International Journal of Cardiology xxx (2014) xxx–xxx

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Use of covered Cheatham-Platinum stents in congenital heart disease☆,☆☆

Ward Y. Vanagt [a,b,c,1], Björn Cools [a,2], Derize E. Boshoff [a,1], Stefan Frerich [b,c,2], Ruth Heying [a,1], Els Troost [a,2], Jacoba Louw [a,2], Benedicte Eyskens [a,1], Werner Budts [a,1], Marc Gewillig [a,*,1]

[a] Department of Congenital and Pediatric Cardiology, University Hospital Gasthuisberg, Leuven, Belgium
[b] Department of Pediatrics, Cardiovascular Research Institute Maastricht CARIM, Maastricht University Medical Center MUMC, Maastricht, The Netherlands
[c] Department of Physiology, Cardiovascular Research Institute Maastricht CARIM, Maastricht University Medical Center MUMC, Maastricht, The Netherlands

ARTICLE INFO

Article history:
Received 27 November 2013
Received in revised form 17 April 2014
Accepted 30 April 2014
Available online xxxx

Keywords:
Congenital heart disease
Covered stent
Cheatham-Platinum
Complication of angioplasty

ABSTRACT

Background: Controversy remains regarding the use of covered stents in congenital heart disease (CHD). We evaluate the possibilities and safety of covered Cheatham-Platinum (CCP) stents in CHD.
Methods: Single-center retrospective CHD-database study of all CCP stents, 2003–2012. Three study groups: aortic coarctation (CoA), right ventricular outflow tract pre-stenting for percutaneous revalvulation (RVOT), and miscellaneous. Continuous data expressed as median (range).
Results: 114 CCP stents in 105 patients, age 16.8 years (4.2–71.2).
CoA group: 54 CCP stents in 51 patients: 3/54 for aneurysm exclusion, in 51/54 covering used "prophylactically" because of increased risk for vessel tear. Overall, CCP stenting increased the coarctation diameter from 6 mm (0–15) to 15 mm (10–20) ($p < 0.001$).
RVOT group: 39 CCP stents in 37 patients (34 with RVOT graft, 3 with transannular patch): the graft lumen had shrunken from nominal 21 mm (10–26) to 13 mm (5–22); with the CCP stent the RVOT was redilated to 22 mm (16–26, $p < 0.001$ vs stenosis).
Miscellaneous group: 21 CCP stents in 17 patients: closure of Fontan-circuit fenestration ($n = 5$), restoration of superior caval vein ($n = 2$) or pulmonary artery ($n = 3$) patency, relief of supra-pulmonary stenosis ($n = 2$), exclusion of aberrant pulmonary arteries ($n = 1$), cavopulmonary conduit expansion ($n = 2$), Blalock–Taussig shunt flow reduction ($n = 1$), and defibrillator lead protection from sharp stents ($n = 1$). Hybrid procedures performed in 3/17 patients. CCP stent was used as rescue treatment in 2/patients to seal iatrogenic bleeding.
Conclusion: CCP stents can safely be applied in CHD patients. The covering allows adequate sealing of existing or expected tears, thereby increasing the safety margin with more complete dilation.

1. Introduction

Although angioplasty alone is an effective treatment of stenotic lesions, disadvantages are recoil, vessel dissection, aneurysm formation and rupture. The former problem can be addressed by the use of bare stents, whereas the latter may be overcome by covered stents [1,2].

Covered stents have been used to treat coarctation of the aorta (CoA) since 1999 [3]. Despite the growing experience, controversy remains regarding indications, effectiveness and safety. Covered stents can be applied as "rescue" treatment in case of bleeding or aneurysm formation during percutaneous interventions. An increasing number of covered stents are used for primary treatment of CoA, re-CoA, and CoA with aneurysm formation [4–7], for stenting the right ventricular outflow tract (RVOT) prior to percutaneous revalvulation [8], and in miscellaneous conditions such as pulmonary artery stenosis, caval vein obstruction, Fontan-circuit obstruction and closure of Fontan-circuit fenestrations [5,9–11].

In this study, we present the various indications, effectiveness and complications of all covered Cheatham Platinum (CCP, Numed Inc.,

☆ Conflict of interest statement: M. Gewillig is proctor for Numed (Numed Inc., Hopkinton, NY, USA).
☆☆ Funding: This work was supported by the Eddy Merckx Research Fund, Belgium (WV) and by the Dutch Heart Foundation grant no. 2010 T042 (WV).
* Corresponding author at: Dept. of Pediatric Cardiology, University Hospital Gasthuisberg, Herestraat 49, 3000 Leuven, Belgium. Tel.: +32 16 343865; fax: +32 16 343981.
E-mail address: Marc.Gewillig@uzleuven.be (M. Gewillig).
[1] MD, PhD, this author takes responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.
[2] MD, this author takes responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

http://dx.doi.org/10.1016/j.ijcard.2014.04.271
0167-5273/

Hopkinton, NY, USA) stents used in patients with congenital heart disease (CHD) in our center.

