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CASE REPORT

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Transcatheter creation of bidirectional cavopulmonary connections by needle punctures in two patients

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Abstract

We report on two patients who received a transcatheter cavopulmonary connection by a needle puncture under deep conscious sedation. In both patients, the vessel-to-vessel connection was achieved by a venous access into the superior caval vein and direct needle puncture of the pulmonary artery. The two cavopulmonary anastomoses were held open by a covered stent and a bare-metal stent, respectively.

KEYWORDS
congential heart disease, adults, congenital heart disease, pediatrics, endovascular intervention, interventional devices/innovation, stenting technique

1 | INTRODUCTION

Transcatheter creation of a cavopulmonary connection has been described in animal experiments [1–4] and was recently described in a patient who was judged as inoperable. [5] Here we report on two additional patients who received the same transcatheter procedure using a simplified approach. We describe and discuss the key steps of the procedure. These are the second and third case described in the literature.

2 | CASE SERIES

2.1 | Patient 1

A 48-year-old patient with double inlet left ventricle (DILV) and Fontan circulation (right atrium [RA] to pulmonary trunk connection) suffered from severe enlargement of the RA with atrial flutter and ascites.

Surgical therapy to relieve congestion at right atrial level was declined by the surgical team due to multiple Fontan-related comorbidities. After an interdisciplinary case conference, it was decided to offer the patient a transcatheter cavopulmonary connection.[2,4,5] After thorough explanation of the particularity of the procedure, the patient gave his informed consent. A cardiac computed tomography-scan with contrast was performed for planning the procedure (Figure 1). Then, in a first step, a 26-mm Andra XXL stent (Andramed GmbH, Reutlingen, Germany) was implanted in the superior caval vein (SVC) to serve as an anchor and—after ingrowth—to seal the connecting stent. The vena azygos was closed with a 10-mm Amplatzer Vascular Plug II (AGA Medical Corporation, Plymouth, MN). Eight weeks thereafter, through a 7F sheath (Terumo Introduced II 7F, Length 10 cm, Terumo Medical Corp., Elkson, MD) in the right femoral vein, a gooseneck snare (PFM Medical AG, Cologne, Germany) was advanced into the right pulmonary artery (RPA) just proximal to the branching of the right upper lobe artery, serving as a marker for the puncture (Figure 2). The SVC measured 20 mm and the RPA 22 mm. Another 7F sheath (Terumo Introduced II 7F, Length 10 cm, Terumo Medical Corp.) was inserted under ultrasound guidance into the right jugular vein above the right clavicle. Then, RPA was punctured with a 15-cm-long 22 G Chiba needle (Optimed GmbH, Ettlingen, Germany) (Figure 2) and a coronary wire (0.014 in., 190 cm length, HI-Torque Floppy II, Extra Support, Abbott Vascular, Santa Clara, CA) placed into the RPA. A Progreat Micro Catheter (Terumo Medical Corporation, Somerset, NJ) inserted into an 4F catheter (right coronary Amplatzer modified Super Torque, 35 in., length 100 cm, Cordis Corporation, Miami Lakes, FL) in a telescope technique were advanced over the coronary wire and placed in the RPA. The coronary wire and the microcatheter were removed and replaced by a noodle wire (Amplatzer™ Guidewire 35 in., length 300 cm, AGA Medical Corporation). Then, a 39-mm covered CP-Stent (NuMED, Inc., Hopkinton, NY) was implanted on a 16-mm balloon (Z-MED II 16 mm/4 cm, NuMED Canada Inc., Cornwall, ON, Canada) across a 12F sheath (Check-Flo Performer 12Fr, Length 30 cm, COOK MEDICAL LLC, Bloomington, IN). For better apposition, a second

