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PEDIATRIC AND CONGENITAL HEART DISEASE

Original Studies

Percutaneous Occlusion of Vascular Malformations in Pediatric and Adult Patients: 20-Year Experience of a Single Center

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Objective: A case series on different vascular malformations (VM) treated with percutaneous occlusion in children and adults is presented. Background: Percutaneous occlusion is usually the preferred treatment method for VM. Previous series have mostly focused on single types of devices and/or VM. Methods: Retrospective analysis of all patients who underwent percutaneous occlusion of VM in a single center, from 1995 to 2014, excluding patent ductus arteriosus. Clinical and angiographic data, procedural details, implanted devices, and complications were assessed. Procedural success was defined as effective device deployment with none or minimal residual flow. Predictors of procedural failure and complications were determined by multivariate analysis. Results: A total of 123 VM were intervened in 47 patients with median age of 12 years (25 days–76 years). The VM included 55 pulmonary arteriovenous fistulae, 39 aortopulmonary collaterals, 10 systemic venovenous collaterals, 8 peripheral arteriovenous fistulae, 5 Blalock-Taussig shunts, 4 coronary fistulae, and 2 Fontan fenestrations. The 143 devices used included 80 vascular plugs, 38 coils, 22 duct occluders, and 3 foramen ovale or atrial septal defect occluders. Median vessel size was 4.5 (2.0–16.0) mm and device/vessel size ratio was 1.4 (1.1–2.0). Successful occlusion was achieved in 118 (95.9%) VM, including three reinterventions. Four (3.3%) clinically relevant complications occurred, without permanent sequelae. Lower body weight was independently associated with procedural failure and complications. Conclusion: To our knowledge, this is the largest series on different VM occluded percutaneously in children and adults, excluding patent ductus arteriosus. Percutaneous occlusion was effective and safe, using different devices. © 2015 Wiley Periodicals, Inc.

Key words: arteriovenous fistula; arteriovenous malformation closure; coil/device/transcatheter embolization; innovation; interventional devices; pediatric intervention

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INTRODUCTION

Vascular malformations (VM) are a diverse group of cardiovascular disorders [1,2]. Percutaneous occlusion of anomalous blood vessels was first reported almost 50 years ago in a patient with patent ductus arteriosus [3]. In parallel with the ongoing developments in technology, different devices are now available in the catheterization laboratory armamentarium, including different vascular plugs, coils, duct occluders, among others [4,5]. In addition, increasing expertise has allowed improvements in the technique of VM occlusion [6]. Therefore, a variety of arterial and venous VM are currently closed percutaneously in many centers and this is usually the preferred treatment method if technically feasible [7–9].

Patent ductus arteriosus is by far the most common VM, with extensive literature reporting results of its percutaneous closure [6,7]. The largest series on percutaneous occlusion of other VM in pediatric and adult patients are mostly focused on a single type of device or a single VM [5,8–14]. In our opinion, this may represent a shortcoming because different devices may be adequate according to specific vessel characteristics and in clinical practice a large variety of VM require treatment [4,7,8]. Several factors may influence the effectiveness and safety of percutaneous occlusion of VM and the predictors of adverse outcome have not been completely addressed in previous studies [7,8].

We report, to the best of our knowledge, the largest series on effectiveness and safety of percutaneous closure of different arterial and venous VM in pediatric and adult patients, excluding patent ductus arteriosus. The predictors of procedural failure and complications were analyzed.

METHODS

Patients and Data Collection

The institutional ethics committee approved the study protocol. All cases of pediatric and adult patients that underwent percutaneous occlusion of VM in our center in the last 20 years, from January 1995 to December 2014, were retrospectively analyzed. The cases of percutaneous closure of patent ductus arteriosus were excluded considering the robust data already published on effectiveness and safety of its percutaneous occlusion [6,7]. Demographic, clinical, and angiographic data, procedural details, implanted devices, and complications were collected from a systematic registry carried out since 1995, and were confirmed using the clinical records. The VM features and the angiographic result following intervention were characterized by reviewing the original angiograms.

Definitions

The VM were classified as arterial or venous according to the afferent segment. The diameter of the VM was measured at the planned site for device deployment and was approximated to the closest 0.5 mm. The device size to vessel size ratio was calculated for all VM.

Procedural success was defined as effective device deployment with none or minimal residual flow, assessed by angiography during the procedure.