2. Methods

2.1. Study design, study groups and outcome parameters

Retrospective single-center database study of the Pediatric and Congenital Cardiology database, University Hospital Gasthuisberg Leuven, Belgium. All consecutive CCP stents implanted in CHD patients from October 2003 until June 2012 were included. The study complies with the Declaration of Helsinki, and was conducted following the institutional review board and ethical committee guidelines. Informed consent was waived.

Patients were divided in 3 groups: coarctation of the aorta (CoA), stenting of the RVOT prior to percutaneous valve implantation (RVOT), and miscellaneous group. Within each group, indication was considered to be either prophylactic (procedures at risk for vessel trauma, presence of sharp calcifications) or therapeutic (exclusion of an acute or chronic aneurysm, rescue use in case of bleeding during intervention). Effectiveness and occurrence of complications were assessed. Since CCP stents require larger sheaths as compared with bare stents [9], each patient file was searched for occurrence of vessel occlusion, bleeding, limb ischemia, and abnormal peripheral pulsations.

The diameter of the aortic coarctation and peak-to-peak gradient (CoA group) and the diameter of the RVOT graft (RVOT group) prior to and following stenting or re-dilation were investigated.

2.2. Stent characteristics

The CCP stent frame is made from 90% platinum and 10% iridium 0.013″ wire, welded in a zig pattern with additional gold soldering. The strut thickness is slightly larger than most other stents, but makes the stent edges relatively atraumatic [1]. The expanded poly-tetra-fluoro-ethylene (ePTFE) covering can be dilated up to 26 mm before tearing [4,12]. The ePTFE is glued at 0° and 180°at each end of the stent; the covering can slide mildly around the stent during expansion, thereby uncovering the distal tips for 1–3 mm at 90° and 270° (Fig. 1). The stent conformability allows the ends to be flared around the target lesion or into a bifurcation. The wire thickness and ePTFE membrane result in a final thickness of 2–3 F when crimping on a balloon [9]. The stent can be crimped down to a profile of 10 F leaving a lumen for a 7 F profile balloon. CCP stents are currently CE-approved in lengths of 16, 22, 28, 34, 39, and 45 mm (non CE-approved for 55 and 65 mm).

2.3. Catheterization technique

All procedures were performed under general anaesthesia. Cook sheaths (Cook Medical Europe, Bjaeverskov, Denmark) were used in all subjects except in the hybrid procedures. Heparin was administered intravenously (100 IU/kg, maximum 5000 IU).

After wire positioning, hemodynamic measurements and angiography, a long sheath of appropriate size was positioned. Stent length was chosen to cover the entire length of the lesion, if possible with both ends of the stent reaching "healthy" tissue, thereby sealing any expected tear at both ends. The CCP stent was hand-crimped on a balloon-in-balloon (BIB, Numed, Hopkinton, NY, USA). A short (±5 cm) cut-off sheath was used for final crimping and to facilitate introduction through the sheath's valve. Hand-inflation of the balloon was performed with a 10 ml syringe on the inner balloon and 20 ml syringe on the outer balloon, automatically limiting inflation pressures to 4–6 atmospheres. Control angiography was performed after stent placement, pressure measurements and dimensions were re-evaluated.

The stenting procedure was technically split into four different aspects: 1] stent delivery, 2] sealing of the anticipated tear by additional flaring if indicated, 3] securing side vessel patency when needed, and 4] dilation of the stenosis. In a simple discrete lesion in a large patient all four aspects were treated with 1 balloon. For more complex lesions or in small patients, several balloons may be required. When sheath size was critical, a lower profile (7 F) low-pressure balloon was used to deploy and anchor the stent typically by wrapping it across the stenosis, without aiming at full dilation at initial implantation. When significant curves were needed to be taken, mild inflation of the outer balloon was used to create "shoulders": anterior shoulder allows to un-kink a sheath; posterior shoulder avoids the stent sliding off the balloon. If sealing the expected tear was essential, a larger balloon or 2 kissing balloons were used to flare the stent. In patients where sealing was required at a vessel bifurcation, the stent was delivered using a dual wire technique and subsequently molded into the bifurcation using a kissing balloon technique [7]. If a critical structure might be compressed during dilation, progressive incremental dilation was performed using different balloons.

In case of proximity between the stent and the coronary arteries, test balloon dilation with simultaneous coronary arteriography was performed to exclude coronary compression prior to stent delivery.

If a large tear or homograft fracture was expected, the operator preferred stent ingrowth/adhesion for several weeks to maximize sealing before proceeding to final stent dilation.

When the RVOT had sharp calcifications causing premature rupture of the predilation balloon, a covered stent was used for "delivery balloon protection".

Heparin was neutralized by protamine after the procedure when activated clotting time was >210 s. Hemostasis was obtained using adequate manual compression (taking 10 min of additional anesthesia when necessary), compression during extubation, and compressive dressing until the next morning. No sutures were used. Anticoagulation and/or anti-aggregation medication was not routinely prescribed except when stents were implanted in Fontan circuits or in complex shunts.

Fig. 1. Covered Cheatham Platinum stent. Above: crimped. Below: expanded.

