Multicenter experience of transcatheter correction of superior sinus venosus defect using the covered Optimus XXL stent

Experiencia multicéntrica en la corrección transcatéter del defecto del seno venoso superior con el stent *Optimus XXL recubierto*

To the Editor,

Superior sinus venosus defect (SVD) is a rare congenital heart disease accounting for 5% to 10% of all cases of atrial septal defect.Transcatheter correction of SVD using covered Cheatham-Platinum stents (NuMED, United States) has emerged as an alternative to open-heart surgery.[1–3] The 50- and 60-mm long stents subsequently received Conformite Europeenne marking and Food and Drug Administration approval. However, the anatomical configuration of SVD often requires a stent longer than 60 mm, which are currently unavailable in many countries.[3] The Optimus XXL stent (AndraTec GmbH, Germany) is a nonpremounted, balloon-expandable, cobalt-chrome, extra large stent, used for endovascular stenting of aortic coarctation or for right ventricle outflow tract stenting.[4] A covered 99-mm long version was specifically developed for SVD correction, as recently reported in one case.[5]

We report a multicenter case serie of 6 additional consecutive cases achieved in 3 centers in 2 countries between November 2021 and March 2022 in adults aged 26 to 72 years. The study design was approved by an ethics committee (GERM, IRB00012157). Informed consent was obtained from the patients.

Patient and procedural characteristics are reported in table 1. All patients complained of dyspnea and had significant left-to-right

Table 1
Description of patients' characteristics, procedural data and outcomes.

Patient	1	2	3	4	5	6
Age	43	26	42	60	49	72
Symptoms	Dyspnea	Dyspnea	Dyspnea, pulmonary hypertension	Dyspnea, atrial fibrillation	Dyspnea	Dyspnea, pulmonary hypertension
Ratio of pulmonary to systemic output		2.5	2.2			2.9
Mean pulmonary artery pressure, mmHg	19	12	38			29
Pulmonary vascular resistance, Wood Unit			5.1			2
High anomalous pulmonary venous return	No	Yes	Yes	Yes	Yes	No
Preprocedural planning	Virtual simulation 3-dimensional printed model hands-on simulation testing	Virtual simulation 3-dimensional printed model hands-on simulation testing	Virtual simulation 3-dimensional printed model hands-on simulation testing	Virtual simulation	Virtual simulation	Virtual simulation 3-dimensional printed model hands-on simulation testing
Pulmonary vein management	No transseptal puncture	Transseptal puncture, no balloon protection	Transseptal puncture, balloon protection	Transseptal puncture, balloon protection	Transseptal puncture, balloon protection	Transseptal puncture, balloon protection
Stent delivery balloon	Covered Optimus 99 XXL Balloon-in-Balloon 22 mm x 80 mm	Covered Optimus 99 XXL Balloon-in-Balloon 22 mm x 80 mm	Covered Optimus 99 XXL Balloon-in-Balloon 18 mm x 80 mm	Covered Optimus 99 XXL Gemini 30 mm x 100mm	Covered Optimus 99 XXL Gemini 30 mm x 100 mm	Covered Optimus 99 XXL Balloon-in-Balloon 22 mm x 70 mm
Additional stent	No	Bare Optimus XL at the upper end	No	No	Bare Cheatham Platinium stent at the upper end	Bare Optimus XL at the upper end
Stent stability	Yes	Yes	Yes	Yes	Yes	Migration to the right atrium - stent stabilized using an additional stent in the superior vena cava
Pulmonary vein obstruction	No	No	No	Pulmonary vein obstruction of the upper right component resolved by dilation and reverse remodelling of the stent	No	No
Periprocedural complication	No	No	No	No	No	Obstruction of right ventricle inflow, with right to left shunt through a foramen ovale - resolved by covered stent strut opening by balloon dilation
Residual shunt	Tiny, nonsignificant	No	No	Moderate	No	Minor
Follow-up	9 mo - clinical success	9 mo - clinical success	6 mo - clinical success	5 mo - remaining dyspnea and moderate residual shunting	4 mo - clinical success	2 mo - remaining dyspnea, residual minor bidirectional shunting