The assessed complications included death, stroke, myocardial ischemia, arrhythmia, device malposition or embolization, vascular complications (occlusion, tear or dissection, and pseudoaneurism or arteriovenous fistula formation), hemolysis secondary to incomplete VM occlusion, any bleeding requiring transfusion and renal failure, occurring during hospital stay or after discharge [15,16]. Complication severity was graded from 1 to 5 according to the CHARM score [17]. Adverse events were considered clinically relevant if they were at least moderate (grade 3), including those potentially life-threatening if not treated by medication or by procedural intervention, or those needing monitoring in the intensive care unit [17].

Statistical Analysis

Discrete data are presented as frequency (percentage), whereas continuous variables are presented as median (minimum-maximum). Procedural success and complication rates were calculated by indexing to the number of intervened VM. Predictors of procedural failure were determined by univariate analysis (considering all clinical and angiographic data, procedural details, and implanted devices) using the chi-square and Mann–Whitney tests, when appropriate, and by multivariate logistic regression analysis. When the Pearson correlation coefficient between two continuous variables was >0.60, only the variable judged to be clinically more important was entered in the multivariate model in order to avoid multicollinearity. Predictors of complications (of any grade of severity) were determined using the same methodology. The level of significance considered was $\alpha = 0.05$. Data were analyzed using the software Statistical Package for the Social Science for Windows, version 20.0 (SPSS Inc, Chicago IL).

RESULTS

A total of 123 VM were intervened in 47 patients, of which 32 (68.1%) were under 18 years. Clinical data is presented in Table I. A total of 72 procedures were performed, including reinterventions, as specified below. Four experienced interventionists (two pediatric cardiologists and two adult cardiologists) were

responsible for all procedures throughout the analyzed period. In pediatric cases the procedure was performed by a pediatric cardiologist; in adult cases it was performed by an adult cardiologist in collaboration with a pediatric cardiologist. All followed the same catheterization and occlusion protocol, with no preferences regarding technique or tools.

An antiplatelet agent was started 24 hr before the procedure. Catheterization was performed under general anesthesia in pediatric patients (50 procedures, 69.4%) and on conscious sedation in adult patients. After obtaining the vascular access, antibiotic prophylaxis and a bolus of 100 IU/kg of unfractionated heparin were administered, and full anticoagulation was maintained throughout the procedure (2.5× activated clotting time). The VM was assessed by selective angiography; in 56.9% of cases a balloon test occlusion was performed. The intervened VM are detailed in Table II.

During the studied period there was a remarkable development of new and more suitable devices for vascular occlusion (Table III). From 1995 to 1998, coils (Flipper detachable embolization coil, Cook Inc., IN) were the only devices available for percutaneous embolization in our center (Fig. 1). Since the introduction of the Amplatzer Duct Occluder (AGA Medical Corp., MN) in 1998, this device was preferred over coils in VM sized over 4 mm (avoiding the use of multiple coils), particularly if the VM had high flow velocity, despite its off-label use (Fig. 2). In 2003, plugs became available in our center and have been the preferred devices. Since then, in our institutional protocol, VM with a diameter up to 14 mm were preferentially closed with a device of the Amplatzer Vascular Plug (AVP) family (AGA Medical Corp., MN) (Fig. 3, Supporting Information Videos 1 and 2) and the use of coils was limited to small VM (usually up to 4 mm). During the studied period, VM over 14 mm of diameter were closed with Amplatzer Septal Occluder or Amplatzer PFO Occluder devices (AGA Medical Corp., MN), introduced in 1998 and 2000, respectively. The 143 implanted devices, which were selected according to the VM size and flow, included 80 of the AVP family, 38 Flipper detachable embolization coils, 22 of the Amplatzer Duct Occluder family, and 3 Amplatzer PFO Occluders or Amplatzer Septal Occluder (Table III).

Angiography was performed in all cases immediately after device deployment and in some it was repeated 10 min after the deployment. Angiographic and procedural details are presented in Table IV. Success was achieved in 115 (93.5%) VM. In the remaining 8 (6.5%), the device was not successfully deployed or it did not effectively occlude the VM. The cases of procedural failure included three aortopulmonary collaterals, two pulmonary arteriovenous fistulae, one Blalock-Taussig shunt, one coronary fistula, and one systemic venovenous collateral. Of these, two aortopulmonary collaterals and the Blalock-Taussig shunt were successfully intervened in a second procedure, accounting for the three (2.4%) reinterventions. Successful occlusion was therefore achieved in 118 (95.9%) VM, including the reinterventions.