2.4. Hybrid procedures

In 3 patients in the miscellaneous group, 5 CCP stents were delivered through sternotomy in a hybrid surgical suite with monoplane high resolution fluoroscopy. The hybrid procedures consisted of creation of a sutureless connection to hypoplastic distal pulmonary arteries ($n = 2$) and of sealing off aortic orifices of aberrant pulmonary arteries ($n = 1$).

3. Statistical methods

Continuous data are expressed as median (minimum maximum range). Prevalence is reported as number and percentages. Comparative statistics were done where applicable. Since the data were not normally distributed, the non-parametric Wilcoxon signed rank test was used. Two sided $p < 0.05$ was considered significant. Statistic analysis was performed with IBM-SPSS version 19 software (SPSS Inc., Chicago, IL, USA).

4. Results

Overall, 114 CCP stents were implanted in 105 patients, 67% male, age 16.8 years (4.2–71.2). After stent deployment, there was no evidence of any contrast extravasation over the stent course. CCP stent length, balloon diameter, radiation exposure and fluoroscopy time are depicted in Table 1.

4.1. CoA group

Fifty-four CCP stents were deployed in 51 patients with CoA, 75% male, age 19 (8–69) years. In 48/51 patients, the choice for a covered stent was "prophylactic", whereas in 3/51 patients the CCP stent was indicated to exclude a chronic aneurysm [31 years after coarctectomy, 4.5 years after primary CCP stent placement (see below), and 2 years after simple balloon dilatation]. In 35/51 patients (69%) CCP stenting was the first intervention, while medical history included previous coarctectomy in 11/51 (21%) and balloon angioplasty in 5/51 (10%) patients. In 18/51 patients (35%), the coarctation consisted of a pinpoint lesion that was passed retrogradely. Five patients (10%) had functional interrupted aortic arch with a hair-like communication to the descending aorta requiring antegrade passage, creating a brachial–femoral artery rail using a snare, followed by retrograde access for stenting. One patient had an interrupted aortic arch that was punctured through left radial artery access.

The diameter of the aorta increased at the stent implantation procedure from 6 (0–15) to 14 (7–20) mm ($p < 0.001$) while peak-to-peak gradient decreased from 23 (0–86) to 4 (0–25) mm Hg ($p < 0.001$). In 30/51 subjects (59%), peak-to-peak gradient was <5 mm Hg

Please cite this article as: Vanagt WY, et al, Use of covered Cheatham-Platinum stents in congenital heart disease, Int J Cardiol (2014), http://dx.doi.org/10.1016/j.ijcard.2014.04.271

Table 1
Catheterization data.

Group	*n*	Stent length (mm)	Balloon diameter (mm)	Sheath size (F)	Radiation exposure (μGym^2)	Fluoroscopy time (min)
CoA	51	39 (22–55)	16 (10–20)	12 (10–14)	7492 (1259–47,000)	11 (4–33)
RVOT	37	39 (28–55)	22 (18–24)	14 (12–16)	8842 (659–64,211)	17 (7–73)
Misc	17	34 (28–45)	16 (12–32)	12 (11–16)	9290 (1581–32,950)	18 (7–44)

n: number of patients, CoA: coarctation of the aorta group, RVOT: right ventricular outflow tract pre-stenting group, Misc: miscellaneous group. Data expressed as median (range).

immediately after CCP stent implantation. In 39/51 patients (76%), a single procedure was performed. In 12/51 patients (24%), further dilation of the stent was performed after 4.5 (1.6–28) months where the diameter of the aorta increased from 10 (6–14) to 15 (11–19) mm ($p = 0.002$) while the peak gradient further decreased from 19 (12–26) to 1 (0–6) mm Hg ($p = 0.005$). As compared with pre-implantation data, the overall result at the latest catheterization (either the implantation procedure or the re-dilation procedure) showed an increase in aortic diameter from 6 (0–15) to 15 (10–20) mm ($p < 0.001$) while the peak-to-peak gradient decreased from 23 (0–86) to 2 (0–25) mm Hg ($p < 0.001$).

In one patient, a second CCP stent was inserted during a separate procedure for late aneurysm formation at the cranial end of the CCP stent. This patient originally had a pinpoint coarctation close to the origin of the left subclavian artery, treated with primary CCP stent placement at the age of 13 years using a conventional 1 balloon technique, leaving the cranial end of the stent in the hypoplastic part of the aortic isthmus. During full expansion of the stent 4 months later, a tear at the cranial margin of the stent occurred, progressing to an aneurysm. A second CCP stent was inserted 4 years later to exclude this aneurysm.

In one patient with the left subclavian artery orifice in the coarctation, the coarctation was stented across the left subclavian artery orifice, followed by retrograde puncture of the CCP stent to restore antegrade left subclavian artery flow (Fig. 2) [6].

There was no acute bleeding, aneurysm formation or life-threatening complication. Procedure-related complications included groin hematoma ($n = 3$), transient nodal rhythm ($n = 1$, no wire present in left ventricle), and transient atrioventricular block with nodal escape rhythm ($n = 1$, while wire was present in left ventricle). During follow-up no stent fractures, nor stent recompression occurred, and none of the patients had limb ischemia or signs of vessel occlusion at the puncture site.

