Original Article

Transthoracic echocardiography is a safe alternative for assessment and guidance of transcatheter closure of secundum atrial septal defect in children

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Background: 2D-transesophageal echocardiography (TEE) is routinely performed to guide percutaneous ASD closure in children. We aimed to assess whether two-dimensional (2D)-transthoracic echocardiography (TTE) is a safe alternative for assessment and guidance of atrial septal defect (ASD) closure in unselected children.

Methods: We performed a retrospective single-center study including 389 consecutive children aged less than 15-year-old who underwent percutaneous ASD closure under 2D-TEE (1998–2005, n=133) or 2D-TTE (2005–2014, n=256). A balloon calibration was performed in all cases for the Amplatz Septal Occluder choice.

Results: ASDs were larger and rims deficiencies were more frequent in the TTE-guided group. The procedure was successful in 376 patients [96.7%; 95% confidence interval (CI), 94.4–98.2%]. The success rate tended to be higher in the TTE- versus TEE-guided group (98.0% versus 94.0%, P=0.069). Device migration occurred in 4 patients (1.0%; 95% CI: 0.3–1.6%), all after TEE-guided procedure (P=0.013). Early major adverse events were observed in 5 patients (1.3%; 95% CI: 0.4–3.0%), all in the TEE group (P=0.004). Fluroroscopic time and irradiation dose were not different among the 2 groups (P=0.450 and P=0.130 respectively). After a median follow-up of 7 years (range, 1–16 years), no adverse events was reported. One (0.3%, 95% CI: 0–1.4%) 12-year-old patient developed atrial fibrillation 5 years after the procedure. Pregnancies were uneventful in 72 cases.

Conclusions: When a balloon sizing is performed, 2D-TTE imaging is as efficient as 2D-TEE to guide percutaneous ASD closure in children. The procedure can safely be done in spontaneously breathing children under TTE guidance alone in experienced centers.

Keywords: Pediatrics; outcomes; effectiveness; echocardiography; atrial septal defect

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Introduction

Transcatheter device closure of secundum atrial septal defects (ASD) is the first-line method of repair when the anatomy is suitable given the lower morbidity rate in comparison to surgery (1,2). Over- or under-sized device increased the risk of complication (3). A careful assessment of ASD size, morphology and rims is the key-step for device selection. Trans-esophageal echocardiography (TEE) or intracardiac echocardiography (ICE) are widely used to guide the procedure (4,5). However, TEE use may lead to oropharyngeal and oesophageal traumas (6-8), and ICE is expensive and require an additional large venous access (9). Given a good echocardiographic window in children, transthoracic echocardiographic (TTE) guidance has been proposed (10-13). However this approach is not universally accepted (14,15) and most publications report either small or old series, always on selected patients (10-13). We aimed in this study to compare efficacy and safety of 2D-TTE versus 2D-TEE to guide percutaneous ASD closure in a large, unselected, consecutive pediatric population.

Methods

Study design

We conducted a retrospective single-center comparative study at the Marie-Lannelongue Hospital in Paris, France. All patients <15-year-old who underwent attempt of transcatheter isolated, secundum ASD closure with the Amplatzer Septal Occluder (ASO) between 1998 and 2014 were included. Data were collected with special attention to echocardiographic data, implantation characteristics, early and long-term outcomes. The study database was reported to the French data protection authority (CNIL No. 1154338, April 27, 2006). Our study complies with the Declaration of Helsinki. Our institutional review board approved the study (No. CCML 2015-4), and all patients or legal guardians gave their informed consent to study inclusion.

Pre-operative echocardiographic assessment

ASD rims and size were assessed by preoperative TTE in all patients. Right ventricular size and function were assessed according to American Society of Echocardiography guidelines (16). Right ventricular systolic pressure was estimated using the Bernoulli equation in patients with tricuspid regurgitation. The ASD diameter was measured in apical and sub-costal four-chamber views, parasternal-short axis view and subcostal bi-caval view. The ASD diameters were measured at the end-systolic frame of the cardiac cycle (17) and the largest ASD diameter on any view was recorded as ASD size. ASO/LA (left atrial) length ratio was defined as the ratio between the diameter of the left atrial (LA) disc of the device and the LA length. LA length was the distance from the anterior mitral valve leaflet to the posterior LA wall on the subcostal view. When not measured, LA length was estimated as 0.597+0.404·log (Body Surface Area) (18). Very large ASD was defined as an echocardiographic diameter ≥15 mm/m^2 in children (19). Device closure was attempted to treat very large ASDs in 204 (52.4%) children.

