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Atrial septal defect closure with the new Cardia Ultrasept II™ device with interposed Goretex patch: Mexican experience – has the perforation of Ivalon's membrane been solved?

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Abstract

Objectives: The objective of this study was to demonstrate the safety and feasibility of using the new Cardia Ultrasept II™ device with interposed Goretex patch referring to the perforation of polyvinyl alcohol membrane. *Background:* Great advances have been made in the development of devices for closure of atrial septal defect. The Cardia Ultrasept II™ with interposed Goretex patch is the modified last generation of Cardia devices, having the advantage of a super-low profile within the atria and an integral locking delivery-retrieval mechanism that ensures safe deployment. In addition, with the interposition of the Goretex, it has been possible to abolish perforation of Ivalon's membrane as a complication. *Methods and results:* Patients with ostium secundum atrial septal defect with surrounding rims with a minimum length of 5 mm and who underwent atrial septal defect closure with the new Ultrasept II™ with Goretex patch were included from two paediatric cardiac centres. Primary end point was to determine perforation of the Goretex membrane at follow-up; secondary end point included right ventricular diastolic diameter. In total, 30 patients underwent atrial septal defect closure at a median age of 6 (1–29) years. At follow-up for 6 (range, 1–15) months, freedom from perforations was 100%. A continuous decrease in right ventricular diastolic diameter was found with an initial median of 30 (25–49) mm and after catheterisation of 27.5 (18–33) mm, $p = 0.01$, and Z-score of 2.6 (1.7–3.6) versus 1.9 (1–2.9) after procedure, $p = 0.01$. *Conclusions:* The new modified generation of the Ultrasept II™ device with interposed Goretex patch is a good alternative to achieve atrial septal defect closure safely and feasibly with no membrane perforation at follow-up.

Device closure is considered safe and offers many intuitive advantages over surgical closure, which include avoidance of cardiopulmonary bypass and its potential adverse neurologic sequelae, avoidance of sternotomy scar, a potentially lower incidence of post-procedure complications, and a shorter hospital stay.[1,2]

King and Mills in 1974 were the first to use a device to successfully close atrial septal defects.[3] Since then, great advances have been made in the elaboration of new devices. The most widely used at present is the Amplatzer™ Septal Occluder device developed by Dr. Kurt Amplatz. In the late 1990s, Cardia Inc. (Eagan, Minnesota, United States of America) developed the PFO-Star device.[4] All generations of Cardia devices had a low-profile Nitinol frame to minimise device material and enhance flexibility, along with a polyvinyl alcohol sail-like coating, which is said to reduce the risk of thrombus formation. The last generation of these devices is the 7th generation (Ultrasept II™)[5] having polyvinyl alcohol (Ivalon)[6] coating too on its flower-like rounded disks, which showed relatively favourable results and received CE mark approval. However, relatively early malfunctions of membrane have been reported in several publications.[7–11] In these, the findings have generally been reported within the first months after the device was placed (from 1 week to 10 months after implant). After the publication of these adverse events, the manufacturer announced the development of a new consolidated device with the interposition of a Goretex patch between the two nitinol discs in order to avoid this complication. This device maintains the same name as the previous one, Ultrasept II™.

Materials and methods

Patients

A retrospective study was conducted at two paediatric cardiac centres of all infants who underwent atrial septal defect closure with percutaneous devices. Institutional review board

approval was obtained at both centres. Procedures performed from December 2015 to July 2017 were included. Patients were included if they had ostium secundum atrial septal defect, were deemed candidates for atrial septal defect closure by the presence of surrounding rims – superior and inferior caval vein rims – with a minimum length of 5 mm measured by transthoracic echocardiogram, and were brought to atrial septal defect closure using the new generation and modified Cardia Ultrasept II™ device with the interposed Goretex patch. Patients were excluded if they had ostium primum atrial septal defect with or without some extension to the venous sinus, had shorter surrounding rims (<5 mm), and were brought to atrial septal defect closure with different percutaneous devices.

Cardiac catheterisation

An informed consent form was given to the relatives of the patients and a complete left and right heart catheterisation with a double femoral venous access was made under general anaesthesia. Anatomy of the atrial septal defect was thoroughly investigated with intracardiac echocardiogram with an AcuNav 10 Fr catheter (Fig 1). The deployment and release procedures were guided by both fluoroscopy and intracardiac echocardiogram (Fig 2). Intravenous heparin was used during the whole procedure at a dose of 100 U/kg – maximum dose of 5000 UI.