Post-procedural chest pain requiring additional diagnostics (CT scan and/or echocardiography) to exclude an acute complication occurred in 8/51 patients (16%), responded well to analgesics and subsided within 24 h in all subjects.

4.2. RVOT group

Thirty-nine CCP stents were implanted in 37 patients prior to percutaneous revalvulation of the RVOT, 70% male, age 16 (6–43) years. An RVOT cryopreserved homograft (European Homograft Bank EHB, Brussels, Belgium) was present in 27/37 (73%) of patients, 7/37 patients (19%) had a Venpro graft (Medtronic Inc., Santa Ana, CA, USA) and 3/37 patients (8%) had a transannular patch.

A CCP stent was chosen for delivery balloon protection after rupture of the pre-dilation balloon in 7/37 patients (19%). In the remaining 30/37 patients (81%) a CCP stent was chosen because tear, rupture, or fracture of the conduit was expected, or further stent expansion following somatic growth was anticipated. Covering the region most at risk for vessel injury required 2 CCP stents (39 and/or 45 mm) inserted telescopically in 2/37 patients (5%) and placement of a long custom-made 55 mm CCP stent in 3/37 patients (8%).

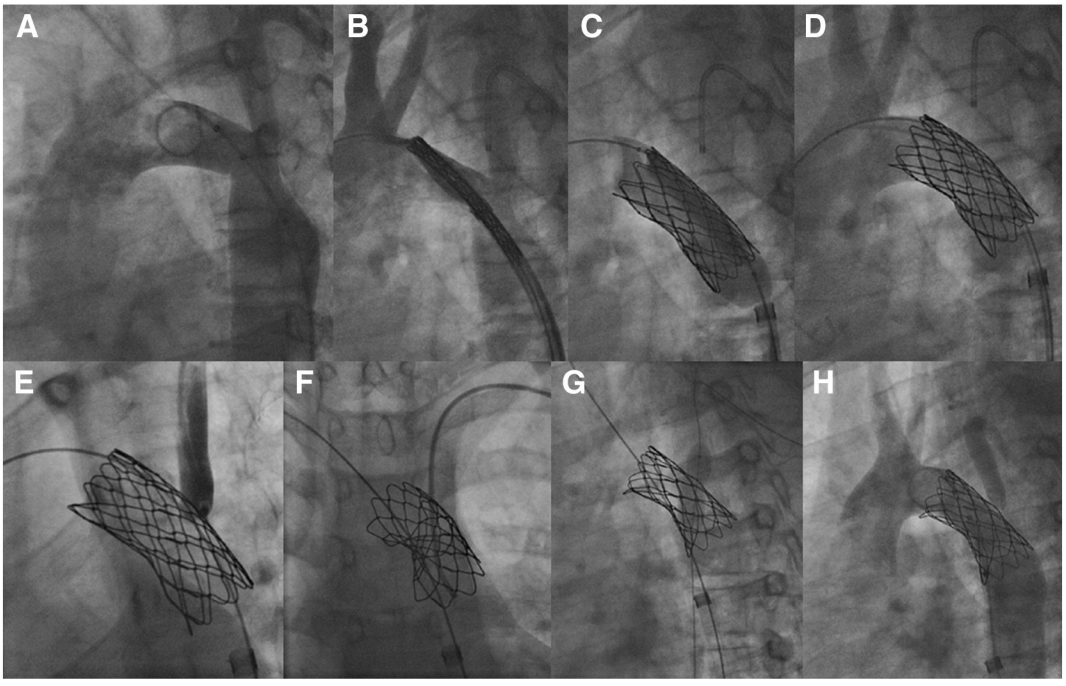

Fig. 2. Coarctation treatment in 10 year-old girl. A: Aortogram shows coarctation at the level of the left subclavian artery (LSA) orifice; B: a 45 mm CCP stent mounted on a 16 mm BIB balloon is positioned through an 11 F sheath; C: deployment of stent; D: aortogram shows exclusion of LSA; E: arteriogram LSA through 4 F catheter to guide retrograde puncture; F: retrograde perforation of covering of CCP with back-end of 0.035″ wire; G: dilation of the puncture hole with 8 mm balloon; H: antegrade flow to LSA is restored; stent is flared at proximal and distal end; no residual gradient, ready for further expansion later after somatic growth.