We labeled ASD rims as proposed by Amin and universally accepted, as aortic (or superoanterior), anteroinferior (or atrioventricular valve), inferoposterior (or inferior venacaval), posterior, posterosuperior (or superior venacaval), and superior (20,21). Special attention was given to anteroinferior and posterosuperior rims on the four-chambers view, aortic and posterior rims on the short-axis left parasternal view, and inferoposterior and superior rims on the subcostal view. Rims less than 5 mm in length were considered deficient (20). Anteroinferior, posterosuperior, aortic, posterior, inferoposterior and superior rims were deficient in 76 (19.5%), 100 (25.7%), 206 (52.9%), 155 (39.8%), 151 (38.8%) and 100 (25.7%) patients respectively.

Procedure characteristics and per-operative echocardiographic guidance

The procedure was performed as previously described (19,22-24). From 1998 to 2005, ASD closure was done in all children (n=133, 34.2%) under general anesthesia with oro-tracheal intubation and 2D-TEE guidance. From 2005 to 2014, 2D-TTE guidance was used in all children (n=256, 65.8%), regardless of age or ASD characteristics. TTE-guided procedures were performed under deep sedation in 213 (54.7%) spontaneously breathing children younger than 12 years and under local anesthesia in the other 43 (11.1%) patients.

Right-sided cardiac catheterization was performed to evaluate hemodynamics and exclude additional congenital heart defects. Ten (2.6%) patients had pulmonary arterial hypertension (defined as mean pulmonary arterial pressure >25 mmHg). Oxygen saturations were analyzed in 197 (50.6%) children, consistently showing substantial left-to-right inter-atrial shunting with a median Qp/Qs ratio

of 2.5 (1.0–4.0). In patients with pulmonary hypertension, criteria for ASD closure were pulmonary vascular resistance <15 WU·m^2, persistent left-to-right inter-atrial shunt (Qp/Qs ratio >1.5), and symptoms onset within the past 6 months (25).

Device choice was based on balloon sizing. Balloon sizing was used in all patients regardless of whether TTE or TEE was utilized. Balloon sizing was performed in all patients using the "pull-through" technique (26). A 27 mm or 33 mm Medi-Tech Equalizer balloon (Boston Scientific, Natick, MA, USA) was fully inflated in the left atrium with diluted contrast and then gently pulled back against the septum. With progressive balloon deflation, a slight deformity of the balloon was seen on fluoroscopy, just prior to its popping through the septum, giving the balloon-stretched diameter of the ASD (27). Median balloon-stretched diameter was 21 mm (range, 8–40 mm) namely 20.9 mm/m^2 (range, 8.1–48.2 mm/m^2). Balloon-stretched diameter/LA length ratio was 53.5% (range, 22.4–98.1%).

Amplatzer Septal Occlusion device was utilized for all the patients. An appropriate sized device was deployed with fluoroscopic guidance, using a standard, previously described placement protocol (19). ASO/LA length ratio was <0.8 in 142 (36.5%) patients, 0.8 to 0.9 in 98 (25.2%), 0.9 to 1 in 67 (17.2%), and >1 in 82 (21.1%).

TTE was used only after device deployement and before its release. TTE was used to evaluate the position of each disk and potential impingement of the device on adjacent cardiac structures. The relation of the device to the atrioventricular valves and the aorta was assessed using the parasternal short-axis, the apical 4-chambers and the subcostal views. Color Doppler assessment of residual shunting, systemic and pulmonary venous return including coronary sinus, and atrioventricular valve function were also assessed, as applicable in these views. Gentle pushing and pulling of the delivery cable was performed to ensure that the device was in a secure position. The device was released only if the echocardiogram demonstrated a correct position without evidence of significant residual shunting, atrioventricular valve malfunction, or venous obstruction.

