Transcatheter implantation of covered stents serving as extravascular conduits—Proof of a CT-based approach in three cases

Peter Ewert PhD, MD | Andreas Eicken PhD, MD | Daniel Tanase PhD, MD | Stanimir Georgiev MD | Albrecht Will | Cornelia Pankalla | Nicole Nagdyman | Christian Meierhofer | Jürgen Hörer

1Department of Pediatric Cardiology and Congenital Heart Disease, German Heart Center Munich, Technical University of Munich, Munich, Germany
2Deutsches Zentrum für Herz-Kreislauflorschung (DZHK), Munich Heart Alliance, Munich, Germany
3Department of Radiology and Nuclear Medicine, German Heart Center Munich, Technical University of Munich, Munich, Germany
4Department of Congenital and Pediatric Heart Surgery, German Heart Center Munich, Technical University of Munich, Munich, Germany
5Division of Congenital and Pediatric Heart Surgery, University Hospital of Munich, Ludwig-Maximilians-Universität, Munich, Germany

Abstract

Background: Covered stents perform similar to surgically implanted conduits, although the stents work inside of vessels. We present a computed tomography (CT)-based workflow for the implantation of covered stents as extravascular conduits.

Methods: We selected three different use cases: 1. Connecting a left-sided partially anomalous drainage of a pulmonary vein to the left atrium. 2. Bypassing an outgrown Dacron conduit in aortic recoarctation. 3. Re-directing hepatic venous blood to the left lung in a Fontan patient with heterotaxy, connecting the innominate vein to the right pulmonary artery like a right-sided cavopulmonary connection. By postprocessing and analyzing CT scans for planning and by the use of long needles under biplane fluoroscopy for the realization of the procedure, we projected and performed the exit of a long needle out of a vessel, the re-entering of a target vessel, and the bridging of the extravascular distance by implantation of covered stents.

Results: In all three cases, the covered stents were placed successfully, connecting vessels of 15–50 mm distance from each other with very good hemodynamic results. In one case, two stents were placed consecutively, overlapping each other to accomplish an exact fitting at the connection sites to the native vessels.

Keywords

congenital heart disease, covered stents, extravascular conduits, transcatheter intervention

1 | INTRODUCTION

Since the 60s of the last century, Dacron- or polytetrafluoroethylene (PTFE)-conduits serve as carriers for biological valves, as vessel substitutes for parts of the aorta or the pulmonary trunk, as aortopulmonary shunts or extracardiac conduits in the Fontan circulation.

In the catheterization laboratory, the introduction of covered stents in the early 90s revealed their ability to work similarly to conduits. They are placed into a vessel like in
aortic coarctation or, more rarely, they connect adjacent vessels.

While surgeons use conduits to connect distant vessels under direct vision, transcatheter stent implantation is dependent on real-time imaging and relies partially on guidance by the vessel anatomy itself. Therefore, and despite the availability of different covered stents, extravascular, transcatheter connections of distant vessels has not been established yet. On the other hand, modern computed tomography (CT) provides high-resolution three-dimensional (3D) datasets of the detailed intrathoracic anatomy. Can these datasets serve as a roadmap to develop an extravascular catheterization technique, in which catheters leave a vessel, re-enter a target vessel, and subsequently covered stents were implanted as bridging conduits?

In this manuscript, we present and describe such an approach in three cases as a new conceptual workflow.

2 | METHODS

2.1 | General strategy

Based on CT scans, we planned transcatheter procedures using long needles to exit one vessel and to re-enter a target vessel, followed by the implantation of covered stents as bridging extravascular conduits. We selected three different cases (Figure 1A–C).

2.1.1 | Case 1

A 52-year-old female patient suffered from partial anomalous drainage of the left upper pulmonary vein (PAPVD) into a vertical vein and a secundum type atrial septal defect (ASD II) (Figure 2A). A CT scan demonstrated a distance of approximately 29 mm from the vein to the roof of the left atrium (LA). It was concluded to bridge this distance with a covered stent.

2.1.2 | Case 2

A 42-year-old male with aortic coarctation and outgrown Dacron conduit of 12 mm diameter (Figure 1B), implanted 40 years ago, suffered from arterial hypertension. To avoid reoperation, it was decided to implant a covered stent parallel to the surgical conduit. A distance of 15 mm outside the Dacron conduit had to be bridged.

2.1.3 | Case 3

A 45-year-old woman with complex univentricular heart including situs inversus thoracalis and continuity of the left-sided azygos vein had been operated on with a left-sided cavopulmonary connection and a hepatic venous conduit to the right pulmonary artery 7 years before (Figure 1C). She suffered from increasing cyanosis with arterial oxygen saturation of 75%–80% due to intrapulmonary shunts in the left lung. It was presumed that the drainage of the hepatic venous blood exclusively to the right lung might be a major responsible factor.