Follow-up

Patients left the hospital 24 hours after the procedure with prophylactic antibiotics and aspirin at a dose of 5 mg/kg, with a maximum dose of 100 mg, during 6 months. During the follow-up, visits were scheduled monthly after the procedure to perform a clinical examination and a transthoracic echocardiogram. We chose monthly visits for the purpose of assessing the integrity of the membrane, as well as the right ventricular diastolic diameter.

Statistical analysis

Numbers and percentages expressed categorical variables. Median and ranges expressed continuous variables. Changes in the dimension of the ventricular chambers were analysed using the Wilcoxon test. The significance was defined as $p < 0.05$. The statistical analysis was performed using the SPSS program and Microsoft Excel 2011 for Mac.

Results

A total of 205 patients with ostium secundum atrial septal defect and with appropriate surrounding borders were treated by catheterisation at two paediatric cardiac centres. Of all patients, we included a total of 30 patients who underwent atrial septal defect closure with the new UItrasept™ II device with Goretex patch interposed. This group included 22 female patients (73.3%) with a group median age of 6 years – ranging from 1 to 29 – and weight of 17 kg – ranging from 7.2 to 90; demographic data are shown in Table 1.

The mean systolic pulmonary arterial pressure was normal at 29.9 ± 8.4 mmHg. The rate of the pulmonary and systemic flow (Qp/Qs) was 2 ± 0.4 and the measured diameter of the septal defect was 14.9 ± 6.6 mm, whereas the balloon expanded diameter of the defect was 16.7 ± 6.7 mm.

The Ultrasept II™ devices used were 8 mm (two patients), 10 mm (three patients), 12 mm (five patients), 14 mm (four patients), 16 mm (three patients), 18, 20 mm (four patients), 22 mm (two patients), 24, 26, 30 mm (two patients), and 32 mm (two patients), with a mean device diameter of 17.5 ± 7.1 mm (Fig 3). All of the devices selected were successfully placed. After the placement of the device, there were no residual shunts evidenced by the angiography or intracardiac echocardiogram.

Median fluoroscopy time was 6 minutes, ranging from 5 to 16.5, and the median procedure time was 48 minutes, ranging from 29 to 125. All patients were discharged 24 hours after the procedure. During follow-up, at 7.1 ± 4.7 months, all patients showed complete closure of the defect and no evidence of perforation was found with transthoracic echocardiogram examination. The longest follow-up was 15 months in two patients (Fig 4) and the shortest follow-up was 1 month. In addition, a continuous decrease of right ventricular diastolic diameter was found with a basal median of 30 mm (25–49) and post-procedure value of 27.5 mm (18–33), $p = 0.01$, and Z-score of 2.6 (1.7–3.6) versus 1.9 (1–2.9) after catheterisation, $p = 0.01$. These data are shown in Table 2.

Discussion

The atrial septal defect is one of the most common heart diseases, comprising 7–10% of all of the CHD.[12] The percutaneous closure of the ostium secundum atrial septal defect is actually considered

