12	0	8	17	yes	4.3	TI
5	7	19	4.5+3.5	1.6	4	+	8	19	yes*	2.9	–
6	40	56	5	1.8	6	+	6	8	yes	2.2	–
7	8	19	4	1.5	5	0	4	16	yes	1.9	–
8	32	71	6	1.6	5	+	10	22	yes*	1.4	–
9	35	54	4.5	1.5	8	+	6	31	yes*	0.8	–

*Abbreviations: MVSDO – Amplatzer Muscular VSD Occluder, * implantation from arterial side, other abbreviations see Table I*

the procedures. Individuals with persistent pulmonary hypertension and documented significant AI were excluded. The techniques of defect occlusion were standardised and were described in detail previously [1, 2, 6]. All procedures were performed following defect exploration from the left ventricular side. Then a guidewire was formed as an arterio-venous loop to create a scaffold that was mandatory for intravenous introduction of a long vascular sheath followed by device implantation. If not possible (due to kinking of the vascular sheath), an attempt at MVSDO implantation from the arterial side was performed.

Statistical analysis

In both groups, clinical data, procedure efficacy and rate of complications during and after the procedure were compared. To test for significant differences regarding clinical data and procedure efficacy Student's t-test was used, and for the complication rate exact Fisher's test was adopted. The results are expressed as means ±SD. AP value <0.05 was considered statistically significant.

Results

Clinical data (Tables I and II) did not differ significantly between the groups except for the aortic rim size, which was markedly bigger in group II ($p=0.05$). The procedure was successful in 16 of 18 patients. No cases of implant embolization (either early or late) or residual shunt after the procedure were noted.

In group I, the procedure was successful in 7 patients. In this group, PMVSDO implants of size ranging from 6 to 12 mm were used (Figure 2 A, B, C). In the first case (patient no. 1 in Table I) the intension of the operator was to occlude the mouth of the aneurysm so a relatively large size of occluder

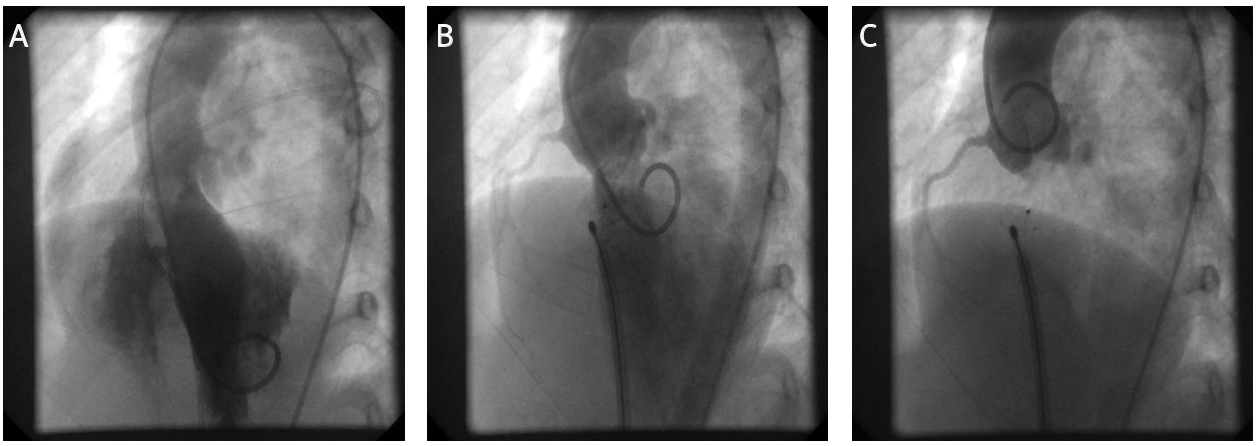

Figure 2. A – Left-sided ventriculography prior to procedure shows perimembranous VSD (pmVSD), **B** – Amplatzer Perimembranous VSD Occluder (PMVSDO) connected with the delivery system, occluding VSD (left-sided ventriculography), **C** – angiography of the aorta following PMVSDO disconnection showing competent aortic valve