Please cite this article as: Vanagt WY, et al, Use of covered Cheatham-Platinum stents in congenital heart disease, Int J Cardiol (2014), http://dx.doi.org/10.1016/j.ijcard.2014.04.271

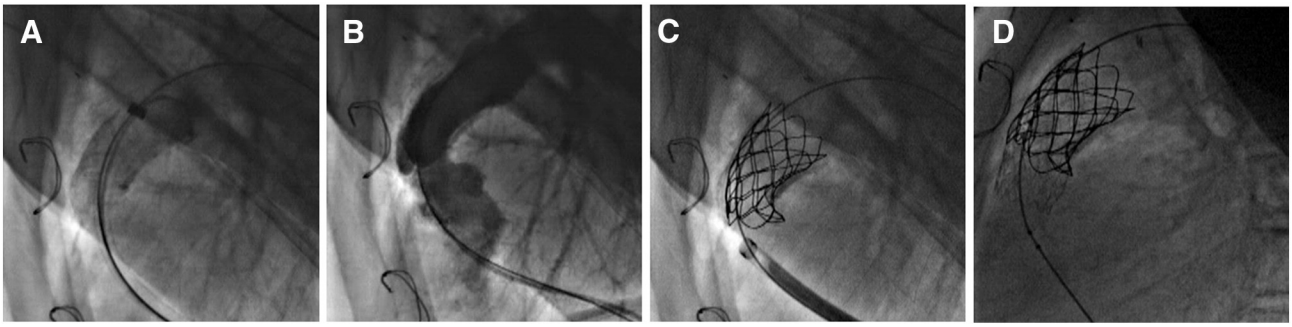

Fig. 3. Lateral projection images from catheterization in a 15-year old patient with Tetralogy of Fallot, pulmonary atresia and stenosed calcified 13 mm (nominal) RVOT homograft (A, B). CCP stent in the RVOT at the end of the delivery procedure, the stent was intentionally incompletely dilated at 16 mm (C). Additional placement of a bare stent proximally in the CCP stent with dilation of both stents to 22 mm during a second procedure after 2 months (D).

CCP stenting and RVOT percutaneous valve delivery were performed in a single procedure in 22/37 subjects (59%), whereas CCP stent re-dilation with percutaneous revalvulation was achieved during a second procedure in 15/37 patients (41%) after 61 (40–146) days (Fig. 3).

When necessary, an additional bare stent was inserted [11 bare stents in 10/37 (27%) patients] until the conduit became a rigid tube without external compression in order to obtain minimal gradient prior to percutaneous revalvulation. The nominal graft diameter (diameter at graft insertion, $n = 34$) was 21 (10–26) mm, stenosed to 13 (5–22) mm ($p < 0.001$ versus nominal size), and increased to 22 (16–26) mm prior to revalvulation ($p = 0.035$ versus nominal size and $p < 0.001$ versus graft stenosis). Dilation beyond the "nominal" graft diameter was performed in 16/34 patients (47%), with the percutaneous valve size 2 (1–9) mm larger than the nominal graft size.

There were no procedure-related complications and no extravasation. Neither embolization nor fracture of CCP stents was found on annual chest X-ray follow-up.

4.3. Misc group

Twenty-one CCP stents were implanted in 17 subjects [53% male, age 13 (4–71) years]. Indication for CCP stenting consisted of Fontan-circuit fenestration closure ($n = 5$), restoration of superior caval vein ($n = 2$) or pulmonary artery ($n = 3$) patency, relief of supra-pulmonary stenosis after arterial switch operation ($n = 2$), sealing of aberrant pulmonary artery orifices ($n = 1$), cavopulmonary conduit expansion ($n = 2$), Blalock–Taussig shunt flow reduction ($n = 1$) and defibrillator lead protection during percutaneous re-revalvulation of a prosthetic tricuspid valve ($n = 1$). In 3/17 abovementioned subjects (15%), 5 CCP stents were delivered during hybrid procedures (Fig. 4).

A covered stent was used as "rescue treatment" in 2 subjects. In a 12-year old patient, rescue CCP stenting was performed because of dissection of the left pulmonary artery creating an aortopulmonary window upon dilation of a Palmaz stent (Cordis Corp., Bridgewater, NJ, USA) that was positioned 11 years before because of peripheral pulmonary artery stenosis after arterial switch procedure. In this patient, CCP stent redilatation 4 years later resulted again in an aorta-pulmonary window, for which another CCP stent was successfully implanted. The other patient requiring rescue treatment with a CCP stent had leakage at the proximal end of a stent upon placement in the left pulmonary artery during a hybrid procedure. During follow-up, there were no stent fractures and no recompression.

5. Discussion

This report describes a 9 year experience with CCP stents as a valuable tool in the management of patients with simple and complex congenital heart disease. The addition of a covering around a stent allows safer and more complete dilatation of stenotic lesions, with a better expected long-term outcome. Moreover, the miscellaneous use of a covered stent permits procedures previously considered un-achievable by creating [13], excluding [11], enlarging [1,14] or restricting vessel segments.

5.1. Optimal results through more complete dilatation

Bare stents do offer an answer to complications of balloon dilation such as recoil and dissection, and diminish the risk for aneurysm formation and vessel tear by no longer requiring overdilation [15]. However, aortic wall complications with bare stenting still occurred in 3.9% of 565 procedures [16]. The highest risk is when a significant increase in