In the absence of complications, patients were discharged on the day following the procedure and antiplatelet therapy was maintained for six months. Seven (5.7%) procedural complications occurred. Two cases of contained vascular tears of aortopulmonary collaterals occurred without clinical impact and without the need for medical or procedural intervention. One case of transient atrioventricular block with spontaneous reversal, possibly mediated by vagal activity, occurred during a pulmonary arteriovenous fistula occlusion. Two cases of inferior limb ischemia followed the catheterization procedures using femoral artery access and

TABLE I. Clinical Characteristics

	$N = 47$
Age (years)[a]	12 (25 days–76 years)
Female, *N (%)*	24 (51.1)
Weight (kg)[a]	45.0 (1.9–90.0)
Congenital structural heart disease, *N* (%)	28 (59.6)
Glenn surgery or Fontan circulation, *N* (%)	16 (34.0)
Number of procedures per patient	1.5
Number of intervened vessels per patient	2.6

[a]Median values with range.

TABLE II. Intervened Vascular Malformations

Vascular malformation	*N* (%)	Size[a]	Devices	Success *N* (%)
Arterial	111 (90.2)			
Pulmonary arteriovenous fistula	55 (44.7)	5.5 (3.5–16.0)	36 AVP, 15 coils, 12 ADO, 1 ASO	53 (96.4)
Aortopulmonary collateral	39 (31.7)	4.0 (2.0–9.0)	28 AVP, 18 coils, 2 ADO	36 (92.3)
Peripheral arteriovenous fistula	8 (6.5)	4.5 (3.0–9.0)	8 AVP, 1 ADO	8 (100.0)
Blalock-Taussig shunt	5 (4.1)	5.0 (4.0–6.0)	5 coils, 3 ADO	4 (80.0)
Coronary fistula	4 (3.3)	7.0 (5.0–9.0)	3 AVP	3 (75.0)
Venous	12 (9.8)			
Systemic venovenous collateral	10 (8.1)	4.5 (3.0–12.0)	5 AVP, 4 ADO	9 (90.0)
Fontan fenestration	2 (1.6)	15.0 (14.0–16.0)	2 APFO	2 (100.0)

ADO: Amplatzer Duct Occluder family; APFO: Amplatzer PFO Occluder; ASO: Amplatzer Septal Occluder; AVP: Amplatzer Vascular Plug family.
[a]Median values with range.

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TABLE III. Devices Used During the Study Period

	N	1995–1999	2000–2004	2005–2009	2010–2014	Available in our center
Vascular plugs						
Amplatzer Vascular Plug	68	–	1	45	22	2003
Amplatzer Vascular Plug II	8	–	–	1	7	2007
Amplatzer Vascular Plug 4	4	–	–	–	4	2009
Duct occluders						
Amplatzer Duct Occluder	20	2	15	3	–	1998
Amplatzer Duct Occluder II	2	–	–	–	2	2008
Amplatzer PFO Occluder	2	–	–	–	2	2000
Amplatzer Septal Occluder	1	1	–	–	–	1998
Flipper detachable embolization coil	38	23	5	2	8	1995
Number of devices	143	26	21	51	45	
Number of intervened vascular malformations	123	18	17	46	42	