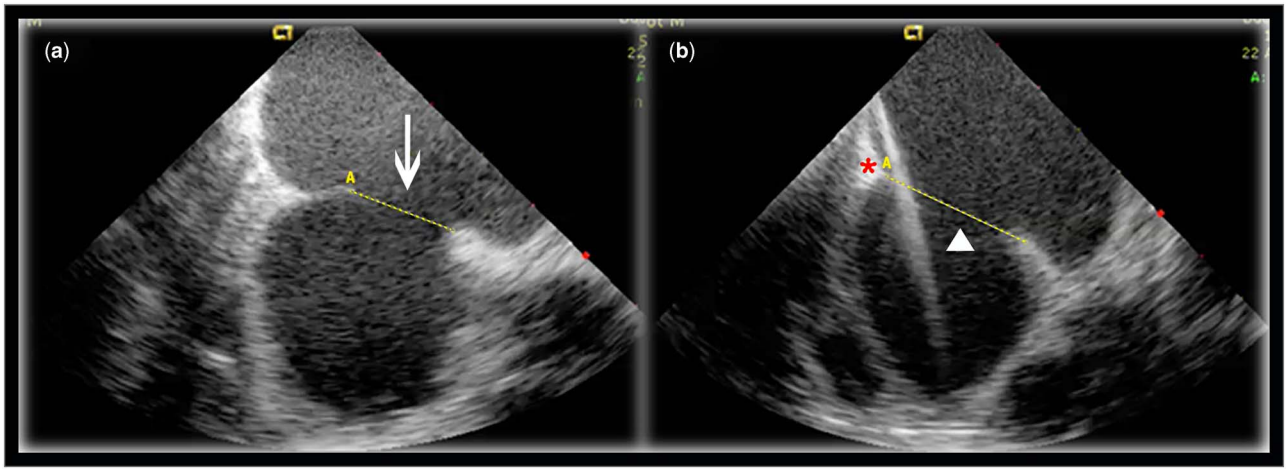

Figure 1. Short-axis intracardiac echocardiogram. (*a*) Measured basal diameter (arrow). (*b*) Catheter expanded diameter (tip of the arrow); the movement of the posteroinferior border can be observed (asterisk).

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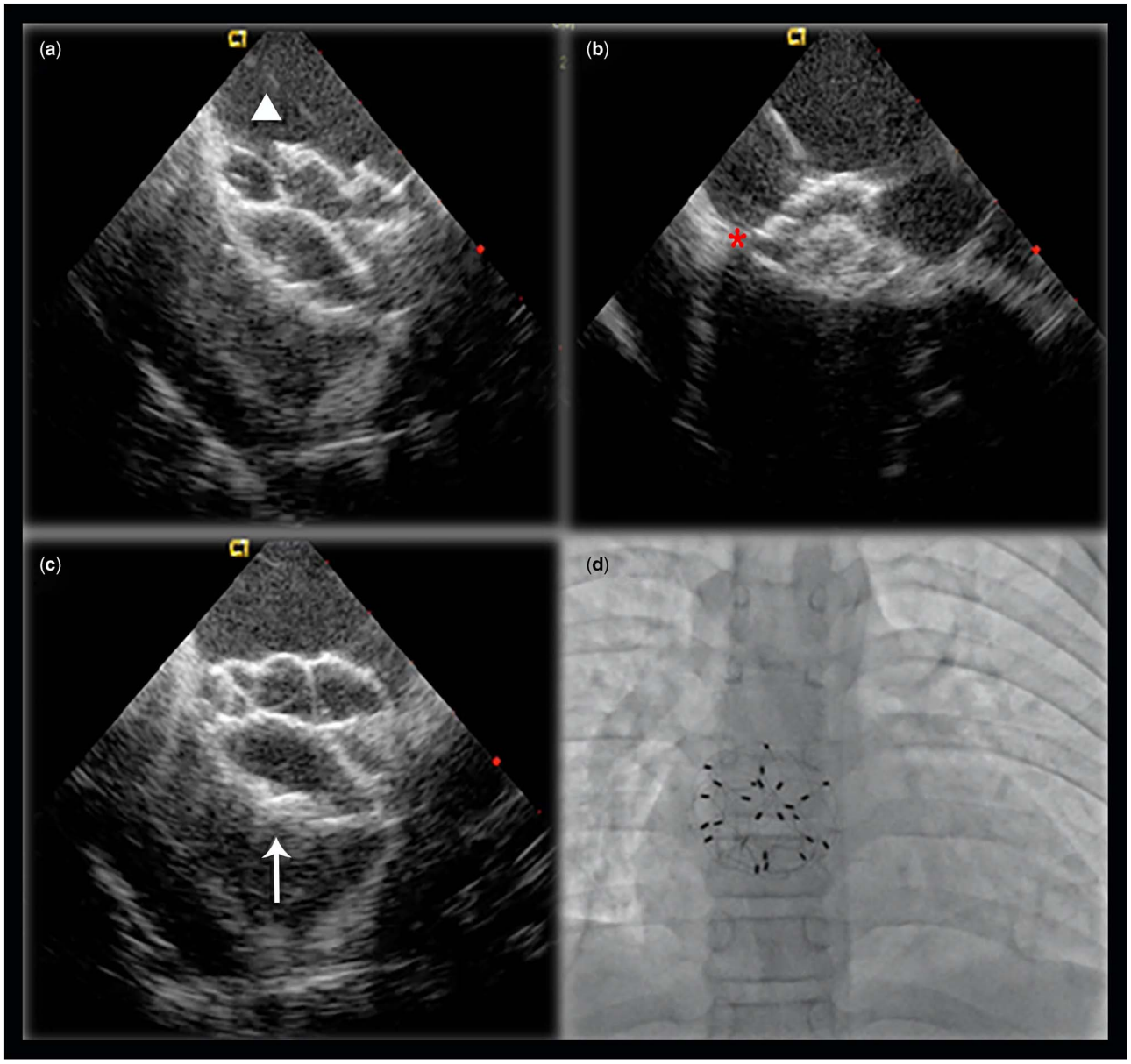