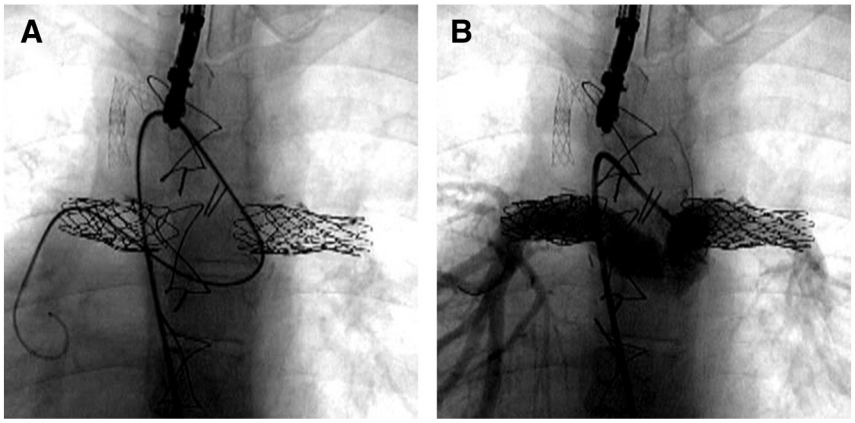

Fig. 4. A: Antero-posterior projection, result of hybrid procedure at 13.5 years of age in a patient with pulmonary atresia, absent pulmonary artery stem and bifurcation (treated neonatally with a bilateral 5 mm Blalock–Taussig shunt): bilateral CCP stents to connect the Gore-Tex central shunt and bifurcation to the distal pulmonary arteries. Stents in the right subclavian artery and Blalock–Taussig shunt from previous interventions are also visible. B: Contrast injection in the central shunt.

Please cite this article as: Vanagt WY, et al, Use of covered Cheatham-Platinum stents in congenital heart disease, Int J Cardiol (2014), http://dx.doi.org/10.1016/j.ijcard.2014.04.271

circumference is imposed on a poorly compliant or calcified wall. "Conservative" stenting of the aorta, while still accepting a mild to moderate residual gradient, is still at risk for major complications due to a non-contained tear. Similarly, "conservative" stenting of a narrowed RVOT conduit up to nominal size frequently leaves a significant gradient, and nevertheless involves a significant tear with intrathoracic bleeding in 1–3% of patients [17,18]. Our results demonstrate that covered stenting allows significant expansion of a target lesion to the desired dimension with no, or minimal gradient, but without any aneurysm or blood extravasation within the stent. Narrow coarctations and an interrupted aorta could be treated safely with adequate expansion leaving no significant gradient, while undoubtedly creating major tears in the vessel wall. Similarly, in patients with a narrowed RVOT with or without a conduit, covered stenting permitted expansion of the RVOT and/or the conduit up to and beyond the nominal graft size. This approach aimed to leave no, or a minimal residual gradient, which then allowed to implant an adequately sized valved stent. In many patients this dilatation must have involved significant tearing and fracturing of the conduit. When created with a bare stent, such tear would result in pericardial, mediastinal or pleural bleeding, depending on the degree of adhesions. By using a covered stent, an adequate landing zone without extravasation was obtained. The aim was to cover the whole conduit with the covered stent even if some parts were not restrictive at implantation, allowing safer future redilation to accommodate for somatic growth.

5.2. Adapted techniques with covered stents

Covered stents were initially chosen and deployed as done previously with bare stents in our center. However a covered stent offers specific opportunities and limitations which require adapted techniques (Fig. 5): 1] longer stent for sealing, 2] flare to seal and to reduce flow disturbance, and 3] maintain side-vessel patency.

1] Longer stent for sealing the target: When a tear or rupture is anticipated, the covering typically will impede extravasation. However a tear may extend until the edge of the diseased tissue, which is typically until where a bare stent would reach. In order to seal the target lesion at both ends to obtain extra safety, a longer covered stent is used. The aim is thus to bridge the target lesion from "healthy to healthy" vessel. Of note, the covering of a CCP stent does not reach the edges of the stent, but will retract for a few millimeters during expansion, except for the 2 glued points at each end. When the anatomy allows it, the covered stent is delivered on a larger balloon to flare the stent at delivery against the vessel wall, without the aim to dilate the target lesion with the delivery balloon. Dilation of the stenosis is subsequently performed with high pressure balloons. If the sealing needs to be more robust, the covered stent is left to adhere to the intimal layer for several weeks before proceeding to further dilatation. We do not consider this a failure of the first intervention, but as an intermediate step in the management using CCP stents. Using this technique, we have never observed extravasation due to a tear. Whether the same result could be achieved safely with full dilation in a single procedure cannot be assessed using our data. In a series of 13 patients with CoA treated with self-fabricated covered stents, acute aneurysm formation and rupture occurred once after full balloon expansion in a single procedure [19].

2] Flaring: this is almost never indicated when using a bare stent. With covered stents, flaring the stent against the vessel wall may be required to get an adequate seal. Other reasons to flare a covered stent are to reduce the overall resistance of the tube graft and to avoid flow vortices that might cause an infolding of the stent.

3] Side vessel patency. When the target lesion is close to a bifurcation, a bare stent may easily be placed across the origin of that side vessel and the stent cells may be dilated if required. A covered stent requires an adapted strategy for side-vessels such as: stent delivery partially covering the orifice (but still allowing probing of the side-vessel for subsequent flaring), double wire delivery which guarantees side-vessel accessibility [7], crossing the side-vessel with the covered stent and either accept the exclusion, surgically translocate and reimplant the vessel, or perform a retrograde puncture and dilation (Fig. 2) of the membrane at the orifice of the side vessel [6].