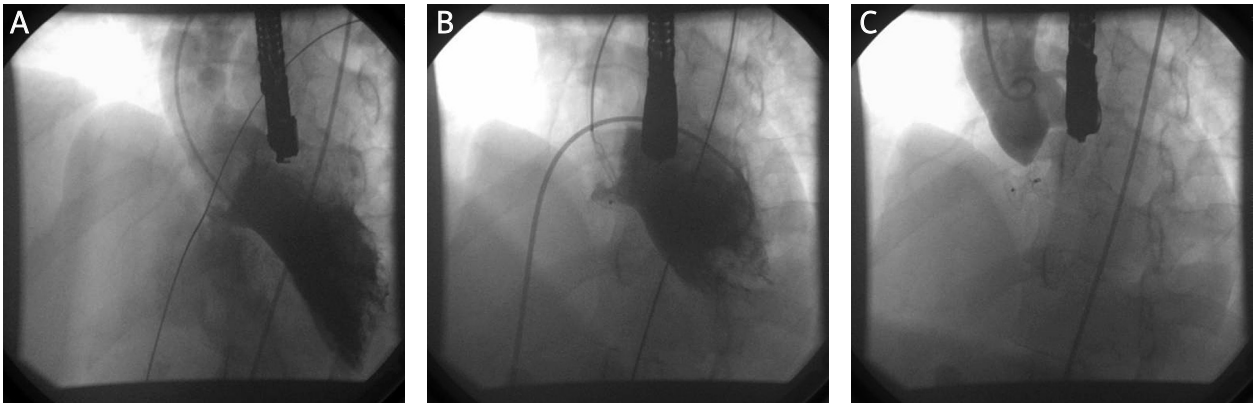

Figure 3. A – Left-sided ventriculography before procedure shows perimembranous VSD (pmVSD) accompanied by aneurysm and with 5 mm aortic rim, **B** – Amplatzer Muscular VSD Occluder (MVSDO) implanted from the arterial side still connected with the delivery system closing VSD (left-sided ventriculography done with a pig-tail catheter introduced through the foramen ovale), **C** – angiography of the aorta following PMVSDO disconnection showing competent aortic valve

was selected. In another case (patient no. 2 in Table I), the procedure was discontinued due to complete atrioventricular block that developed during introduction of a long vascular sheath for PMVSDO implantation. After sheath removal, the heart block commenced. In one case (patient no. 5 in Table I) ventricular tachycardia occurred immediately after release of both implant discs. Arrhythmia was terminated with high energy shock and the vascular sheath was removed without disconnecting it from the delivery PMVSDO system. In this case the procedure was not completed either.

Two serious adverse events were observed in group I following device implantation. During the first postoperative week one child (patient no. 7, Table I) developed first 2nd degree and then 3rd degree AV block. Block commenced after one-week therapy with corticosteroids. In another child (patient no. 3, Table I) symptomatic complete AV block occurred in the second postoperative week (manifested as a loss of consciousness) necessitating implementation of a temporary pacing wire. With negative response to corticosteroids implantation of a permanent DDD pacemaker was necessary. In one case (patient no. 8, Table I) mild and non-progressing in time AI was observed and another patient (with a significantly oversized implant) (patient no. 1, Table I) developed moderate tricuspid valve regurgitation that remained stable during follow-up.

In group II, MVSDO devices of 4 to 10 mm size were implanted (Figure 3 A, B, C). They were placed from the venous side in 6 children and from the arterial aspect in 3 patients (in cases no. 5, 8 and 9, Table II). The arterial approach was necessary in cases when, as mentioned before, kinking of the vascular sheath occurred. No arrhythmia or conduction abnormalities were noted (either during the procedure or throughout follow-up). In three cases (patients no. 1, 3 and 4, Table II) immediately after the procedure mild but non-progressing tricuspid valve incompetence was observed.

Serious conduction disturbances were insignificantly more frequent in group (p=0.08).

