Scientific letter

Alterra device and Edwards SAPIEN 3. Pushing the boundaries of percutaneous pulmonary valve implantation

Dispositivo Alterra y válvula Edwards SAPIEN 3, ampliando los límites de la valvulación pulmonar percutánea

To the Editor,

Patients with congenital heart disease involving the right ventricular outflow tract (RVOT) sometimes require surgical or percutaneous treatment. This can lead to varying degrees of pulmonary insufficiency that, with time, can cause dilation and distortion of the right ventricle and the pulmonary trunk and branches, a condition known as dysfunctional RVOT.[1] Before the advent of new self-expanding valve systems and dedicated devices, such as the Alterra Adaptive Prestent (Edwards Lifesciences, USA), many patients with dysfunctional RVOT were not suitable candidates for percutaneous pulmonary valve implantation (PPVI) because of large RVOTs and the absence of a stable landing zone for valve placement.[1,2]

The Alterra Adaptive Prestent is a self-expanding device designed to reconfigure the RVOT and enable PPVI with a 29-mm Edwards SAPIEN 3 transcatheter heart valve (THV) (figure 1A). Computer simulations of the sequential deployment of the Alterra device and the SAPIEN 3 THV have been described in the literature.[3]

We present the first 2 cases in Europe of the combined use of the Alterra device and the SAPIEN 3 THV deployed using the new Edwards pulmonic delivery system. On the eve of the procedures, potential deployment sites were assessed using 3-dimensional (3D) computed tomography (CT) images of the RVOTs. Physical patient-specific 3D models were also constructed to simulate deployment of the Alterra device. In both cases, prior informed consent was obtained for the compassionate use of the device and publication of the case reports.

The first patient was a 17-year-old boy with tetralogy of Fallot who had undergone transannular patch repair at 7 months of life but developed severe pulmonary insufficiency during follow-up. Magnetic resonance imaging (MRI) showed a right ventricular end-diastolic volume (RVTV) of 169 mL/m^2. A distal location was selected for the implantation. The minimum trunk diameter was 34 mm (figure 1B, video 1 of the supplementary data). An initial attempt to deploy the Alterra device through the right pulmonary artery was unsuccessful due to a significant lack of coaxiality (figure 1C, video 2 of the supplementary data). A subsequent attempt via the left artery was successful (figure 1D, video 3 of the supplementary data). The Edwards pulmonic delivery system was then used to implant a 29-mm SAPIEN 3 THV (figure 1E, video 4 of the supplementary data). Echocardiographic assessment at 24 hours showed correct valve implantation and no evidence of pulmonary insufficiency (figure 1F, videos 5 and 6 of the supplementary data).

The second patient was a 16-year-old boy with congenital pulmonary stenosis treated by percutaneous valvuloplasty in the neonatal period; he had developed severe pulmonary insufficiency during follow-up. When he was 14 years old, he underwent percutaneous foramen ovale closure due to a history of cerebrovascular disease. At that time, MRI showed a minimum pulmonary trunk diameter of 30 mm and an RVTV of 152 mL/m^2. Use of the Alterra Adaptive Prestent was considered when the boy was 16 years old, as he was showing diminishing physical capacity. Proximal deployment was simulated using 3D-CT angiography (figure 2A). The initial angiogram showed marked RVOT dilation (figure 2B, video 7 of the additional material). After an unsuccessful attempt to deploy the Alterra device through the left pulmonary artery due to a lack of coaxiality, it was decided to switch to the right artery (figures 2C and D, videos 8 and 9 of the supplementary data). PPVI of the 29-mm SAPIEN 3 THV using the pulmonic delivery system was completed without difficulty (figure 2E, video 10 of the supplementary