5.3. Prophylactic versus curative use

Some physicians will only implant a covered stent after a proven complication (aneurysm or non-contained tear) of a bare stent occurred, either by personal preference or because of local regulations (FDA restriction in USA). A covered stent is then implanted in stressed conditions as a rescue treatment in a potentially hemodynamically unstable patient. A tear in the middle of a narrowing will usually be shielded easily; however a tear at the edge of a conduit with a pre- or post stenotic dilation, or at a bifurcation may be very difficult to control, as the bare stent will impede adequate flaring of the covered stent over the tear. We therefore have evolved from "curative" to "prophylactic" use, not only when an acute tear or fracture of the target lesion is expected, but also to avoid late aneurysm formation.

Because of the possibility of a tear in the membrane, we always keep a large covered stent, balloon and sheath available for fast deployment to add to the safety of the procedure [20].

5.4. Interventions possible owing to covered stents

The CCP stent is useful in hybrid procedures to access anatomic locations that are most difficult to reach surgically. The CCP stent is also an effective tool in miscellaneous congenital or post-surgical cardiac

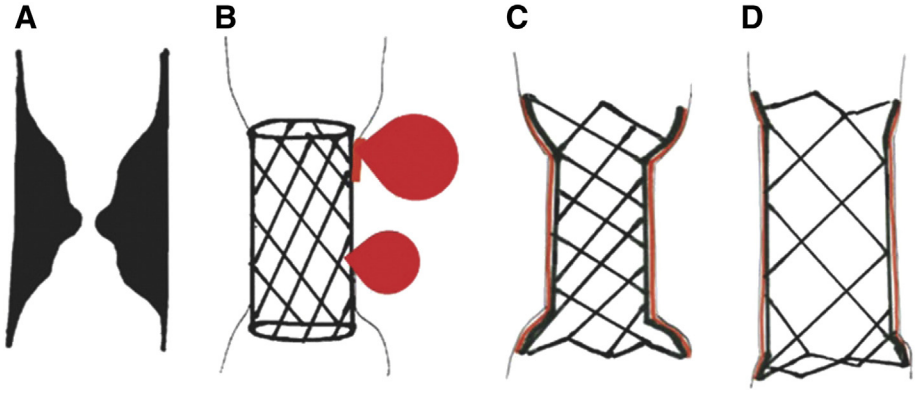

Fig. 5. Cartoon of technical differences bare versus covered stent. A: stenotic lesion in blood vessel or conduit; B: expansion of bare stent with subtotal expansion, but 2 possible complications: aneurysm-tear in mid-lesion, or tear at cranial end with bleeding/aneurysm beyond the zone covered by this stent; C: deployment of a covered stent which is longer; any tear in the middle is automatically covered, the tear at the end is sealed by extra length which is flared; D: covered stent allows safe near-total expansion of the stenotic segment.

Please cite this article as: Vanagt WY, et al, Use of covered Cheatham-Platinum stents in congenital heart disease, Int J Cardiol (2014), http://dx.doi.org/10.1016/j.ijcard.2014.04.271

anomalies, where the goals of relieving obstruction, restoring vessel or conduit patency, or closure of communications were reached.

5.5. Performance of the membrane

The membrane is designed to stretch without tearing until 26 mm. Theoretically, a sharp calcified lesion might tear the membrane prematurely. We never observed perforations during placement, or aneurysms in the course of the CCP stents, suggesting that membrane integrity was preserved. When previously still using shorter stents not reaching "healthy" tissue, we observed one aneurysm at the cranial end of a stent in CoA during chronic follow-up; this was treated with an additional CCP stent. Overall, the membrane at the edge of a tear sealed the lumen very adequately: in obligatory tears (interrupted arch, hybrid sutureless anastomosis) no extravasation was observed.

Our data confirm that CCP stents can be re-dilated without ePTFE membrane rupture after somatic growth, or when the CCP stent was not fully dilated initially [21,22]. We observed one CCP stent tear when redilating it 4 years after insertion (see results section, miscellaneous group), where "sandwiching" of the ePTFE membrane between the outer bare stent and inner CCP stent apparently made the covering vulnerable for tear.

5.6. Vascular access issues

In comparison with delivery of a bare stent, covered stent insertion requires a 1–2 F larger sheath size [9], with a minimum sheath size of 10 F. We did not observe significant complications at the vascular access site. In the typical adolescent and adult with CoA, a 14 F sheath was used and well tolerated.

6. Study limitations

We do not routinely perform CT scanning to detect aneurysm formation after CCP stent placement. Therefore, under-reporting of aneurysm formation cannot be excluded. Furthermore, the long-term formation of peal in the stent was not assessed.

In this retrospective study, there are no control groups with bare stents, the lack of which is inherently related to the fact that some of these procedures would have been impossible, or significantly less safe, if bare stents were used.

7. Conclusions

CCP stents can safely be applied in a broad range of CHD patients. The covering allows adequate sealing of existing or expected tears, thereby increasing the safety margin with more complete dilation in selected patients.