Discussion

Percutaneous occlusion of pmVSD is a real challenge for interventional cardiologists. These procedures are considered technically demanding, which was true also in our series, as evidenced especially by the relatively long mean fluoroscopy time (26 minutes in group I and 24 minutes in group II). Ventricular septal defects are commonly accompanied by aneurysms and such lesions represent an anatomical form of the defect better suited to transluminal treatment. Haemodynamic criteria used to select patients for transluminal closure are usually the same as for surgery. In our series indications were consistent with the standard recommendations for occlusion of left-right shunts. The pulmonary to systemic flow rate (Qp/Qs) exceeded 1.5 in all patients. Nowadays, due to many potential complications associated with these procedures, we (sharing the point of view of many others) believe that these criteria should be more stringent (Qp/Qs >2.0 and both left atrial and left ventricular enlargement).

Asymmetrical implants are dedicated to occluding perimembranous VSDs only. The PMVSDO Amplatzer is specially designed with a left-sided disc having a small upper retention flange (0.5 mm in length) that enables its use even in cases of residual rim adjacent to the aortic valve (Figure 1 A). It prevents iatrogenic IA. Our experience, consistent with observations reported by others [7-9], indicates that this device is as effective as promised by its designer (Dr Amplatz).

Theoretically, similarly effective may be implants with symmetrical disc design dedicated to percutaneous defect closure of the muscular portion of the ventricular septum. A requirement in this case is the presence of a rim of at least 4 mm at the aortic side. The MVSDO devices are equipped

with 4 mm retention flanges, so their employment in patients with a smaller aortic rim might result in AI. Our findings published earlier support such a hypothesis [6]. On the other hand, the use of these implants is associated with an increased risk of tricuspid valve incompetence that is linked to cardiac anatomy. We observed 3 cases of regurgitation in 9 patients, although none was haemodynamically significant and no clinical progression in time was observed during follow-up.

The most serious adverse events related to the use of PMVSDO include conduction and/or rhythm disturbances. In our group they were observed in 4 of 9 patients with a percutaneous VSD closure attempt. In 2 cases they occurred during device implantation leading to procedural failure. Another 2 patients developed such complications 1 to 2 weeks post procedure, already after hospital discharge. In one case (a 15-year old boy) conduction disturbances commenced after corticosteroids [10], but in the other (a 12-year old girl) corticosteroid therapy failed and the patient required permanent pacemaker implantation. In the latter case, the pacemaker was active only for first three months, then AV conduction was restored with persisting residual first degree AV block and RBBB, as reported earlier [11]. Our findings are not consistent with those of Buttera et al. [12], who noted cases of high degree AV block among children after PMVSDO implantation only in the subgroup of children below 6 years of age.

The nature of conduction disturbances following the use of an asymmetrical Amplatzer device needs to be clarified. Compression by the implant discs, local oedema or allergic reaction followed by fibrosis are taken into consideration as possible explanations. The incidence of such complications reported by various authors ranges between 0 and 22,2% [6-8, 13, D. Predescu – verbal report]. Of note, conduction blocks after surgical correction are less prevalent (0.7-2%) and they are observed mainly in the early period, during hospital stay [3-5, 14].

The previously mentioned facts as well as commercial unavailability of PMVSDO in the past forced us to occlude pmVSD with Amplatzer devices designed for muscular ventricular septal defects (group II). No cases of arrhythmia or conduction disturbances were seen in this group, indicating that employment of these implants is efficient and safe when their use complies with appropriate indications. It seems that different MVSDO design (longer 7 mm disc connecting part (talia), contrasting with 1.5 mm in PMVSDO) (Figure 1 A, B) may contribute to the observed complications. It may prevent compression of the adjacent bundle branch system by PMVSDO discs (only in the lower portion of the defect).