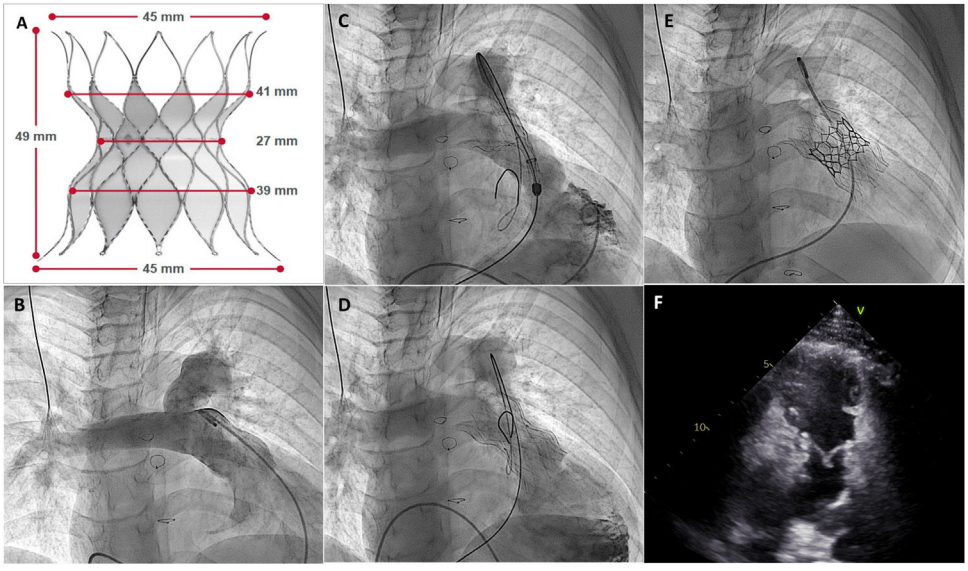

Figure 1. A: Alterra Adaptive Prestent. B, Initial pulmonary angiogram. C: partially deployed device. D: fully deployed device. E: Alterra device with the Edwards SAPIEN 3 valve. F: 2-dimensional echocardiography; parasternal short axis view showing the percutaneous valve inside the Alterra device.

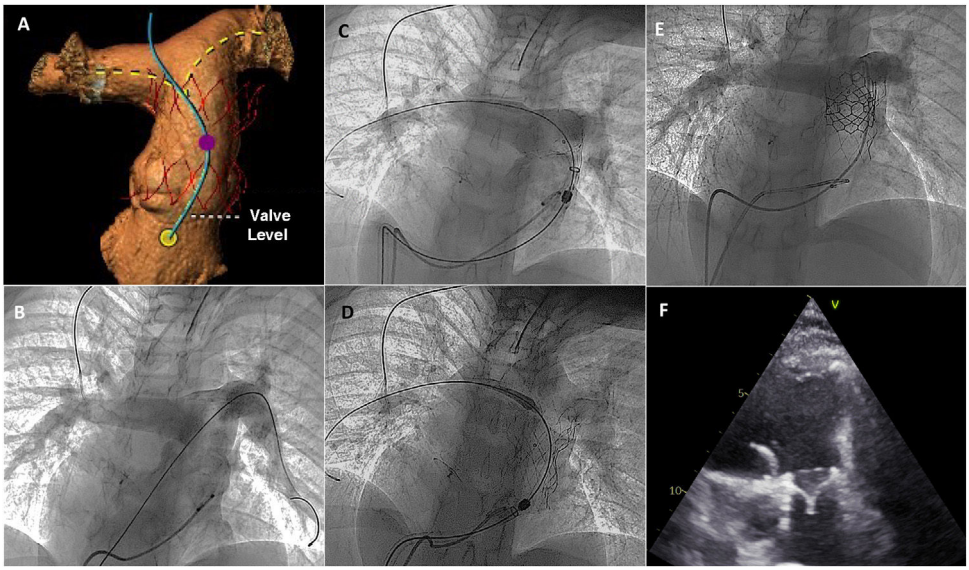

Figure 2. A: 3-dimensional computed tomography angiogram; simulated deployment of the Alterra Adaptive Prestent. B: initial pulmonary angiogram. C: partially deployed device. D: fully deployed device. E: Alterra device with the Edwards SAPIEN 3 valve. F: 2-dimensional echocardiography; parasternal short axis view showing the percutaneous valve inside the Alterra device.

data). Echocardiographic assessment at 24 hours showed correct valve implantation and functioning (figure 2F, videos 11 and 12 of the supplementary data).

The Alterra Adaptive Prestent is a self-expanding nitinol stent that reconfigures the RVOT to enable implantation of a 29-mm SAPIEN 3 THV. Its 27-mm central section provides a stable landing zone for the valve. It is partially covered with polytetrafluoroethylene, which seals the trunk, preventing perivalvular leaks and leaving the distal cells uncovered to facilitate blood flow to the pulmonary arteries. The device measures 45 mm at both ends, which have flared tips to facilitate adaptation and anchorage when working with large, elastic RVOTs. It is fitted with an adjustment wheel for precise stent positioning and retraction even when 65% is uncovered.[2]

Although long-term follow-up data are not yet available (the first implants were performed some 5 years ago in the United States), Shahanavaz et al.[1] reported 100% implantation success and no cases of valve dysfunction after 6 months in a series of 15 patients with a median age of 20 years and pulmonary trunk diameters ranging from 27 to 38 mm.