Procedural success was defined as presence of all three following criteria: successful ASO delivery without peri-procedural complications; well-positioned ASO as assessed by TTE after 6 and 48 hours, with no ASO migration; and hospital discharge on post-procedure day-1. Cardiac erosion, pericardial effusion, air embolus, ASO-related valvular regurgitation, thromboembolism, pulmonary edema, stroke, atrioventricular block, ventricular arrhythmias, and hemolysis were considered major complications. At hospital discharge, patients were prescribed oral antiplatelet therapy for 6 months.

Follow-up

ECG was checked at day-1. A physical examination, 12-lead ECG and TTE were performed 6 and 24 hours post-procedure. A physical examination, 12-lead ECG and TTE were done 1 week, 3 months, and 1 year post-procedure. The referring cardiologists provided subsequent follow-up. Long-term outcomes were assessed by telephone interviews of all patients and all referring cardiologists to obtain information on cardiac status, data at the last visit, and any delayed complications.

Statistical analysis

Analysis were performed using StatEL software (www.adscience.eu, adScience, Paris, France). Categorical variables were described as numbers and percentages. Continuous variables were expressed as median (min-max). Data regarding TEE-guided and TTE-guided procedures were compared using the nonparametric Mann-Whitney test. Categorical variables were compared using chi² test and Fischer exact test. Successful and failed procedures were also compared according to rim deficiencies using the chi² test and Fischer exact test. A p-value <0.05 was considered statistically significant.

Results

Demographic and ASD characteristics of the 389 pediatric procedures are detailed in *Table 1*. Hemodynamic and device characteristics are detailed in *Table 2*. Linear regression analysis demonstrated that the mean balloon-stretched diameter was greater of 5.59±1.38 mm/m^2 in the TTE-guided group than that of the TEE-guided group (P<0.001).

Immediate post-procedural outcome

The procedure was successful in 376 (96.7%; 95% CI: 94.4–98.2%) patients (*Table 3*). A trivial residual inter-atrial shunt was observed in 8 children (2.1%, 95% CI: 0.9–4.1%). In the 204 children with very large ASD, the procedure was successful in 196 (96.1%; 95% CI: 92.4-98.3%) cases, 143 (70.1%) of them being TTE-guided. Results of this specific subgroup have been reported in details elsewhere (18). Rim

Table 1 ASD characteristics according to echocardiographic guidance technique

	TEE-guidance (n=133 patients)	TTE-guidance (n=256 patients)	P value
m/f sex ratio	0.53	0.65	0.029
Age (yrs)	9.0 (2.0–15.0)	8.9 (2.0–15.0)	0.480
Weight (kg)	27 [10–70]	27 [11–79]	0.760
BSA (m^2)	1.0 [0.5–1.8]	1.0 [0.6–1.9]	0.760
ASD diameter (mm)	15 [5–41]	15 [8–40]	0.260
ASD diameter (mm/m^2)	14.3 (3.9–31.8)	15.5 (5.7–33.9)	0.118
ASD diam./LA length ratio (%)	37.0 (13.9–86.1)	38.4 (17.6–87.8)	0.132
Large ASD (n, %)	59 (44.4)	145 (56.6)	0.028
Deficient rims			
Aortic	68 (51.1%)	138 (53.9%)	0.602
Posterior	35 (26.3%)	120 (46.9%)	<0.001
Antero-inferior	12 (9.0%)	64 (25.0%)	<0.001
Postero-superior	26 (19.6%)	74 (28.9%)	0.045
Inferior	40 (30.1%)	111 (43.4%)	0.012
Superior	26 (19.6%)	74 (28.9%)	0.045

Table 2 Procedural characteristics according to echocardiographic guidance technique

	TEE-guidance (n=133 patients)	TTE-guidance (n=256 patients)	P value
PAH (n, %)	4 (3.0)	6 (2.3)	0.368
Balloon-stretched diameter (mm)	20 [8–40]	22 [12-40]	0.003
Balloon-stretched diameter (mm/m^2)	19.8 (8.9–35.4)	21.8 (8.1–48.2)	0.002
ASO LA disk (mm)	32 [22–50]	34 [26–50]	0.070
ASO LA disk / LA length ratio (%)	82.3 (57.1–137.4)	86.3 (54.4–150.8)	0.048
ASO migration (n, %)	4 (3.0)	0 (0)	0.013
	(n=71 patients)	(n=124 patients)	
Qp: Qs ratio (%)	2.5 (1.5–4.0)	2.5 (1.8–4.0)	0.310
	(n=54 patients)	(n=107 patients)	
Fluoro time (min)	5.1 (2.4–19.8)	4.7 (2.1–9.3)	0.450
Irradiation dose ($\mu Gy/m^2$)	208.7 (85.8–2863.2)	197.4 (52.6–967.0)	0.130

deficiencies were not associated with procedural failure (*Table 4*).