To conclude, currently we perform transluminal and percutaneous occlusion of pmVSD only in adult patients, only after informing patients in detail about the risk of potential complications and obtaining consent. It seems mandatory to monitor patients using telemetric devices for at least one month. In consequence, the number of patients meeting criteria for pmVSD closure is limited. In our opinion (shared commonly by other authors) a PMVSDO implant device requires significant design modifications that may enable expanded clinical use in the future. Currently the manufacturer is increasing availability of different PMVSDO sizes (every 1 mm instead of 2 mm as in the past) and recommends using the following formula to choose the appropriate size of the device:

Device size = root of defect diameter in the narrowest and the largest portion ratio (pmVSD usually has an oval shape). This equation is intended to decrease the use of too large implants, which likely contributed at least partially to the previously described complications.

A limitation of this study is the small number of included patients. It would be useful to verify our findings in a larger group of patients undergoing pmVSD occlusion with the two methods.

Conclusions

Transluminal occlusion of perimembranous ventricular septal defects is an interesting alternative to surgery. In carefully selected patients use of implants indicated primarily for occluding congenital muscular VSD seems a useful therapeutic approach.

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Przezskórne zamykanie okołobłoniastych ubytków międzykomorowych z zastosowaniem korków Amplatzer – doświadczenia własne

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Streszczenie

Wstęp: Okołobłoniaste ubytki międzykomorowe (VSD) są najczęściej występującą wadą serca. Przezcewnikowe ich zamykanie stanowi jedno z największych wyzwań kardiologii interwencyjnej.

Cel: Przedstawienie doświadczeń własnych na bazie przeprowadzonych 18 zabiegów tego typu.

Materiał i metody: Chorych podzielono na tych, u których VSD zamykano za pomocą implantu Amplatzer Perimembranous VSD Occluder (PMVSDO) – grupa I (n=9), oraz tych, u których w tym celu zastosowano Muscular VSD Occluder (MVSDO) – grupa II (n=9). U tych ostatnich obligatoryjna była obecność co najmniej 4-milimetrowego rąbka od strony zastawki aorty. Średni wiek wynosił 17,1 roku (3,2–40 lat), średnica ubytku 4,7 (4–8) mm, a stosunek przepływu płucnego do systemowego (Qp/Qs) 1,84 (1,5–4,6). Tętniak okołobłoniastej części przegrody międzykomorowej występował w 5 przypadkach. Do zamykania VSD kwalifikowano jedynie tych chorych, którzy mieli istotny hemodynamicznie ubytek (Qp/Qs >1,5). Wyłączano chorych z VSD podtętniczymi, utrwalonym nadciśnieniem płucnym oraz z niedomykalnością aortalną. Techniki zamykania ubytku były standardowe.

Wyniki: Zabieg ukończono z powodzeniem u 16 z 18 chorych. W ani jednym przypadku nie wystąpiła embolizacja implantu do układu krążenia (ani wczesna, ani późna). Po zabiegu u wszystkich stwierdzono szczelne zamknięcie VSD. W grupie I obserwowano tendencję do częstszego występowania istotnych zaburzeń rytmu serca (p=0,08). Podczas 2 zabiegów doszło do incydentów poważnych arytmii, co było przyczyną odstąpienia od ich ukończenia. U 2 kolejnych chorych (w wieku 12 i 14 lat) w 2. tygodniu po implantacji PMVSDO obserwowano całkowity blok przedsionkowo-komorowy, który u jednego chorego ustąpił po sterydoterapii, a u drugiego był powodem założenia stałego rozrusznika serca. W grupie II nie obserwowano żadnych poważnych komplikacji, u 3 chorych występowała niewielka, nienarastająca niedomykalność trójdzielna.

Wnioski: Przenaczyniowe zamykanie okołobłoniastych ubytków międzykomorowych jest interesującą alternatywą dla leczenia kardiochirurgicznego. W szczególnych, wyselekcjonowanych przypadkach dobrą opcją terapeutyczną wydaje się zastosowanie implantów przeznaczonych wyjściowo do zamykania wrodzonych mięśniowych VSD.

Słowa kluczowe: okłobłoniasty ubytek międzykomorowy, kardiologia interwencyjna

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