In an attempt to improve the drainage of hepatic venous blood to the left lung, it was concluded to redirect a competitive venous blood flow from the innominate vein to the right pulmonary artery by implanting a covered stent like a right-sided cavopulmonary connection (Figure 1C). The distance from the innominate vein to right pulmonary artery was 50 mm.

2.2 | Planning the procedures

We performed CT scans in end-inspiration and mid-diastole by a dual-source CT (SOMATOM Force; Siemens Healthineers) with acquisition times of less than 0.3 s and an average dosage of 1.6 mSv (Table 1). Using the postprocessing software Syngo.via, Version VB30A_HF06 (Siemens Healthineers), we determined...
the best implantation sites for the covered stents: From multiple angles and under different presets, we analyzed the anatomy and excluded any possible delicate structures like abnormal vessels or bronchi in the target regions. An example is given in Figure 3.

Once the extravascular path was appointed, we looked for landmarks, which could be aimed at during the procedure. We defined the optimal angulations for the biplane fluoroscopy projections and looked from the perspectives and angles of each monoplane projection for further landmarks of the needle pathway (Table 1).

The results served for the elaboration of a detailed stepwise description of the procedure as well as backup plans for possible complications or emergencies.

During the procedures, all patients were breathing spontaneously under deep conscious sedation with Propofol and Piritramide as needed. A surgical team was available at any time.

All patients gave their consent after being informed about the technical aspects and the novelty of the procedures.

All three procedures were exempted from review by the institutional review board (Ethics Commission) of The Technical University Munich, Munich, Germany.

3 | RESULTS

3.1 | Case 1

After right femoral and left jugular venous access, a 10 mm Amplatz Goose Neck Snare (ev3) was placed across the ASD under the roof of the LA as a target for the needle puncture. Angiographies of the PAPVD were made according to the projections deduced from the CT scan. Through a 6F guiding catheter (JR4; Cordis), a manually straightened transseptal needle (St. Jude) with the stiff end of a 0.014″ coronary wire (Balance Middleweight; Abbott) was placed at the corresponding site opposite to the snare catheter. Exiting and entering punctures were performed with wire and needle, which were caught with the snare immediately after entering the LA (Figure 2C). A wire rail from femoral to jugular vein was established and a 7F long sheath (Terumo) advanced over the wire from the jugular vein to the LA. Through the sheath, an 8 × 38-mm Advanta V12 covered stent (Getinge) was positioned (Figure 2D) and implanted to establish an open connection from the PAPVD to the LA (Figure 2E). A CT scan demonstrated the correct placement of the stent (Figure 2B). Five days later, balloon test occlusion of the vertical vein excluded any gradient across the stent. The vertical vein and the
### TABLE 1  Transcatheter implantation of covered stents as extravascular conduits: Imaging and planning

| Case   | Diagnosis                        | Planned intervention                                      | CT data | Fluoroscopy projections | Critical structures nearby                                      |
|--------|----------------------------------|-----------------------------------------------------------|---------|-------------------------|---------------------------------------------------------------|
|        |                                  |                                                           | Collimation (mm) | Dosage (mSv) | Plane A | Plane B | Landmarks<sup>a</sup> |                                                                 |
| Case #1| Left PAPVD                        | Redirecting left upper PV into LA                        | 0.28    | 0.6                     | 1.87    | 0° RAO | 90° LAO | Small aberrant pulmonary vein; protuberance at LA roof | Main pulmonary artery; left main bronchus |
| Case #2| Recoarctation, outgrown Dacron conduit | Implantation of a covered stent as a second jump graft | 0.25    | 0.6                     | 1.37    | 60° RAO | 30° LAO | Calcifications; surgical clip | Trachea |
| Case #3| Heterotaxy, PAVM                   | Redirecting hepatic venous blood to the left lung        | 0.25    | 0.6                     | 1.56    | 0° RAO | 90° LAO | Snare in aortic arch; surgical clip | Aorta; right lung; right upper pulmonary vein |

*The target vessels were additionally marked with a snare catheter in all cases.*

### Abbreviations:
- CT, computed tomography
- LA, left atrium
- LAO, left anterior oblique
- PAPVD, partial anomalous pulmonary venous drainage
- PAVM, pulmonary arteriovenous malformation
- PV, pulmonary vein
- RAO, right anterior oblique
- TI, acquisition time