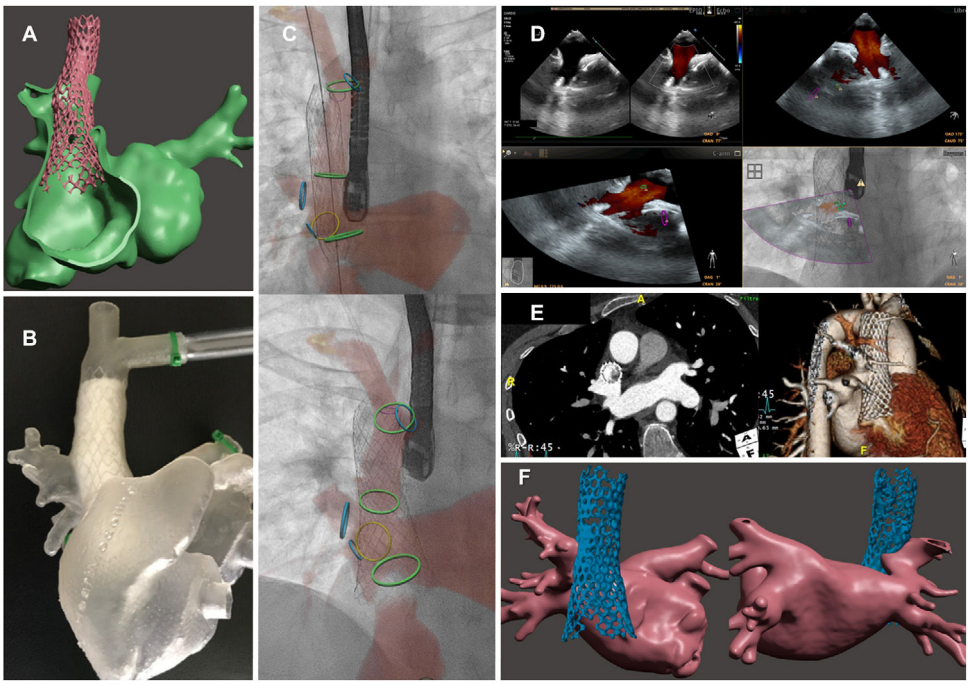

Figure 1. Clinical case 1. A 43-year-old man with SVD. A: computer simulation of Optimus stent implantation. B: hands-on simulation testing. C: stent implantation under fusion imaging guidance. D: color Doppler flow showing a widely patent pulmonary vein channel toward the left atrium. E and F: cardiac tomography confirms excellent position of the stent, complete occlusion of the SVD and widely patent pulmonary vein channel.

shunt. High opening of the anomalous pulmonary venous return in the superior vena cava (SVC) was idenfied in 4 cases. Procedural feasibility was tested on virtual simulation in all patients and hands-on simulation training in 4 (figure 1).[6] To define the best treatment option, a multidisciplinary team including heart surgeons assessed the imaging and simulation processes. Transcatheter correction was considered as an alternative to surgery in all patients. As previously described,[1–3,6] all procedures were performed under general anesthesia and transesophageal echocardiography guidance. Multimodal fusion imaging was applied in 5 patients (figure 1). A venous femoro-jugular rail was used. Transseptal access was employed to establish an anomalous pulmonary venous return pathway in 5 patients, with balloon inflation simultaneous to Optimus stent deployment in 4.

In 2 patients, a single size (outer/inner balloon of 30/14-mm diameter and 100-mm length) Gemini balloon-in-balloon was used to implant the stent (AndraTec GmbH, Germany). The maximum diameter of this ballon was larger than the SVC diameter. In 4 patients, the single size 100-mm length Gemini balloon was not chosen given a too large diameter and other 20 to 30 mm shorter balloon-in-balloon stents were used (NuMED, United States), with an outer balloon diameter between 18 to 22 mm to match the diameter of the SVC (figure 1). This setting required additional inflations of the extremities of the stent that were not fully expanded by the smaller balloons. A second uncovered stent was implanted at the upper part of the stent in 3 patients to provide additional anchoring to the SVC.

In 4 patients, we achieved technical and clinical success. One procedure was marked by pulmonary vein obstruction reversed by pulmonary vein balloon dilation but leading to residual shunting and persistant dyspnea. One of the 4 patients in whom a shorter balloon-in-balloon was used was complicated by displacement of the stent toward the right atrium. The stent was subsequently anchored in the SVC using another uncovered stent and struts of the Optimus stent had to be opened to restore flow toward the right ventricle. In this patient, a modified suture control technique may have been useful to secure the stent position before full stent deployment and impaction on SVC was obtained.[5] Outcome was favorable. Unadequate diameter or length of the balloon-in-balloon contributed to these 2 complications.