Figure 2. Final sequence once the Cardia Ultrasept II™ device has been placed. (*a*) Intracardiac echocardiogram. The correct placement of the device that is still being held by the cable (tip of the arrow). (*b*) Minnesota Manoeuvre where the correct position of both disks around the posteroinferior border can be observed (asterisk). (*c*) Intracardiac Echocardiogram. The device after being released (arrow). (*d*) Final position of the device seen by fluoroscopy.

as the elective treatment, and therefore many occluder devices have been developed to accomplish an adequate closure of this kind of defects. Since 1998, Cardia has created prostheses, which have been re-designed in multiple occasions. The Ultrasept II™ is the last generation of these devices created to close defects that measure between 6 and 38 mm in diameter.[6]

When performing the percutaneous closure of atrial septal defect, several post-procedure complications have been reported. In a review published in 2011 by Butera et al[13] where 1812 patients were catheterised, the percentage of complications was 5.4%, of which only 1.9% were major and in which embolisation and erosion with perforation were discarded. Chan et al[14] reported a total of 100 patients with minor complications such as one transient ST elevation, one transient AV block, one presumed deep-vein thrombosis, and one presumed transient ischaemic attack. Chessa et al[15] concluded that atrial septal defect closure is safe, with a low rate of early and late complications. However, some aspects need further and longer investigations, especially the possibility of late thrombus formation on the device, systemic embolisation, and, the most worrisome event, sudden death presented 1.5 years after the device was placed. In addition, with regard to follow-up, no follow-up has been reported in relation to patients who underwent atrial septal defect closure with the Cardia Ultrasept II™ device. However, the maximum limit at which the perforation of the polyvinyl alcohol membrane has been detected is at 10 months after closure.[8] In our series, there were no post-procedure complications in the short- or medium-term follow-up, and although this is relatively short it far exceeds the usual time of encountering this entity.

It has been reported in several publications about the malfunctioning (perforation) of the polyvinyl alcohol membrane

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Table 1. Demographic characteristics of the patients.

Cases	Age	Gender	Weight (kg)	Height (cm)	Diameter of device (mm)	BMI	Co-morbidities	Follow-up
1	8	F	30	130	20	17.7	None	15
2	8	M	32	145	30	15.2	None	15
3	11	F	42.5	152	14	18.3	None	14
4	13	F	40	142	32	19.8	None	13
5	6	M	27	124	26	17.5	None	13
6	29	M	90	178	32	28.4	None	13
7	10	M	39	144	12	18.8	None	12
8	1	F	7.7	67	16	17.1	None	12
9	3	F	10.3	92	22	12.1	None	12
10	1	F	7.2	71	12	14.2	None	10
11	13	F	38	140	24	19.3	None	10
12	15	F	52	157	30	21	None	9
13	8	F	29	132	12	16.6	None	8
14	4	F	13	93	20	15	None	6
15	6	F	18	108	20	15.4	None	6
16	7	M	19	115	18	14.3	None	6
17	3	F	14	95	8	15.5	None	5
18	1	F	12	90	14	14.8	None	4
19	3	F	12.6	92	16	14.8	None	4
20	6	F	17	109	22	14.3	None	4
21	2	F	11.5	85	16	15.9	None	4
22	3	F	12	93	10	13.8	None	4
23	8	F	17	135	12	9.3	None	4
24	1	F	11	69	14	23.1	None	4
25	6	F	14	122	20	9.4	None	4
26	3	F	14	119	12	9.8	None	1
27	5	M	24	125	8	15.3	None	1
28	4	M	14	91	10	16.9	None	1
29	4	M	18	100	14	18	None	1
30	9	F	27	129	10	16.2	None	1