The procedure failed in 13 (3.3%; 95% CI: 1.8–5.6%) of the 389 children (*Table 5*). The ASO was deployed but not delivered in 9 (5 TTE-guided, 4 TEE-guided) then considered unstable or too large to be closed and withdrawn, without incident. In these cases the ASO was retrieved before being delivered, to avoid cardiac deformation or device-related atrioventricular valve regurgitation. ASO migration occurred in the remaining 4 patients (1.0% 95% CI: 0.3–1.6%; 1 in the right atrium, 1 in the right ventricle, 1 in the left atrium and 1 in the left ventricle), of whom 3

Table 3 Procedural outcomes according to echocardiographic guidance technique

	TEE-guidance (n=133 patients)	TTE-guidance (n=256 patients)	P value
Procedural success	125	251	0.069
Excessively large ASO or instability	4	5	0.498
ASO migration	4	0	0.013
Residual shunt	3	5	0.391
ASO-related cardiac perforation	0	0	
ASO-related valve regurgitation	0	1	1.000
ASO-related endocarditis	0	0	
ASO-related thromboembolism	0	0	
ASO-related conduction disorders	0	0	
ASO-related hemolysis	1	0	0.341
Stroke	0	0	
Length of follow-up (years)	13 [9–16]	6 [1–9]	<0.001

Table 4 Impact of rim deficiencies on procedural success

	Successful closure	Failed closure	P value
TEE and TTE guidance (n=389)	n=376	n=13	
Deficient aortic rim (n, %)	197 (52.4%)	8 (61.5%)	0.245
Deficient superior rim (n, %)	94 (25.0%)	4 (30.8%)	0.357
Deficient anteroinferior rim (n, %)	71 (18.9%)	3 (23.1%)	0.371
Deficient posterosuperior rim (n, %)	94 (25.0%)	4 (30.8%)	0.357
Deficient posterior rim (n, %)	90 (23.9%)	3 (23.1%)	0.398
Deficient inferior rim (n, %)	145 (38.6%)	4 (30.8%)	0.339
TEE guidance alone (n=133)	n=125	n=8	
Deficient aortic rim (n, %)	63 (50.4%)	5 (62.5%)	0.320
Deficient superior rim (n, %)	23 (18.4%)	3 (37.5%)	0.167
Deficient anteroinferior rim (n, %)	11 (8.8%)	1 (12.5%)	0.375
Deficient posterosuperior rim (n, %)	23 (18.4%)	3 (37.5%)	0.167
Deficient posterior rim (n, %)	20 (16.0%)	2 (25.0%)	0.320
Deficient inferior rim (n, %)	37 (29.6%)	3 (37.5%)	0.357
TTE guidance alone (n=256)	n=251	n=5	
Deficient aortic rim (n, %)	134 (53.4%)	3 (60.0%)	0.382
Deficient superior rim (n, %)	71 (28.3%)	1 (20.0%)	0.367
Deficient anteroinferior rim (n, %)	60 (23.9%)	2 (40.0%)	0.282
Deficient posterosuperior rim (n, %)	71 (28.3%)	1 (20.0%)	0.367
Deficient posterior rim (n, %)	73 (29.1%)	2 (40.0%)	0.346
Deficient inferior rim (n, %)	108 (43.0%)	1 (20.0%)	0.234

