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REC Scientific letter

Multicenter Experience of Transcatheter Correction of Superior Sinus Venosus Defect Using the Covered Optimus XXL Stent

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

Short title: Optimus stent for superior sinus venosus defect repair

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To the Editor,

Superior sinus venous defect (SVD) is a rare congenital heart disease accounting for 5–10% of cases of all atrial septal defects. 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 that are unavailable currently in many countries.³ The Optimus XXL stent (AndraTec GmbH, Germany) is a non-premounted, 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 multicentre case-series of 6 additional consecutive cases achieved in three centres from 2 countries between november 2021 and march 2022 in adults aged 26 to 72 year-old. The study design was approved by an ethical committee (GERM, IRB00012157). Informed consent of the patients was collected. Characteristics of patients and procedures are reported in table 1. All patients complained of dyspnoea and had significant left-to-right shunt. High opening of the anomalous pulmonary venous return in the superior vena cava (SVC) was identified in 4 cases. Procedure feasibility was tested on virtual simulation in all patients and hands-on simulation training in four (figure 1).⁶ A multidisciplinary team including heart surgeons assessed the imaging and simulation processes to define the best treatment option. Transcatheter correction was considered as an alternative to surgery for all patients. As previously described,^{1-3,6} all procedures were done under general anesthesia, transesophageal echocardiography guidance. Multimodal fusion imaging was applied in 5 cases (figure 1). A venous femoro-jugular rail was used. Transseptal access to establish an anomalous pulmonary venous return pathway was used in 5 cases, with balloon inflation simultaneously to Optimus stent deployment in 4. In 2 cases, 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 maximal diameter of this balloon was larger than the SVC diameter. In 4 cases, 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 were used (NuMED, United States), with an outer balloon diameter between 18 to 22 mm to match the diameter of the SVC (figure 1). Such setting required additional inflations of the extremities of the stent that were not fully expanded by those smaller balloons. A second uncovered stent was implanted at the upper part of the stent in 3 cases to provide additional anchoring to the SVC.

In 4 cases, 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 persistent dyspnoea. One of the 4 cases where a shorter balloon-in-balloon was used was complicated by displacement of the stent towards 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 case, 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 The outcome was favorable. Unadequate diameter or length of the balloon-in-balloon have contributed to these 2 complications.

Transcatheter correction of a SVD using a covered Optimus XXL 99mm in length stent was feasible in all six patients. The strengths of the Optimus stent are its adequate length and high conformability. This allows a long and stable implantation in the SVC, whereas the great flexibility allows optimal flaring of the proximal part of the stent end in order to achieve complete shunt closure. When the area of stent implantation in the SVC is too short, the stent may migrate as observed in one case. A modification of the Optimus stent with a longer uncovered part at the upper end has been done to address this issue and strengthen the anchoring in the SVC. Gemini balloons with multiple balloon sizes that are now available will also optimise 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, V. Ciobotaru, participated in the study design and pre-clinical testing. C. Batteux, V. Ciobotaru, H. Bouvaist, A. Kempny, A. Fraisse and S. Hascoet participated to 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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Table 1

Description of patients' characteristics, procedural data and outcomes.

Case	1	2	3	4	5	6
Age	43	26	42	60	49	72
Symptoms	dyspnoea	dyspnoea	dyspnoea, pulmonary hypertension	dyspnoea, atrial fibrillation	dyspnoea	dyspnoea, 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 3d printed model hands-on simulation testing	virtual simulation 3d printed model hands-on simulation testing	virtual simulation 3d printed model hands-on simulation testing	virtual simulation	virtual simulation	virtual simulation 3d 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 22mm x 80mm	covered Optimus 99 XXL Balloon-in- Balloon 22mm x 80mm	covered Optimus 99 XXL Balloon-in- Balloon 18mm x 80mm	covered Optimus 99 XXL Gemini 30mm x 100mm	covered Optimus 99 XXL Gemini 30mm x 100mm	covered Optimus 99 XXL Balloon-in- Balloon 22mm x 70mm
Additional stent	No	Bare optimus XL at the upper end	No	No	Bare Cheatham Platinum 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 solved by dilation and reverse remodeling of the stent	No	No
Per-procedural complication	No	No	No	No	No	Obstruction of right ventricle inflow, with right to left shunt through a foramen ovale - solved by covered stent strut opening by balloon dilation
Residual shunt	Tiny, non significant	No	No	Moderate	No	Minor
Follow-up	9 months - clinical success	9 months - clinical success	6 months - clinical success	5 months - remaining dyspnoea and moderate residual shunting	4 months - clinical success	2 months - remaining dyspnoea, residual minor bidirectional shunting

Figure legends

Figure 1. Clinical case 1. A 43-year-old man with SVD. **A** :Computerised simulation of Optimus stent implantation. **B**: Hands-on simulation testing. **C**: The stent is implanted under fusion imaging guidance. **D**: Color Doppler flow shows that the pulmonary vein channel toward the left atrium is widely patent. **E and F**: Cardiac tomography confirms excellent position of the stent, complete occlusion of the SVD and widely patent pulmonary vein channel.