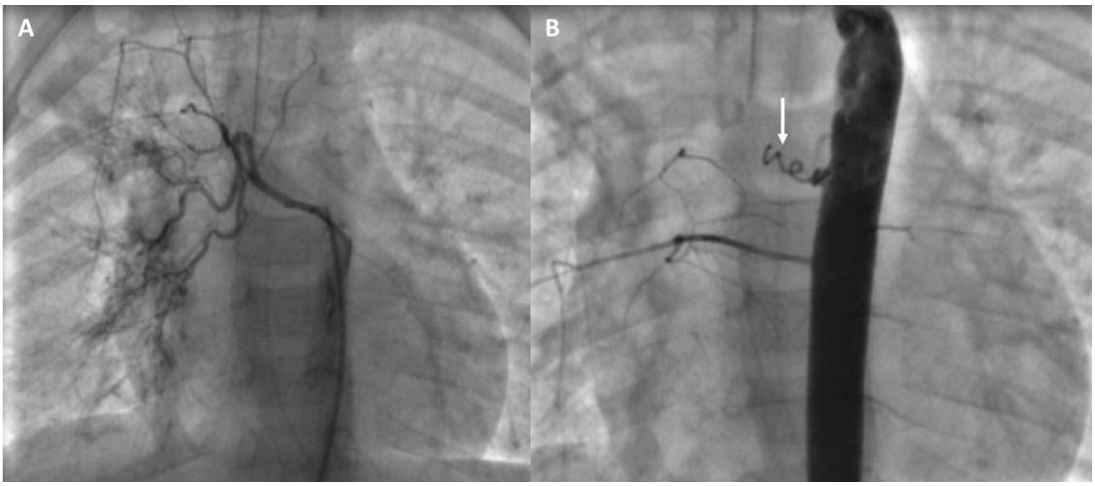

Fig. 1. A: Aortopulmonary collateral with 2 mm of diameter before intervention, (B) and after closure with a Flipper detachable embolization coil (arrow), with no residual flow through the device.

were reversed with intravenous anticoagulation. One case of macroscopic hematuria occurred after device deployment with incomplete closure of a Blalock-Taussig shunt, disappearing after successful occlusion in a second procedure. One coil embolized to the femoral artery and was removed surgically, uneventfully. Therefore, three (2.4%) complications were minor (grade 2) and four (3.3%) were moderate or severe (grades 3 or 4), none resulting in permanent sequelae.

In univariate analysis, procedural failure was associated with lower body weight (median 15.0, 3.8–52.0 kg vs. 58.0, 1.9–90.0 kg, $P = 0.006$), younger age (median 4 years, 2 months-15 years vs. 15 years, 25 days–76 years, $P = 0.006$), smaller vessel size (median 3.0, 2.0–5.0 mm, vs. 5.0, 2.0–16.0 mm, $P = 0.031$), and coil use (16.7% failure in VM treated with coils vs. 4.0% in VM treated without coils, $P = 0.046$). Since body weight and age were significantly correlated ($r = 0.65$, $P < 0.001$), only body weight was included in the multivariate model. Lower body weight was independently associated with procedural failure (OR 1.05, 95% CI 1.01, 1.10, $P = 0.019$).

Regarding the seven complications, lower body weight (median 10.0, 3.8–26.5 kg vs. 55.0, 1.9–90.0 kg, $P = 0.003$), younger age (median 17 months, 2 months–11 years vs. 16 years, 25 days–76 years, $P = 0.001$), and coil use (16.7% complications in VM treated with coils vs. 3.0% in VM treated without coils, $P = 0.027$) were associated with the occurrence of complications in univariate analysis. Considering the correlation between body weight and age, only body weight was included in the multivariate model, for the reasons aforementioned. Lower body weight was independently associated with the occurrence of complications (OR 1.08, 95% CI 1.01, 1.15, $P = 0.018$).

DISCUSSION

We report a single center experience on percutaneous occlusion of different arterial and venous VM, using a variety of devices. This treatment option was effective and safe in patients with a wide range of ages, from 25 days to 74 years.