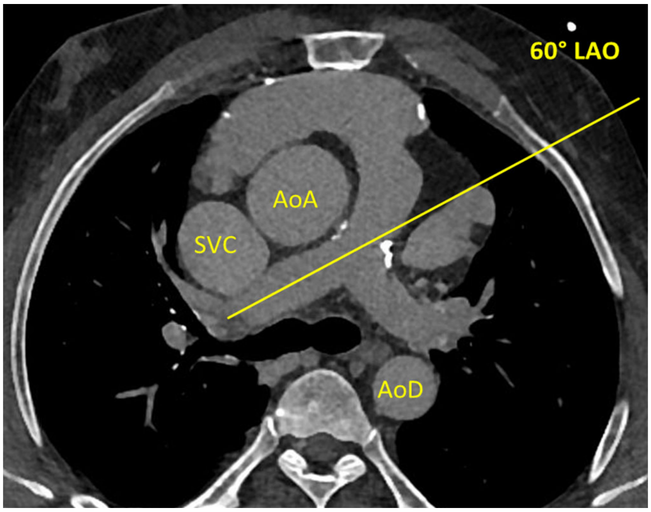

FIGURE 1 Transverse plane of a CT-scan (Patient 1). The angle of the RPA long axis is determined to 60° LAO (yellow line). This angle serves as orientation for the lateral fluoroscopy plane to guide the needle puncture from the SVC to the RPA. RPA, right pulmonary artery; LAO, left anterior oblique; SVC, superior vena cava [Color figure can be viewed at wileyonlinelibrary.com]

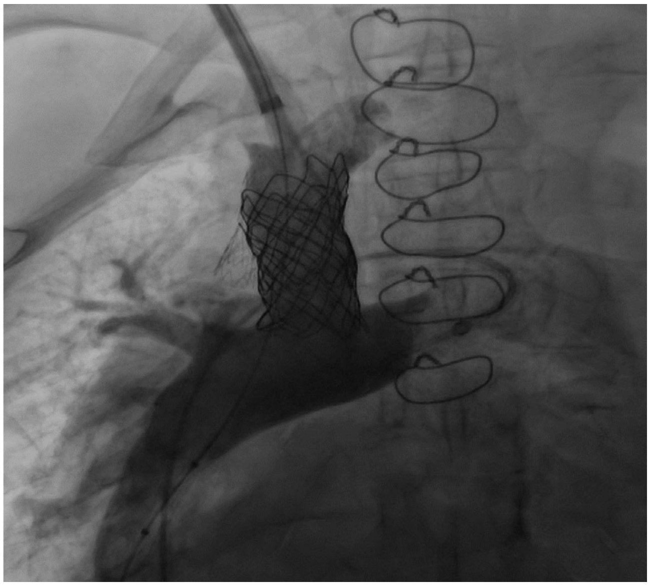

FIGURE 3 Cavopulmonary anastomosis (Patient 1). Successfully established partial cavopulmonary connection by a bare-metal stent (prestent) and two covered CP-Stents. Angiography into the superior caval vein opacifying the right pulmonary artery