### TABLE 2  Transcatheter implantation of covered stents as extravascular conduits: Procedural data

| Case   | Age | Vascular access (French) | Donor vessel (diameter) | Recipient vessel (diameter) | Inter-vascular distance | Needle | Type of stents (diameter × lengths) | Hemoglobin (g/dl) pre-/postprocedure |
|--------|-----|--------------------------|-------------------------|-----------------------------|-------------------------|--------|------------------------------------|--------------------------------------|
| Case #1| 52  | V. jug. sin. (11F)       | Left upper pulmonary vein (14 mm) | Left atrium (n.a.) | 29 mm | Transseptal needle 0.014” wire | Advanta V12 (8 mm × 38 mm) | 15.0/13.7 |
|        |     | V. fem. dex. (10F)       |                          |                             |                         |        |                                    |                                      |
| Case #2| 42  | A. fem. sin. (7F)        | A. desc. (21 mm)         | Transverse aortic arch (18 mm) | 15 mm | Transseptal needle 0.014” wire | Bentley BeGraft (9 mm × 27 mm) | 16.5/14.5 |
|        |     | A. axill. dex. (4F)      |                          |                             |                         |        |                                    |                                      |
| Case #3| 45  | V. jug. dex. (7F)        | V. subcl. dex. (10 mm)   | Right pulmonary artery (12 mm) | 50 mm | Puncture Sheath<sup>a</sup> | 2 Bentley BeGrafts (10 mm × 37 mm) | 14.5/14.0 |
|        |     | V. jg. sin. (7F)         |                          |                             |                         |        |                                    |                                      |
|        |     | A. fem. dex. (6F)        |                          |                             |                         |        |                                    |                                      |

<sup>a</sup>Somatex; for illustration see Figure 6.
FIGURE 3  One example of one screenshot, planning the procedure in Case #1. A combination of 2D and 3D images is used to understand the topography and to look for possible pathways and procedural fluoroscopic views for a needle puncture from the PAPVD to the left atrium (LA). 2D, two dimensional; CAUD, caudal; LAO, left anterior oblique; PA, pulmonary artery; PAPVD, partial anomalous pulmonary venous drainage [Color figure can be viewed at wileyonlinelibrary.com]

FIGURE 4  Recoarctation 40 years after implantation of a 12 mm Dacron prosthesis. The CT scan served to find the best possible projections for the biplane fluoroscopic views (A: Plane A; B: Plane B). It gave important information about calcifications (white spots) and the spatial relationship of a surgical clip (arrows) to the intended extravascular pathway. (C) Successful puncture and re-entering of the descending aorta with a transseptal needle armed with the stiff end of a 0.014″ wire. A snare catheter from the right axilla has already captured the wire. (D) The result after implantation of a 9 mm covered stent. (E) Nine months later, implantation of a bare-metal stent into the Dacron conduit and simultaneous dilatation of both stents with 12 mm balloons. (F) In final angiography, the residual gradient across this “double arch” was 5 mmHg. CAUD, caudal; CT, computed tomography; LAO, left anterior oblique; RAO, right anterior oblique [Color figure can be viewed at wileyonlinelibrary.com]
ASD were closed with a 16/12 mm Amplatzer Vascular Plug II and a 16 mm Amplatzer ASD Occluder, respectively (Abbott). Ten months after the procedures, a CT scan showed a patent-covered stent and a closed vertical vein (Table 2).

3.2 | Case 2

After femoral and right axillary arterial access, biplane angiographies of the aortic arch were made according to the optimal projections derived from the CT dataset (Figure 4A,B). A manually straightened transseptal needle (St. Jude) with the stiff end of a 0.014” coronary wire (Balance Middleweight; Abbott) was worked through the extravascular tissue parallel to the prosthesis (Figure 4C). After re-entering the aortic arch, predilation was necessary to advance a 7F long sheath (Flexor; Cook) through the tissue next to the prosthesis. Subsequently, a covered stent (Bentley BeGraft peripheral, 9 × 27 mm; Bentley) was implanted (Figure 4D). Nine months later, the Dacron prosthesis was stented with an Intra Stent LD Mega (ev3) and both stents were simultaneously dilated with 12 mm balloons (Powerflex Pro; Cordis and Atlas Gold; Bard) (Figure 4E). The residual gradient across the so constructed artificial double arch (Figure 4F) was 5 mmHg. At discharge, there was no pressure gradient between the right arm and legs (noninvasive pressure measurements).

3.3 | Case 3

In a CT scan, a straight pathway from the innominate vein to the right pulmonary artery was identified, passing the aortic arch and the right-sided pleura (Figure 5). The extravascular distance was determined to be approximately 5 cm.