Transcatheter correction of a SVD using a covered Optimus XXL 99-mm stent was feasible in all 6 patients. The strengths of the Optimus stent are its adequate length and high comformability. This allows deep and stable implantation in the SVC, whereas its good flexibility allows optimal flaring of the the proximal part of the end of the stent to achieve complete shunt closure. When the area of stent implantation in the SVC is too short, the stent may migrate, as observed in 1 patient. A modification of the Optimus stent with a longer uncovered part at the upper end was performed to address this issue and strengthen the anchoring in the SVC. Currently available Gemini balloons with multiple balloon sizes will also optimize stent implantation.

To conclude, the Optimus covered, 99 mm-long, Optimus XXL stent allows successful transcatheter SVD. Further experience and a wider range of stent/balloons are needed.

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AUTHORS' CONTRIBUTIONS

C. Batteux, and V. Ciobotaru participated in the study design and preclinical testing. C. Batteux, V. Ciobotaru, H. Bouvaist,

A. Kempny, A. Fraisse and S. Hascoet participated in the clinical cases and data collection. S. Hascoet and A. Fraisse drafted the manuscript. All authors critically revised the manuscript.

CONFLICTS OF INTEREST

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Safety and efficacy of a sedation protocol combined with propofol as the second step in transesophageal echocardiography

Eficacia y seguridad de un protocolo de sedación combinado con propofol como segundo escalón para el ecocardiograma transesofágico

To the Editor,

Transesophageal echocardiography (TEE) causes nausea, pain, and anxiety and must be performed under sedation and analgesia. The American Society of Echocardiography and the Society of Cardiovascular Anesthesiologists recommend a number of drugs for this purpose (topical anesthesia, benzodiazepines, opioids, and, with a narrower safety profile, propofol), but they do not specify doses, combinations, or order of administration.[1] Midazolam is recommended as the drug of choice by the European Association of Cardiovascular Imaging, which proposes fentanyl as an alternative but does not mention propofol.[2] Spanish law does not dictate which physicians are allowed to use propofol. This drug is widely used to induce anesthesia during procedures requiring deep sedation, but its use has spread to TEE, where it is sometimes administered by cardiologists. A study comparing anesthesiologist-administered propofol, midazolam, and midazolam-alfentanil during TEE found that propofol produced deeper, more rapid sedation without major complications.[3] Another study comparing propofol administered by anesthesiologists and nonanesthesiologists during TEE found that mild respiratory complications were more common in the first group because the patients had a higher risk profile.[4] Propofol has also been shown to be an effective sedation agent in a clinical trial setting.[5]

We describe our experience with a sedation and analgesia protocol that includes propofol as a second option when adequate sedation is not achieved with midazolam and pethidine. The anesthesia department at our hospital is familiar with and has endorsed the use of this protocol.

We prospectively included all patients who underwent TEE from May 2020 to April 2021. The study was approved by the local ethics committee. A 10-item safety checklist was administered before each procedure, and propofol was not allowed in patients allergic to peanuts, soy, or eggs. Four expert echocardiographers performed the procedures in a room with cardiopulmonary resuscitation equipment. All patients received oxygen via a nasal cannula (3 L/min) and were administered topical lidocaine at the discretion of the echocardiographer. The protocol is shown in figure 1. Frail patients and patients with a high American Society of Anesthesiologists score were administered half a dose of pethidine (25 mg) or none. Following TEE examination, patients were transferred to the recovery room and their intravenous access maintained until they regained consciousness and their vital signs were stable.

Blood pressure, heart rate, oxygen saturation, and sedation level (Ramsay scale) were recorded at baseline and every 3 minutes. Sedation time was defined as the time from sedation initiation to probe withdrawal and recovery time as the time from probe withdrawal to discharge from the recovery room. Before leaving the hospital, patients completed a questionnaire in which they were asked to rate the following: *a*) their perceived level of sedation on a 10-point visual analog scale (VAS), where 10 represented ideal sedation, and *b*) level of discomfort or pain,