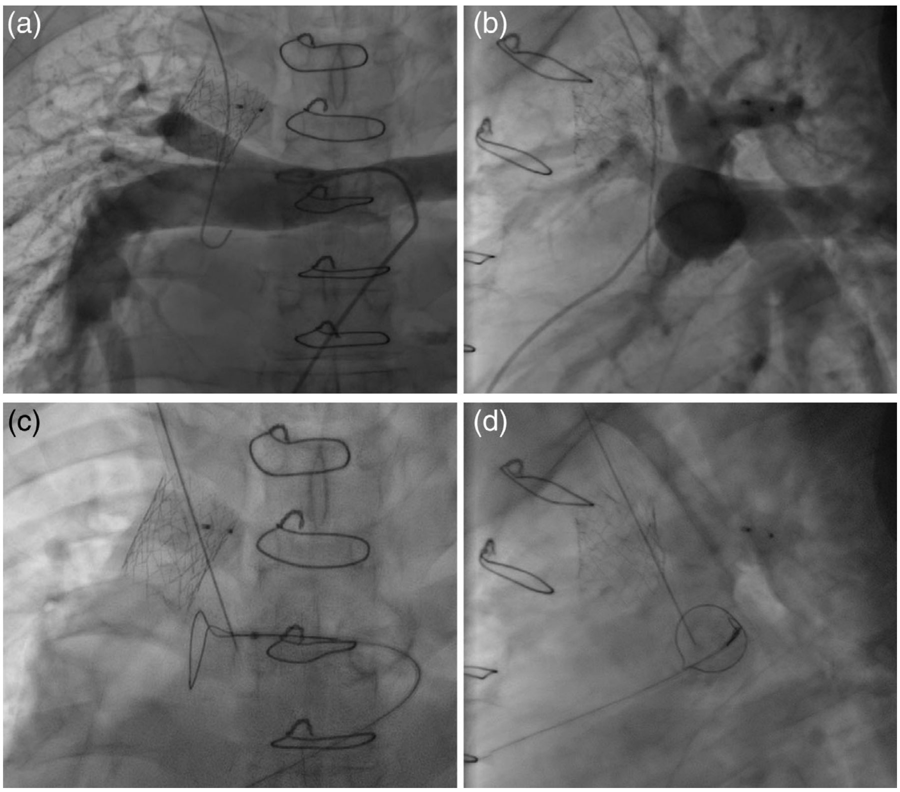

FIGURE 2 Preparative angiography and puncture (Patient 1). Top panel: Angiography into the RPA (posterior anterior and 60° LAO). The prestent marks the SVC. Bottom panel: Puncture needle across the prestent in the RPA (same projections as above). The needle was advanced through side cells and the covered stent placed via that route. RPA, right pulmonary artery; LAO, left anterior oblique; SVC, superior vena cava

CP-Stent was implanted and the stents were flared to the SVC with a 24-mm Atlas balloon (Bard Peripheral Vascular, Tempe, AZ). As a result, a broad connection without stenosis or significant residual flow to the RA could be demonstrated (Figure 3).

Preintervention, this patient had an intractable heart failure. After the procedure, the clinical condition improved but atrial flutter remained. He was discharged 5 days after the procedure and monitored in our outpatient clinic. After the procedure his clinical condition remained stable initially, but begun to worsen after 4 months. There were neither clinical signs of venous congestion of arms or head nor signs of stent dysfunction such as leakage or perforation. Unfortunately, heart failure was too advanced, and the patient died at home 6 months after the procedure.

2.2 | Patient 2

An 18-year-old patient with complex univentricular heart defect (left isomerism, complete atrioventricular septal defect, ventriculoarterial discordance with pulmonary atresia and discontinuity of the pulmonary vessels, bilateral ductus, and partial anomalous pulmonary veins drainage) received a total cavopulmonary connection (TCPC) at the age of 2 years. During the following 16 years, a small left SVC without bridging vein to the right SVC drained an increasing amount of venous blood draining into the left atrium, leading to a significant right to left shunt with arterial saturations of 78%. In a prior procedure, the vein was successfully closed percutaneously at its orifice to the left atrium, with the perspective that a small bridging vein to the right SVC may develop. However, venovenous fistulas developed to the left pulmonic veins instead and the arterial saturation dropped again. In an interdisciplinary case conference, decision was made for a percutaneous cavopulmonary connection and a subsequent transcatheter closure of the fistulas.

Informed consent was obtained, and a 7F sheath (Terumo Introduced II 7F, Length 25 cm, Terumo Medical Corp.) was placed in the left jugular vein. To mark the target vessel, a 10-mm Multi Snare® (PFM Medical AG) was placed in the left pulmonary artery (LPA). The vessel-to-vessel access was achieved by direct puncture of the LPA with a 15-cm-long, 18G needle (Somatex® Medical Technologies GmbH, Berlin, Germany). A 35-in. guidewire (Amplatzer™, Abbott,