Table 5 Characteristics of failed procedures

	Age (yrs)	Weight (kg)	TTE diam (mm/m^2)	Balloon-stretched diam (mm/m^2)	Aneury smal septum	PAH	Deficient rims						Echo guidance	ASO (mm)	ASO/LA length (%)	Reason for failure
							Aortic	Post	Ant-inf	Post-sup	Inf	Sup				
Pt 1	9	36	18.5	21.9	No	No	No	No	No	No	No	No	TEE	24	80–90	Unstable ASO
Pt 2	6	16	16.7	22.7	No	No	Yes	Yes	No	Yes	Yes	Yes	TEE	24	>100	ASD too large
Pt 3	6	18	26.4	34.3	No	No	Yes	Yes	No	Yes	Yes	Yes	TEE	22	>100	ASD too large
Pt 4	4	16	21.7	28.9	No	No	Yes	No	No	No	No	No	TEE	22	>100	ASD too large
Pt 5	11	44	28.2	16.9	No	No	Yes	No	No	No	No	No	TTE	18	<80	Unstable ASO
Pt 6	6	11	26.6	37.6	No	No	No	Yes	No	Yes	Yes	Yes	TTE	34	>100	ASD too large
Pt 7	7	16	15.5	26.8	No	No	Yes	No	No	No	No	No	TTE	34	>100	ASD too large
Pt 8	12	20	11.3	20.0	No	No	No	No	Yes	No	No	No	TTE	22	80–90	Unstable ASO
Pt 9	13	56	13.1	16.2	No	No	Yes	No	Yes	No	No	No	TTE	20	<80	Unstable ASO
Pt 10	5	21	14.6	21.9	No	No	No	Yes	No	Yes	Yes	Yes	TEE	14	<80	LV embolization
Pt 11	8	30	14.3	25.7	No	No	Yes	No	No	No	No	No	TEE	28	>100	RA embolization
Pt 12	15	51	10.6	19.9	No	No	No	No	No	No	No	No	TEE	24	80–100	LA embolization
Pt 13	11	30	11.7	15.4	No	No	Yes	Yes	Yes	No	Yes	Yes	TEE	36	>100	RV embolization

PAH, pulmonary arterial hypertension; LA, left atrium; RA, right atrium; RV, right ventricle; post, posterior; antinf, anteroinferior; postsup, posterosuperior; inf, inferior; sup, superior; TEE, transesophageal echocardiography; TTE, transthoracic echocardiography.

were managed by transcatheter ASO retrieval and surgical ASD closure and 1 by same-stage surgical ASO retrieval and ASD closure. All the 4 patients whose device embolized had had TEE-guided procedure (P=0.013). No other major or minor complications occurred during the procedure or within the first 48 post-procedural hours in these patients. A 10-year-old, 21-kg boy who had a successful TEE-guided ASD closure with a 24 mm-ASO associated to an Ebstein disease, underwent surgical device retrieval and ASD closure via a sternotomy at the post-procedural day 11 because of severe device-related hemolysis. This complication was favored by a lateralized tricuspid regurgitation jet directed against the device. Overall, early major adverse events were observed in 5 patients (1.3% 95% CI: 0.4-3.0%), all in the TEE group (P=0.004).

Procedural outcome according to the echocardiographic guidance technique

Children whose procedure was TTE-guided had significantly more posterior, anteroinferior, posterosuperior, inferoposterior and superior deficient rims (*Table 1*). In the TTE-guided group, very large ASDs were more frequent and both balloon-stretched diameter and ASO/LA length ratio were greater than in TEE-guided procedures (*Tables 1*,*2*).

The procedural success rate tended to be higher in the TTE-guidance group (98.0%, 95% CI: 95.5–99.4% *vs.* 94.0%, 95% CI: 88.5–97.4%, P=0.069). ASO migrations occurred only in case of TEE-guided ASD closure (3.0%; 95% CI: 0.8–7.5% *vs.* 0.0%, 95% CI: 0.0–1.4%, P=0.013) (*Table 5*). The failure rate due to excessively large or unstable ASO was not significantly different between the TEE and TTE groups (P=0.498) (*Table 3*). In both groups, rim deficiencies were not associated with procedural failure (*Table 4*).

Long-term outcome

After a median follow-up of 7 years (range, 1–16 years), no patient was lost to follow-up. All patients were alive and asymptomatic and no one had been rehospitalized for device-related complication. None experienced late complications; more specifically, no cases of cardiac perforation or ASO migration were recorded. No regurgitation through the aortic, mitral, or other valves developed in any patient. There were no instances of ASO-related endocarditis, thromboembolism, conduction

disorders, or ventricular arrhythmias. After ASD closure, 67 women had 75 uneventful pregnancies; more specifically, no intra- or postpartum thromboembolic events occurred. All patients had normal left ventricular systolic function at the last visit. One (0.3%, 95% CI: 0–1.4%) 12-year- old patient developed atrial fibrillation 5 years after the procedure, controlled effectively by pharmacological treatment.