BMI = body mass index; F = female; M = male

early after the closure of the atrial septal defect causing significant clinical deterioration in some of the patients who have been subjected to closure with the Ultrasept II™ device. Aubry et al[7] reported two cases in a series of nine consecutive patients: a 77-year-old man and a 41-year-old woman with dysfunction of 24 and 32 mm prostheses, respectively. Perforation zones in the Ivalon membrane were found with echocardiography 3 months after the implant. Bhattacharyya et al[8] reported the same complication in a 69-year-old man, 10 months after the placement of a 28-mm device. Ramoglu et al[9] also reported a case

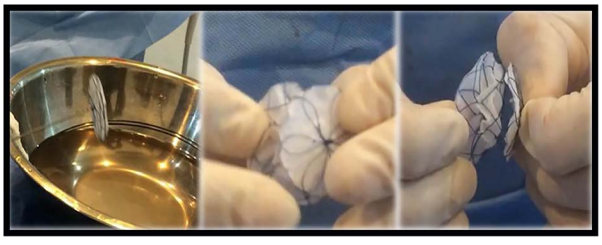

Figure 3. New Cardia Ultrasept II™ device with interposed Goretex patch.

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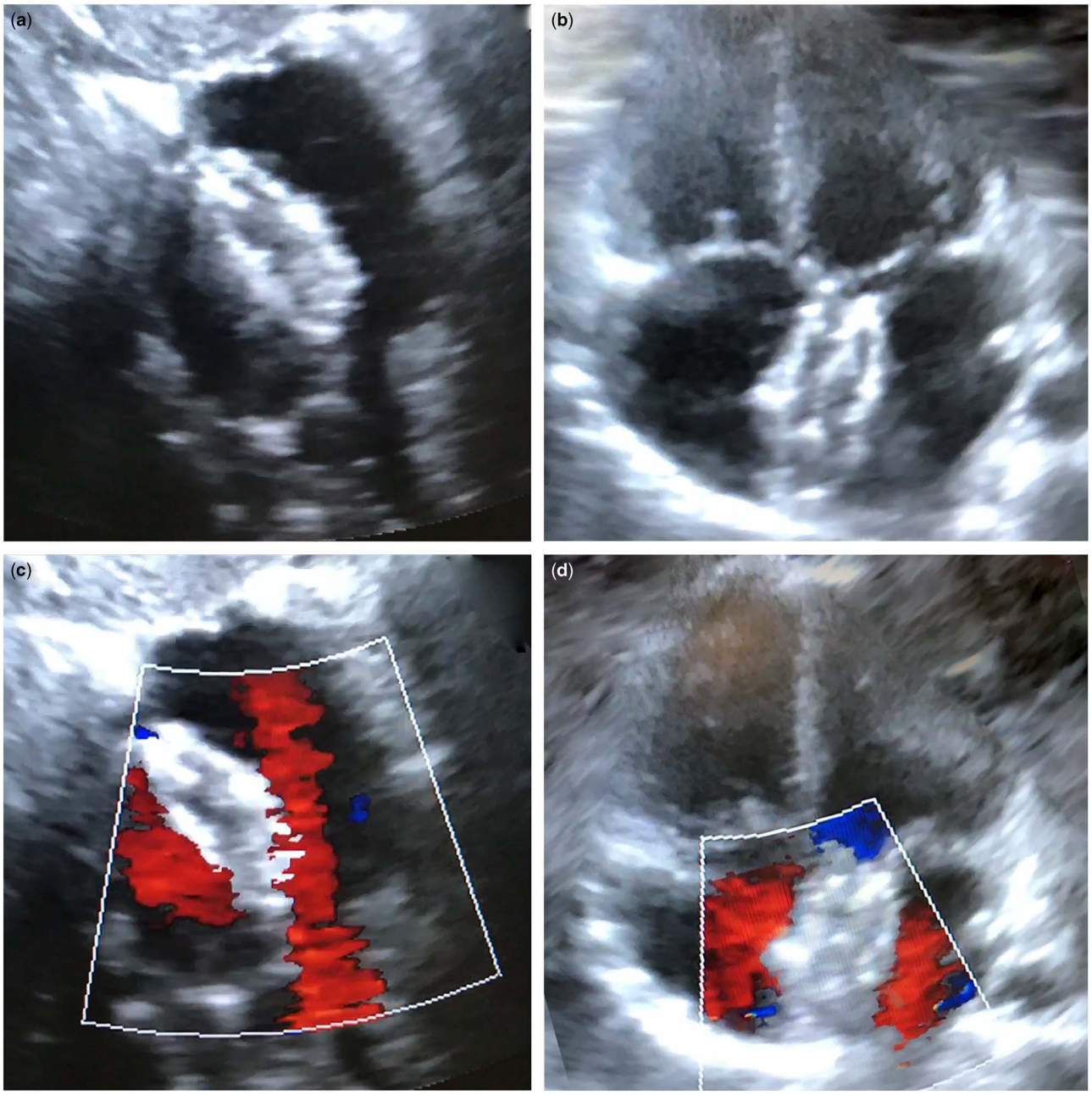