Vascular access was gained from both jugular veins. From the left side, a 15 mm snare (Multisnare; pfm) was placed into the right pulmonary artery. From the right jugular access, a 15 cm long Puncture Sheath (Somatex) (Figure 6) was introduced and advanced under biplane fluoroscopy guidance in the caudal posterior direction aiming at a surgical clip and beyond until the needle entered the right pulmonary artery marked by the snare.

A 0.035” guidewire was introduced through the puncture sheath and snared (Figure 7A,B). Over a wire rail from right to left jugular vein a 7F long sheath (Terumo) was introduced from the left jugular vein across the pulmonary artery and the mediastinum into the innominate vein (Figure 7C).

A 10 × 37mm covered stent (Bentley BeGraft peripheral; Bentley) was positioned with its distal end into the innominate vein (Figure 7D) and dilated (Figure 7E). Thus, the proximal opening of the stent ended in the mediastinum. To avoid uncontrolled bleeding the lumen of the stent was blocked with a saline/contrast-filled balloon of a 6F wedge catheter (Arrow) (Figure 7F). A second identical stent was implanted overlapping the first one (Figure 7F) so that it fitted precisely in the right pulmonary artery puncture site. (Figure 7G,H). In the left azygos vein, the pulmonary arteries, and the hepatic veins, pre- and postintervention pressure was 10 mmHg. Six months after the intervention, the oxygen saturation had increased from 75%–80% to 85%–89%.

4 | DISCUSSION

While the extravascular implantation of the covered stents was a minimally invasive treatment, the standard treatment of left PAPVD is the surgical redirection of the anomalous vein to the left atrial appendage.12

![FIGURE 5](https://wileyonlinelibrary.com/content/2059)
Aortic recoarctation in adults has to be operated on if the lesion is complex like in our case. Due to extensive arterial collaterals and scar tissue, surgery can be difficult, and a lateral thoracotomy causes adult patients considerable discomfort.

The surgical redirection of hepatic venous blood for the treatment of pulmonary arteriovenous malformations in Fontan patients is challenging. Interestingly, Wu and Nguyen connected a hepatic conduit directly to the innominate vein, implanting a conduit similar to the extravascular stents in Case #3, although with opposite flow direction. In addition, transcatheter solutions by intravascular stents have been reported, but in contrast to our case, they were based on ipsilateral or bilateral superior caval veins.

In the past, innovative transcatheter therapies have often emerged through the introduction of new devices. Dilatation balloons, stents, occluders, and heart valves – each of them are examples of breakthroughs in the treatment of structural cardiac and vascular diseases.

Imaging modalities like transesophageal echocardiography, intravascular or intracardiac ultrasound, 3D echocardiography, or optical coherence tomography have refined these interventions, but are more helpful adjuncts than originators.

Our concept of exiting and re-entering veins and arteries in the chest to implant covered stents as bridging conduits is not originated from new devices but is based on – processing and analyzing a 3D CT dataset and – translating the CT information into a plan for an
extravascular transcatheter procedure with long needles and covered stents.

The workflow is illustrated in Figure 8.

4.1 | 3D-rotational angiography and CT overlay

3D-rotational angiography (RA) is often used to improve the understanding of a 3D vascular anatomy and to find the best angulation for an intravascular transcatheter procedure. In the presence of a CT scan, however, the detailed vascular and extravascular anatomy, as well as the optimal projection, can be determined without a 3D-RA.

It has to remain open whether a superimposed CT scan would have been helpful. Prospective studies, proving the advantages of a CT overlay, are still lacking.18 For the decisive steps of the workflow (Figure 8, blue frame), overlay was not necessary.

4.2 | Technical aspects of the interventions

4.2.1 | Needle punctures

For the perforations, we used needle punctures as a straightforward method10 – in two cases armed with a coronary wire. Especially for long distances up to several centimeters like in Case #3, the exact steering facilities of a needle under biplane guidance had been very useful. Whether radiofrequency applied with stiff wires through a very stiff sheath would have been an alternative, as described by others,19 has to remain open. The handling of the needles is simple, is possible with high accuracy, and is independent of an electric generator or specific electrodes. Furthermore, we believe, that in Case #2 radiofrequency would probably have failed due to the calcifications of the tissue.

4.2.2 | Wire rails and sizing up

In all cases, we established a wire rail. It enables the gradual and alternate sizing up of sheaths from both access sites keeping the punctures sites of the exited and entered vessels continuously stuffed to avoid inadvertent bleeding. Furthermore, it enables angiographies for the exact positioning of the undilated stent: In contrast to the conventional intravascular stenting, an angiography through the introducer sheath of the stent cannot opacify the distal vessel or – more important – bares the risk of injecting dye outside the vessel into the mediastinum.