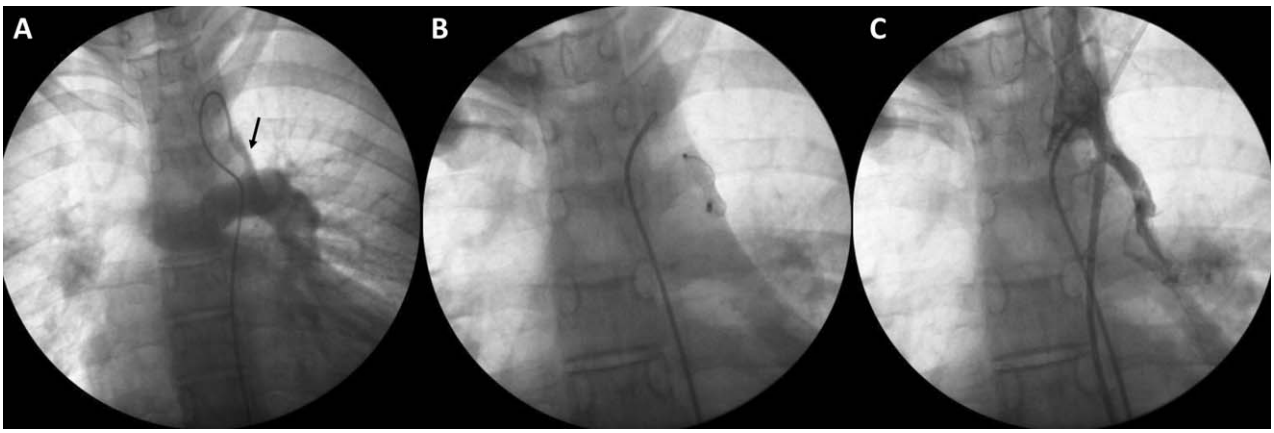

Fig. 2. A: Blalock-Taussig shunt with 5 mm of diameter and high flow velocity before intervention (arrow), (B) an Amplatzer Duct Occluder device well positioned, (C) and minimal residual flow after deployment.

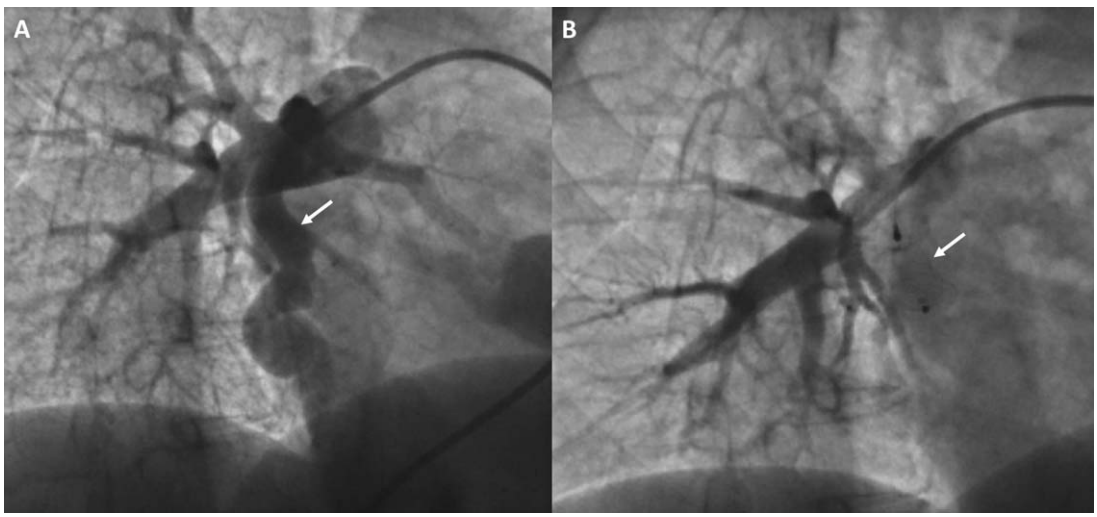

Fig. 3. A: Large pulmonary arteriovenous fistula with 13 mm of diameter before intervention (arrow), (B) and after closure with an Amplatzer Vascular Plug II (arrow), with no residual flow through the device.

TABLE IV. Angiographic and Procedural Details

Vessel size (mm)[a]	4.5 (2.0–16.0)
Device size (mm)[a]	6.0 (3.0–18.0)
Device size/vessel size ratio[a]	1.4 (1.1–2.0)
Number of devices per vessel[b]	1 [0–5], 1.2 ± 0.6
Fluoroscopy time (minutes)[a]	17 (7–44)
Procedural success, *N* (%)	115 (93.5)
Complete occlusion, *N* (%)	98 (79.7)
Minimal residual flow, *N* (%)	17 (13.8)
Procedural failure, *N* (%)	8 (6.5)
Device not deployed, *N* (%)	5 (4.1)
Incomplete occlusion by the device, *N* (%)	3 (2.4)
Final success (including reinterventions), *N* (%)	118 (95.9)

[a]Median values with range.
[b]Median value with range, mean ±SD.

Percutaneous occlusion is usually the preferred treatment method for VM if technically feasible [8,9]. Patent ductus arteriosus is relatively common and it is probably the VM that most often requires percutaneous closure in pediatric patients [6,7]. Since there is already extensive data on percutaneous occlusion of patent ductus arteriosus [6,7], on the contrary to other VM, it was excluded from our study.