References

[1] Butera G, Piazza L, Chessa M, et al. Covered stents in patients with complex aortic coarctations. Am Heart J 2007;154(4):795–800.
[2] Tanous D, Collins N, Dehghani P, Benson LN, Horlick EM. Covered stents in the management of coarctation of the aorta in the adult: initial results and 1-year angiographic and hemodynamic follow-up. Int J Cardiol 2010;140(3):287–95.
[3] Gunn J, Cleveland T, Gaines P. Covered stent to treat co-existent coarctation and aneurysm of the aorta in a young man. Heart 1999;82(3):351.
[4] Erdem A, Akdeniz C, Saritas T, et al. Cheatham-Platinum stent for native and recurrent aortic coarctation in children and adults: immediate and early follow-up results. Anadolu Kardiyol Derg 2011;11(5):441–9.
[5] Schranz D, Jux C, Vogel M, Bauer J, Akinturk H, Valeske K. Large-diameter graft-stent (Advanta V12) implantation in various locations: early results. Cardiology in the young 2011;21(1):66–73.
[6] Tsai SF, Hill SL, Cheatham JP. Treatment of aortic arch aneurysm with a NuMED-covered stent and restoration of flow to excluded left subclavian artery: perforation and dilation of e-PTFE can be done! Catheter Cardiovasc Interv 2009;73(3):385–9.
[7] Lampropoulos K, Budts W, Gewillig M. Dual wire technique for aortic coarctation stent placement. Catheter Cardiovasc Interv 2011;78(3):425–7.
[8] Boshoff D, Cools B, Heying R, et al. Off-label use of percutaneous pulmonary valved stents in the right ventricular outflow tract: time to rewrite the label? Catheter Cardiovasc Interv 2013.
[9] Ewert P, Schubert S, Peters B, Abdul-Khaliq H, Nagdyman N, Lange PE. The CP stent–short, long, covered–for the treatment of aortic coarctation, stenosis of pulmonary arteries and caval veins, and Fontan anastomosis in children and adults: an evaluation of 60 stents in 53 patients. Heart 2005;91(7):948–53.
[10] Brown SC, Boshoff DE, Meyns B, Gewillig M. Sutureless rescue of a severely hypoplastic pulmonary artery. European journal of cardio-thoracic surgery: official journal of the European Association for Cardio-thoracic Surgery 2010;37(3):741–3.
[11] Marini D, Boudjemline Y, Agnoletti G. Closure of extracardiac Fontan fenestration by using the covered Cheatham Platinum stent. Catheter Cardiovasc Interv 2007;69(7):1002–6.
[12] Tzifa A, Ewert P, Brzezinska-Rajszys G, et al. Covered Cheatham-platinum stents for aortic coarctation: early and intermediate-term results. J Am Coll Cardiol 2006;47(7):1457–63.
[13] Butera G, Heles M, Carminati M. Percutaneous treatment of aortic isthmus atresia: Use of Radiofrequency Perforation and Covered Stents. Catheter Cardiovasc Interv 2011;78(6):933–9.
[14] Qureshi SA, Zubrzycka M, Brzezinska-Rajszys G, Kosciesza A, Ksiazyk J. Use of covered Cheatham-Platinum stents in aortic coarctation and recoarctation. Cardiol Young 2004;14(1):50–4.
[15] Gewillig M, Budts W, Boshoff D, Maleux G. Percutaneous interventions of the aorta. Future Cardiol 2012;8(2):251–69.
[16] Forbes TJ, Garekar S, Amin Z, et al. Procedural results and acute complications in stenting native and recurrent coarctation of the aorta in patients over 4 years of age: a multi-institutional study. Catheter Cardiovasc Interv 2007;70(2):276–85.
[17] Khambadkone S, Coats L, Taylor A, et al. Percutaneous pulmonary valve implantation in humans: results in 59 consecutive patients. Circulation 2005;112(8):1189–97.
[18] Powell AJ, Lock JE, Keane JF, Perry SB. Prolongation of RV-PA conduit life span by percutaneous stent implantation. Intermediate-term results. Circulation 1995;92(11):3282–8.
[19] Kenny D, Cao QL, Kavinsky C, Hijazi ZM. Innovative resource utilization to fashion individualized covered stents in the setting of aortic coarctation. Catheter Cardiovasc Interv 2011;78(3):413–8.
[20] Hijazi ZM. Catheter intervention for adult aortic coarctation: be very careful! Catheter Cardiovasc Interv 2003;59(4):536–7.
[21] Butera G, Gaio G, Carminati M. Redilation of e-PTFE covered CP stents. Catheter Cardiovasc Interv 2008;72(2):273–7.
[22] Bruckheimer E, Dagan T, Amir G, Birk E. Covered Cheatham-Platinum stents for serial dilation of severe native aortic coarctation. Catheter Cardiovasc Interv 2009;74(1):117–23.

Please cite this article as: Vanagt WY, et al, Use of covered Cheatham-Platinum stents in congenital heart disease, Int J Cardiol (2014), http://dx.doi.org/10.1016/j.ijcard.2014.04.271