4.2.3 | Stent placements

Generating an end-to-side anastomosis by covered stents implicates a protrusion of the stent into the target vessel which may potentially cause obstruction. In Case #2, this was not an issue since the connecting stent was placed parallel to the long axis of the aorta. Furthermore, in all cases, the diameters of the implanted stents remained well under the diameter of the target vessels.

4.2.4 | Choice of stents

We used balloon dilatable covered stents because they have small introducer sheaths, offer a selection of appropriate stent lengths, and provide considerable radial force. The latter was anticipated to be necessary to keep perforated vessel walls,10 the perforated pleura, or the left atrial wall open. Especially in Case #2, we experienced extremely firm scar tissue, which made a self-expanding graft unlikely to be efficient. The specific selection of the covered stents was based on available stent lengths and diameters.
4.2.5 | Overlapping stents

To tailor the conduit lengths in the third case as accurately as possible, two covered stents were overlapped as needed. This technique was already described by Noeldge et al. for transjugular portosystemic shunts, but they had no need for blocking the orifice of the first stent, as we did in our case to avoid mediastinal bleeding.

4.2.6 | Naïve versus postsurgery tissue

Case #1 had never been operated before. Thus, the tissue was soft and bore the risk of uncontained bleeding into the pleural or pericardial space. On the other hand, native tissue can be perforated with ease and good predictability. In Case #2, in contrast, 40 years after the last of two operations, the tissue was extremely scarred, firm, and cumbersome to penetrate. Therefore, the risk of uncontained bleeding into the mediastinum or the left-sided pleura was very low. In Case #3, bleeding could have occurred from the innominate vein, from the right pulmonary artery and – by an unintentional puncture – from the aorta into the mediastinum or the right-sided pleura. The patient was indeed operated before, but the extent of scar tissue along the needle pathway could not be anticipated. Luckily, the surgeons left metallic clips in the chest, which were included in the planning and the realization of the procedure (Figures 5 and 7A,B).

4.2.7 | Anticoagulation

All patients received 5000 IU heparin at the beginning of the catheterizations and an additional 2500 IU according to ACT controls during the procedures.

In Case #1, we prescribed apixaban to prevent thromboembolism from the surface of the covered stent and the remnants of the vertical vein.

In Case #2, no anticoagulation was administered after the procedure in accordance with our institutional guidelines for stents in aortic coarctation.

In Case #3, the patient was on warfarin (international normalized ratio 2–3) according to our institutional guidelines for Fontan patients. We did not change this regimen.

4.2.8 | Complications

We monitored the patients closely for pleural effusions and hemopericardium by echocardiography. No bleedings occurred. There was one minor complication in Case #3: We inadvertently made a hand injection of approximately 10ml dye into the implantation sheath after the placement of the first stent. Thus, we injected the dye into the mediastinum. It is visible as an opacified area on the right margin in Figure 7F,G. It was reabsorbed without sequelae and no longer visible in a CT-scan 3 months after the procedure (Figure 7H). No further complications were encountered.

4.3 | Limitations

We present three different cases of extravascular transcatheter placement of covered stents. They document the principal feasibility under a variety of anatomic and hemodynamic conditions in veins and arteries but, of course, they cannot provide valid data about the incidence of possible procedural risks, complication rates, or long-term outcomes.

The covered stents used in this case series are intended for restoring and improving the patency of the iliac and renal arteries (Advanta V12) and for the treatment of intraluminal aneurysms, acute perforations, acute ruptures, and fistulas (Bentley BeGraft peripheral). Therefore, we used them off-label. However, since they are manufactured with a complete PTFE cover for reliable sealing of arterial vessels, their performance as extravascular conduits was predictable.

The transseptal needles and the puncture sheath are not intended for the purpose we used them and therefore they are not ideal. Thus, the development of specific equipment for extravascular procedures would be very helpful.

Yet, based on the procedural successes, we feel encouraged to take advantage of the presented methods in similar cases.

5 | CONCLUSION

With a workflow, combining postprocessed CT scans for procedural planning and the use of long puncture needles under biplane fluoroscopy, extravascular connections between intrathoracic veins or arteries can be established with covered stents by transcatheter means. The technique may serve as a conceptual workflow for the introduction of similar transcatheter procedures in structural heart disease.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ORCID

Peter Ewert http://orcid.org/0000-0003-0253-1190
Daniel Tanase http://orcid.org/0000-0003-1723-1254
Stanimir Georgiev http://orcid.org/0000-0002-6239-8160

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