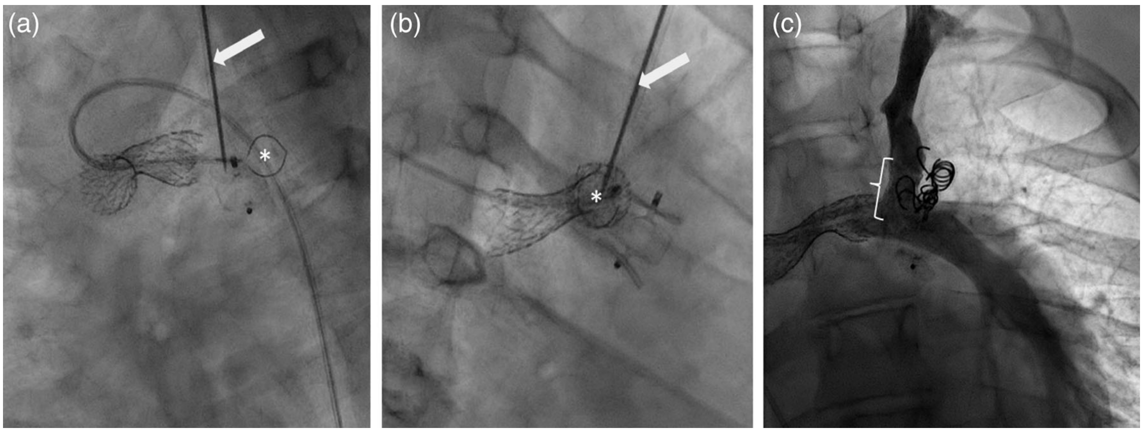

FIGURE 4 Procedural steps and result (Patient 2). (a) and (b) The biplane puncture (a: 50°LAO; b: 40°RAO, 9°caudal). The arrows mark the puncture sheath, and the asterisks represent the 10 mm snare. C: After implantation of a 10-mm bare-metal stent (bracket) and closure of venovenous fistulas (coils), the new transcatheter cavopulmonary connection between left superior caval vein and left pulmonary artery is demonstrated by angiography (13°LAO). *Note*: the LPA Stent and the plug into the SVC were placed 2 years earlier. LAO, left anterior oblique; RAO, right anterior oblique; LPA, left pulmonary artery; SVC, superior vena cava

TABLE 1 Procedural data

	Total duration (hh:mm)	DAP (Gy × cm^2)	Total fluoroscopy (min)	Amount contrast agent (ml)
Patient 1				
Prestent	01:23	7.8	15	57
Main procedure	03:18	22.6	26	60
Patient 2				
Main procedure	00:42	14.1	10	21
Fistula occlusion	01:13	16.1	11	34

Notes: As Patient 1 received two procedures, separate data are presented for the implantation of the present and the main procedure. For the second patient the time needed for the interventional PCPC and the time needed for coil closure are stated separately. In detail, the total duration of the procedures, the DAP, the total length of the fluoroscopy time, and the total amount of the applied contrast agent.

Abbreviations: DAP, dose area product; PCPC, partial cavopulmonary connection.

TABLE 2 hemodynamic parameters of both patients

	Patient 1		Patient 2	
	Pre	Post	Pre	Post
SO2%	94	94	78–82	93
SVC mmHg	22	20	16	16
LPSVC mmHg	—	—	16	14
RPA mmHg	22	20	16	14
LPA mmHg	22	20	10	14

Notes: SO2 indicates the measured oxygen saturation in the abdominal aorta in percent. Patient 1 had a failing Fontan circulation with an atriopulmonary connection. Over time, the pressures in the venopulmonary connection have increased to 22 mmHg leading to hepatic dysfunctions and chronic ascites. Additionally, the right atrium was severely enlarged, leading to chronic atrial flutter. Post intervention the venopulmonary pressures decreased not to the extent expected. Patient 2 suffered from hypoxemia. The venopulmonary pressures were in the upper range (16 mmHg). Additionally, there was a pressure gradient of 6 mmHg between RPA and LPA. After converting his hemodynamics into a bidirectional PCPC, the venopulmonary pressures dropped to 14 mmHg and his oxygen saturation normalized.
Abbreviations: LPA, left pulmonary artery; PCPC, partial cavopulmonary connection; RPA, right pulmonary artery; SVC, superior vena cava.

Chicago, IL) was placed in the LPA through the needle and the 7F sheath advanced over the wire into the LPA. The left persistent superior vena cava and the LPA were connected by a 10 × 20 mm bare-metal premounted Formula Stent (COOK MEDICAL LLC) and the Fistula was closed with Nester® Embolization Coils (COOK MEDICAL LLC) (Figure 4). The SVC and RPA were measured with 7 and 10 mm, respectively. This saturation level rose up to 94% after the procedure. After 5 months of follow-up, he was still in good condition and was monitored in our outpatient clinic. Procedural and hemodynamic data of both procedures are shown in Tables 1 and 2, respectively.