The five largest published series on pediatric and adult patients with different arterial and venous VM treated with percutaneous occlusion, excluding patent ductus arteriosus, are discussed below [5,8–11]. Four of these have focused on a specific type of device, even though different devices may be adequate

according to specific vessel characteristics, including diameter and flow [4,5,8–10]. Perry et al. [10] have reported the use of Gianturco coils to embolize 77 VM, including aortopulmonary collaterals, Blalock-Taussig shunts, arteries involved in pulmonary sequestrations, and vena cava. The success rate was 94.7% and 10.4% of complications occurred, including device embolization and severe hemolysis after incomplete occlusion of a Blalock-Taussig shunt [10]. More recently, three series have focused on the AVP family [5,8,9]. In a multicentric study, Hill et al. [8] reported the occlusion of 84 vessels in 52 patients with congenital heart disease using 89 AVP devices. Vessels included collaterals, pulmonary arteriovenous fistulae, coronary artery fistulae, transhepatic tracts, central shunts, patent ductus arteriosus, and excluded hepatic vein [8]. Complete vessel occlusion was demonstrated within 10 min in 94% of devices and one case required surgical intervention due to significant residual flow in a patent ductus arteriosus [8]. In a single center registry by Schwartz et al. [9], 52 vessels of different types were occluded in 50 patients using the AVP and AVP II devices. Two (3.8%) access site complications occurred; in a median follow-up of one week there was imaging or clinical evidence of complete occlusion of all VM, including those with residual flow immediately after device deployment [9]. Therefore, minimal residual flow after deployment may be an adequate measure for procedural success, as we considered in our analysis. In another study by Barwad et al. [5], complete occlusion occurred in 92% of the 39 intervened VM, using the AVP, AVP II, AVP III, and AVP 4 devices, with no complications. Girona et al. [11] have reported the use of coils and vascular plugs to occlude 51 different VM, all showing complete occlusion, without complications. The reintervention rate in our cohort is non-negligible. Nevertheless, the final success rate is in line with the aforementioned series, most of which are relatively recent, even though the definitions for technical success are not homogeneous in the literature [5,8–11]. The rate of complications in our series appears to be higher than the reported in these studies, but definitions of adverse events were not homogeneous as well [5,8–11]. Of note, the rate of adverse events that we report is comparable with that described in large multicentric registries of different catheterization procedures [5,8–16].

If patent ductus arteriosus is not considered, other series on percutaneous occlusion of different VM in pediatric and adult patients include smaller samples and the results are therefore difficult to compare [18–25]. Larger series have only analyzed the occlusion of pulmonary arteriovenous fistulae, predominantly in adults [12–14]. The procedural and clinical results were good but the devices used were almost restricted to coils or detachable balloons [12–14]. Data on percutaneous occlusion of different VM is presented in our study, using different devices, which may be more useful for clinicians than data focused on a single VM or a specific device [8,9].

Predictors of procedural failure have not been completely addressed in previous studies [8,9]. Septal and duct occluder devices have been reported to be difficult to deliver due to their bulkier profiles, especially across tortuous and angulated vessels, on the contrary to vascular plugs, which may be easier to track and to deliver [5,8]. Coils have been associated with lower success rate of VM occlusion [5,10,26]. In our series, 6.5% of the VM were not successfully occluded in the first procedure, either due to inadequate catheter support which precluded device deployment, or due to incomplete occlusion by the device. Coil use was associated with procedural failure in univariate analysis, along with lower body weight, younger age, and smaller vessel size. Lower body weigh was independently associated with procedural failure, which may reflect a more difficult percutaneous access to the VM and a poorer support for device delivery. Regarding safety, the use of coils was associated with higher rate of complications in univariate analysis; this finding is consistent with previous series, which also reported safety issues with the use of coils, including embolization [5,10,26]. Lower body weight was the only independent predictor of complications, which may be related to a higher risk of access site complications, poorer support for device delivery, and more fragile and prone to rupture VM. Further prospective studies are needed to evaluate the consistency of these findings.

Limitations

The retrospective nature of the study is the main limitation. However, the results are based on a fairly complete systematic registry carried out since 1995, on clinical, angiographic, and procedural data. This study truly reflects clinical practice over a long period of 20 years, including clinical and technical challenges.

CONCLUSION

To the best of our knowledge, this is the largest series on different arterial and venous VM treated with percutaneous occlusion in pediatric and adult patients, excluding patent ductus arteriosus. This treatment option was effective and safe, although lower body weight was associated with procedural failure and complications.

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