Figure 4. Transthoracic echocardiogram. (*a*, *b*) Two-dimensional echo shows complete device integrity. (*c*, *d*) Color Doppler echo. No perforations observed.

of early dysfunction after 1 week of the placement of a 20-mm Ultrasept II™ device in a 4-year-old boy, demonstrating the presence of multiple perforations in the polyvinyl alcohol membrane. Finally, Labombarda[10] reported in 2016 the largest series of patients with the presentation of this complication. They reported a total of four relatively early malfunctions of the polyvinyl alcohol membrane observed in a series of six consecutive patients treated with atrial septal defect Ultrasept II™ closure device from January to December 2014. Chamié et al[11] informed about four cases of early failure of the polyvinyl alcohol membrane and, in fact, they proposed a new and less invasive treatment for patients who present with early to mid-term failure of the polyvinyl alcohol sail-based devices.

After 2015, Cardia Inc. developed a new version of this same device – Ultrasept II™ – in which a Goretex patch has been interposed between both discs. In our series of 30 cases, patients have been monitored monthly with transthoracic echocardiogram, and at a follow-up of 7.1 ± 4.7months no residual shunts evidencing perforations in the Ivalon membrane have been found. This is probably because of the new Goretex patch placed in the new modified Ultrasept II™ device.

In addition, our follow-up data have corroborated the continuous decrease in the right ventricular diastolic diameter reaching even normal indexed diameters in most of the patients. To our knowledge, there are no reports to date informing the evolution of patients regarding the measurement of these diameters and the Z-score, which might be considered as a direct evidence of improvement after the implantation of the device.

These results might change the perspective of many institutions regarding this device.

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Table 2. Changes at the end of the diastole of the right ventricle diameters before and after the closure of the atrial septal defect using the new Cardia Ultrasept II™ device with Goretex patch.

Patient	Basal RVDD (mm)	Z-score	Follow-up RVDD (mm)	Z-score	Follow-up (months)
1	38	3.03	25	1.29	15
2	42	3.35	30	1.95	15
3	40	2.94	29	1.64	14
4	35	2.46	30	1.82	13
5	38	3.12	28.5	1.93	13
6	49	2.12	None	None	13
7	None	None	None	None	12
8	30	3.62	23	2.52	12
9	25	2.39	18	1.03	12
10	25	2.89	20	1.96	10
11	38	2.84	3.1	1.99	10
12	35	2.19	33	1.95	9
13	31	2.20	29	1.92	8
14	25	2.17	24	2.0	6
15	None	None	None	None	6
16	None	None	None	None	6
17*	26	2.25	25	2.09	5
18*	29	2.88	28	2.74	4
19*	30	2.96	29	2.82	4
20*	33	2.98	33	2.98	4
21*	26	2.51	23	2.0	4
22*	28	2.71	28	2.71	4
23*	30	2.45	28	2.16	4
24*	27	2.85	27	2.85	4
25*	31	2.81	30	2.68	3
26*	25	1.94	24	1.77	1
27*	27	1.78	27	1.78	1
28*	25	2.12	23	1.77	1
29*	30	2.59	28	2.3	1
30*	28	2.24	28	2.24	1

RVDD = right ventricular diastolic diameter
*To date, the follow-up has not reached 6 months

Conclusion

The new and modified generation device from Cardia is a safe and effective alternative for atrial septal defect closure. The main difference with other devices is the Ivalon cover and the interposed Goretex patch, which allows for an easy display of the disks, a subtle contact with adjacent structures within the atria while the device is being placed, and, most importantly, avoids major complications such as perforation of the polyvinyl alcohol membrane.

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Conflicts of Interest. None.

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