3 | DISCUSSION

Transcatheter perforation techniques have become accepted and used therapies to avoid open-heart surgery. Recently the first interventional creation of a cavopulmonary anastomosis was reported in humans. [5] The RPA was connected with the SVC by an electrified guide wire, advanced in a complex telescoping technique through a guiding catheter, a microcatheter, a 0.014 guide wire and a 0.035-in. wire converter. A three-dimensional rotational angiography and a superimposed CT-scan were used to guide the perforation. For the anchoring of the covered stent, two bare-metal stents were implanted in the SVC and the RPA, respectively.

In our approach, we performed a CT-scan to rule out any unforeseen anatomical obstacles and to plan the biplane conventional x-ray machine (Figure 1). As a valuable marker for the target region, we used a gooseneck snare of corresponding size of the pulmonary artery and oriented it perpendicular to its long axis. In the first patient, the snare was placed directly in front of the bifurcation of the right upper lobe artery to make sure the puncture is directed to the main RPA. In the second patient, the snare was placed about 1.5 cm beyond the distal end of a LPA stent. Thus, the stent and the snare defined a short tubular target region (Figure 4a). As a consequence, in a fluoroscopy view along the long axis of the target vessel, the snare marked the vessel and provided an excellent circular landing zone for the needle puncture (Figures 2a and 3b).

3.1 | Needle puncture versus electric energy-based perforation techniques

In previous animal experiences and in the first human case,[2,5] the perforation of the vessels had been performed by high-energy application to a perforation wire. The wire has to be placed and stabilized by a guiding catheter. In our experience, the forward push during energy application may result in wire or catheter dislodgment as well as in an unpredictable course through the tissue. A needle, in contrast, can be oriented very precisely and the puncture itself is very predictable and extremely well controlled. [3] Theoretically, the needle could be bend to be more convenient to the anatomy. [4] In our cases, however, it was not necessary and we did not in order to keep the procedure as much straightforward as possible.

3.2 | Anastomosis

The use of the 18G needle enables the immediate placement of a 0.035-in. guidewire and allows the advancement of a conventional sheath in order to prevent bleeding. Additionally, this provides a well-sized access for safe stent placement at the same time. The risk of extravasation should be limited, albeit the fact that massive bleeding in the low-pressure system is unlikely in any case.

While in the first patient, a covered stent separated the SVC from the RA, in the second patient, the connection to the atrium was already closed by a plug. Thus, in the latter, we used a bare-metal stent to connect the LPA. This concept had been successfully proven by our former studies connecting aorta and pulmonary artery in piglets. [1] During stent placement, the stent is dilated from both ends, forming an hourglass shape and thus, pushing the vessel walls to each other. The dilation of the tissue itself forms a bulge in each vessel wall, which creates an additional sealing.

Our modified approach with straightforward needle puncture not only allows the avoidance of open-chest surgery with longer recovery time, it even enabled us to perform the procedure—since it is our standard approach in almost all transcatheter interventions—under deep conscious sedation, providing optimal hemodynamic support for the passive inflow across the anastomosis by spontaneous breathing.

Interventional creation of a cavopulmonal anastomosis is a demanding technique, but, as demonstrated, can be performed without sophisticated equipment in a conventional catheterization lab. Whether this promising technique could be applied to infants has to be determined in the future. This has to take into account implantation of stents dilatable to adult size, redilations of the stents and a concept for the cannulation of the stented SVC at the time of surgical completion of the Fontan circulation.

4 | CONCLUSION

To the best of our knowledge, this is the first report about the creation cavopulmonary connections in deep conscious sedation. This is a manageable, technically feasible procedure and the hemodynamic-morphologic result is comparable to that of surgery. Although the proof of concept was achieved just in two individual cases so far, we feel that the procedure has the potential to become an established technique at least in a limited group of adults with congenital heart disease.

CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

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