Other self-expanding stents are available for the treatment of pulmonary insufficiency in patients with a dysfunctional RVOT, but unlike the Alterra device, they have an integrated valve. Examples are the Venus P-Valve (MedTech, China), the Pulsta transcatheter pulmonary valve (TaeWoong Medical, South Korea) and the Harmony TPV 22 and TPV 25 (Medtronic, USA).[1,4] The Alterra device also differs in that it is available in a single size and is also shorter, enabling it to be implanted in the pulmonary trunk without invading the ventricular cavity. Edwards valves have been implanted in the pulmonary position since 2006, providing sufficient experience to help predict outcomes.[5] This positioning also enables future valve-in-valve implantation, prolonging freedom from reintervention according to a retrospective European multicenter study involving hospitals that voluntarily collect data on procedures and patients treated with the SAPIENS 2 THV for PPV for reporting purposes (Mid-Term Outcomes of Transcatheter Pulmonary SAPIEN 3 Valve Implantation: An International Multicenter Registry).

The Alterra Adaptive Prestent represents a potential turning point in the treatment of dysfunctional RVOTs. By enabling PPVI, it could provide large numbers of patients with a viable alternative to surgical intervention.

FUNDING

None.

AUTHORS' CONTRIBUTIONS

M. Figueras-Coll: study conception and design; data acquisition; data analysis and interpretation; writing of article; critical review of intellectual content; final approval. P. Betrián-Blasco: data acquisition; data analysis and interpretation; writing of article; critical review of intellectual content; final approval.

CONFLICTS OF INTEREST

None.

APPENDIX A. SUPPLEMENTARY DATA

Supplementary data associated with this article can be found in the online version available at doi:10.1016/j.rec.2023.08.001.

Marc Figueras-Coll[a,b,*] and Pedro Betrián-Blasco[a]

[a]*Unidad de Hemodinámica Pediátrica, Hospital Universitari Vall d'Hebron, Barcelona, Spain*
[b]*Unidad de Cardiología Pediátrica, Servicio de Pediatría, Hospital Universitari de Girona Dr. Josep Trueta, Girona, Spain*

* Corresponding author.
E-mail address: mfiguerascoll@gmail.com (M. Figueras-Coll).
𝕏 @mfiguerascoll

Available online 23 August 2023

REFERENCES

1. Shahanavaz S, Balzer D, Babaliaros V, et al. Alterra Adaptive Prestent and SAPIEN 3 THV for Congenital Pulmonic Valve Dysfunction: an Early Feasibility Study. *JACC Cardiovasc Interv.* 2020;13:2510–2524.
2. Zahn EM, Chang JC, Armer D, Garg R. First human implant of the Alterra Adaptive Prestent™: A new self-expanding device designed to remodel the right ventricular outflow tract. *Catheter Cardiovasc Interv.* 2018;91:1125–1129.
3. Edwards Lifesciences. Edwards SAPIEN 3 Transcatheter Heart Valve System with the Alterra Adaptive Prestent. 2022. Available from: https://youtu.be/hVweMsjm_xA. accessed 3 Jun 2023.
4. Guiguno L, Faccini A, Carminati M. Percutaneous Pulmonary Valve Implantation. *Korean Circ J.* 2020;50:302–316.
5. Le Ruzz R, Plessis J, Houeijeh A, et al. Edwards SAPIEN XT transcatheter pulmonary valve implantation: 5-year follow-up in a French Registry. *Catheter Cardiovasc Interv.* 2021;98:990–999.

https://doi.org/10.1016/j.recesp.2023.08.001
1885-5857/

Cost-utility of cardiac telerehabilitation versus conventional hospital rehabilitation after ACS in Spain

Coste-utilidad de la telerrehabilitación cardiaca frente a la rehabilitación hospitalaria convencional tras SCA en España

To the Editor,

The European Society of Cardiology guidelines on cardiovascular disease prevention recommend cardiac rehabilitation for patients with acute coronary syndrome.[1] Cardiac rehabilitation is a multidisciplinary program associated with lower cardiovascular morbidity and mortality, better health-related quality of life,[1] and reduced health care costs.[2] Cardioplan is a cardiac telerehabilitation (CTR) system that tracks everyday adherence to healthy heart habits in patients with acute coronary syndrome. In a randomized clinical trial (NCT04942977), we found that 10 months of CTR increased physical activity levels, favored a return to work, and improved adherence to the Mediterranean diet, emotional well-being, and inflammatory and lipid profiles compared with regular follow-up over the same period. Regular follow-up included 2 months of conventional center-based cardiac rehabilitation (CBCR).[3,4]

The aim of this study was to evaluate the cost-utility of prolonged CTR vs CBCR from a societal perspective (number of sick days and trips to the hospital) and the perspective of the Spanish national health system (NHS) (use of health care resources [visits, admissions, hospital tests, and rehabilitation sessions).