Discussion

Echo guidance of ASD closure

TEE was required in the pivotal trial of the ASO device and continues to be the most widely used technology for ASD assessment, device selection, and guidance during implantation (2,28,29). However the rational to consider TTE guidance as an alternative is driven by some rare reports of TEE-related esophageal perforation in adults and children (6-8), as well as the fact that TTE-guidance may allow to shorten both procedure time and fluoroscopy time (30) and to avoid general anesthesia and orotracheal intubation in spontaneously breathing children (30,31). Additionally, one can present the argument that in TTE-guided procedures, the interventionist may be able to complete the whole process himself without the need for an additional echographist and without additional irradiation (10,30). We report here a routine experience on 2D-TTE guided ASD closure in 256 unselected children compared to 133 2D-TEE guided procedures. Our main finding is that in experienced hands, 2D-TTE associated with balloon-sizing is a valuable alternative to 2D-TEE for ASD closure guidance. Our results are in accordance to other groups (30,31).

TTE-guidance is not universally accepted and published data are limited to either small series or selected patients (10-12). However one monocenter prospective randomized study suggested non-inferiority of 2D-TTE compared to 2D-TEE in 40 selected children (11).

In 2D-TTE guided procedures, devices were positioned under fluoroscopy only, whereas in 2D-TEE guided procedures, real-time TEE images of the ASD and surrounding structures such as the aorta root were available for the interventionist, thus theoretically facilitating the positioning. Our results underline the pivotal role of the method of choice of the device, which is closely related to procedural success and complication rate. 2D-TEE and 2D-TTE images underestimate the ASD maximal size compared to balloon-sizing (5,32-34). In our experience, a balloon calibration was performed in all cases minimizing the impact of the echo technique on the device choice.

Obviating the need for the transesophageal echocardiography in TTE-guided procedures seems not to have impaired the decision making process. This makes TTE-guided procedure a highly interesting alternative strategy, especially when percutaneous ASD closure is performed in developing countries, where expensive techniques such as ICE or TEE are not easily affordable (35,36).

Our successful ASD device implant rate of 96.7% was similar to procedural success rates of 95.7% in the IMPACT Registry, 96% in the MAGIC report, 95% in the C3PO report, and 95.7% in the Amplatzer Septal Occluder FDA study (2,29,37,38). Major adverse events were observed in 1.3% in our study. This rate compares with 1.2% in IMPACT patients, 1.1% in MAGIC patients, 4.7% in C3PO patients and 1.6% in the FDA study (2,29,37,38). As previously described, device embolization was successfully managed percutaneously in most cases (34). Moreover we did not observe late adverse events. Although rare, late complications like conduction abnormality, endocarditis, thrombo-embolism or aortic valve regurgitation have been occasionally described (38-40). Device related aortic erosion remains a dreaded complication occurring in 0.5% in the literature (40). In our study, TEE and TTE guided procedures seems to compare favorably with regards to both early and long-term outcomes.

Limitations

We focused on severe early and delayed complications. Complete data on supraventricular arrhythmias were not collected. Given the large number of patients coming from all parts of the country, detailed follow-up of cardiac rhythm with regular 24-hour ECG Holter monitoring would not have been feasible in all patients. Our study describes two different groups of patients with different ASD characteristics and from two different eras (namely 1998-2005 for TEE-guidance and 2005-2014 for TTE-guidance). As experience has evolved with time, complications observed in the TEE group may have been part of the learning curve of the ASD closure technique.

Conclusions

2D-TTE is safe and efficient to guide percutaneous ASD closure in unselected children. This modified technique

allows a shortened and simplified procedure performed in spontaneously breathing children. Our results strongly support the fact that 2D-TTE can be considered as an efficient alternative to 2D-TEE for assessment and guidance of pediatric ASD closure in experienced centers.

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Footnote

Conflicts of Interest: Dr. Fraisse is a proctor and consultant for St Jude Medical. Dr. Baruteau received a research grant from St Jude Medical. Other coauthors have no conflict of interest to disclose.

Ethical Statement: Our institutional review board approved the study (No. CCML 2015-4), and all patients or legal guardians gave their informed consent to study inclusion.

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