Fifty-nine patients who met the inclusion criteria and showed no differences in baseline demographic or clinical characteristics were randomized to receive CTR or CBCR. All patients provided signed informed consent and the study was approved by the ethics committee at Hospital Arnau de Vilanova in Valencia, Spain, and the Spanish Agency for Medicines and Health Products (AEMPS). Patients in the CTR group (n = 31) completed 4 educational and physical training sessions (walking and resistance training) at the hospital, where they were also instructed on the use of the Cardioplan smartphone application. This application was then used to monitor the different study variables at home and send messages promoting adherence to healthy lifestyle habits. Patients in the CBCR group (n = 28) participated in 16 cardiac rehabilitation sessions at the hospital and underwent regular follow-up for a total of 10 months (see Dalli Peydró et al.[3] for methods).

The effects of the CTR and CBCR interventions on patient quality of life were measured using the EuroQol 5-dimention 5-level survey (EQ-5D-5L).[5] This tool provides a summary index value (utility index) that facilitates calculation of quality-adjusted life years (QALYs).

Direct health care costs were calculated by multiplying resources consumed by unit costs. Additional costs considered in the CTR group were the annual license fee for the Cardioplan system and the cost of the support service.

QALYs were estimated using a regression model. The final values were calculated using the baseline index value obtained for each patient. The cost results (€2022) were grouped according to the 2 perspectives (societal and NHS).

Nonparametric sampling with replacement was used to assess uncertainty in the estimates and obtain 95%CIs. The results of the cost-utility analysis were reported using the incremental cost-effectiveness ratio (ICER) (ratio between difference in costs and difference in QALYs between the CTR and CBCR interventions).

Adjusted mean QALYs were similar in the CTR and CBCR groups (0.929; 95%CI, 0.891-0.966 vs 0.931; 95%CI, 0.904-0.958). The

Table 1
Summary of costs per patient (mean and 95%CIs obtained by nonparametric sampling with replacement)

	CBCR (n = 28)		CTR (n = 31)		Difference	
	Mean	95%CI	Mean	95%CI	Mean	95%CI
Primary care visits, €	208.59	(157.23-259.94)	98.78	(73.98-123.59)	−109.80	(−166.84 to 230.78)
Primary care telephone visits, €	28.45	(9.37-47.53)	9.72	(1.42-18.02)	−18.73*	(−39.53 to −0.15)
Cardiology visits, €	517.50	(426.78-608.14)	573.39	(485.73-661.05)	55.89	(−70.24 to 1323.2)
Emergency department visits, €	38.53	(1.36-75.7)	41.76	(1.38-82.14)	3.23	(−51.65 to 7.04)
Hospital admissions, €	277.00	(−258.52 a 812.43)	125.08	(−110.81 a 360.96)	−151.92	(−737.07 to 399.37)
Medical tests,[a] €	165.25	(−154.25 a 484.75)	36.51	(−32.34 a 105.36)	−128.74	(−455.58 to 180.17)
Cardioplan CTR license, €	0	0	100.20	NA	100.20	NA
Total cost national health care system perspective, €	1754.71	(812.26-2697.16)	1147.78	(813.82-1481.75)	−606.93	(−1606.82 to 392.96)
Trips to hospital, €	42.15	(40.52-43.79)	20.61	(19.03-22.19)	−21.55*	(−23.82 to −19.27)
Loss of productivity, €	3265.52	(1856.56-4674.48)	1122.75	(462.32-1783.17)	−2142.77	(−3698.87 to 1607.21)
Total cost from societal perspective, €	5062.38	(3119.44-7005.33)	2291.13	(1534.38-3047.89)	−2771.25[b]	(−4856.06 to −686.44)

CBCR, center-based cardiac rehabilitation; CTR, cardiac telerehabilitation; NA, nonapplicable.
[a] Includes ultrasound examinations, stress tests, cardiac magnetic resonance scans, coronary angiograms, and stents.
[b] Statistically significant difference (the CI does not cross 0).