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Covered stent placement for treatment of coarctation of the aorta: immediate and long-term results

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ABSTRACT

Objectives: This study aimed to describe the safety and efficacy of covered stents in patients with coarctation of aorta (CoA) for immediate and long-term follow-up.

Background: Covered stents are increasingly being used in (re)CoA, mainly to reduce the risk of aortic wall injuries (AWI). However, limited data are available on intermediate and long-term outcome.

Methods: In 89 patients (67.4% male) with a mean age of 23.9 ± 15.8 (min max range 5.1–71.6) years were 102 covered stents implanted (January 2003 – December 2017). Short-term pre/post-implant hemodynamics and angiographic data were reported. Changes in blood pressure, the use of antihypertensive drugs and complications were recorded during follow-up.

Results: The procedural success rate was 100%. The mean invasive ascending-to-descending aorta systolic gradient under general anaesthesia decreased from 25 ± 16 mmHg to 4 ± 7 mmHg (p < 0.001). After a mean follow-up time of 6.6 ± 3.7 years, there was a persistent improvement of the mean systolic blood pressure gradient between right arm and leg (7 ± 18 vs 38 ± 24 mmHg; p < 0.001). A larger proportion of patients required antihypertensive medication (33.7% vs 50.0%, p = 0.017) and needed ≥ 2 drugs (20.2% vs 27.4%, p = 0.066) to control blood pressure. Long-term adverse events were found in 4.5% of patients (covered stent fracture (n = 3), aneurysm formation (n = 2)).

Conclusions: Covered stent implantation for CoA is highly successful, safe and results in a persistent hemodynamic improvement in the immediate and long-term outcome. Lifelong follow-up with additional antihypertensive drug treatment is mandatory to maintain favourable hemodynamic results after stenting.

CONDENSED ABSTRACT: Long-term follow-up data on covered stents in patients with coarctation of the aorta are scarce. A cohort of 89 patients was reviewed. The procedural implantation success rate was 100%. The invasive gradient decreased from 25 ± 16 mmHg to 4 ± 7 mmHg (p < 0.001). After follow-up of 6.6 ± 3.7 years, there was a persistent improvement of the clinical systolic blood pressure gradient (7 ± 18 vs 38 ± 24 mmHg; p < 0.001). A larger proportion of patients required antihypertensive medication (33.7% vs 50.0%, p = 0.017). Covered stent implantation results in favourable hemodynamic effects, but lifelong follow-up with additional antihypertensive drug treatment is mandatory to maintain these results.

Introduction

Coarctation of the aorta (CoA) is a congenital cardiovascular malformation, characterised by a restriction of the lumen of the thoracic aorta. This restriction is often just distal to the left subclavian artery and described as the adult type of CoA, whereas other patients have a more diffuse hypoplastic aortic arch or the combination of both. It occurs in approximately 4 of 10,000 live births and comprises 5% to 8% of congenital heart disease [1]. Mostly, CoA is detected in childhood and repaired surgically or by endovascular therapy. Occasionally it is diagnosed in adolescence or adulthood by investigations done for systemic hypertension. Exact numbers of late diagnosis of CoA are not reported in literature, but in a high-volume centre of adult congenital heart disease, it ranges between 2 and 4 diagnoses per year (data from the University of...
The natural history of CoA carries a poor prognosis due to complications such as left ventricular failure, intracranial haemorrhage, aortic rupture or dissection, premature coronary artery disease and sudden death [2–6].

Smaller and younger infants are typically treated surgically but remain at risk for recurrent obstruction with up to 10% requiring further intervention during adulthood [5,7].

In older children and adults, the preferred treatment method depends on the individual anatomy and nature of the lesion, but endovascular therapy with either balloon angioplasty or stent implantation is commonly preferred over surgery [8–14]. Although balloon angioplasty results in excellent acute hemodynamics, it is associated with a high rate of aortic wall injury and recurrent obstruction [14–16]. Because of these concerns, stent implantation is usually favoured to avoid over-dilation or the elastic recoil of the aorta. Bare stent implantation has become a worthy alternative to surgery and balloon angioplasty and seems to lead to better results and fewer complications [10,11,15–18]. However, although interventions with bare stent implantation seem efficient and generally safe, major complications such as local aneurysm formation, aortic rupture, dissection and even death may occur [12,13]. To prevent these aortic wall injuries (AWI) during the stent procedure, covered stents are increasingly used and their safety and efficacy for immediate and intermediate follow-up have been demonstrated [19–23]. However, long-term results remain limited. Therefore, we aimed to investigate the impact and safety of covered stent placement for treatment of (re)CoA during a longer follow-up period.

**Methods**

**Study design and patients**

This retrospective study assessed 89 patients with CoA who were treated with 102 covered stents in 93 procedures from 2003 to 2017 at the University Hospitals Leuven, Belgium.

All patients with a covered stent implantation for a native CoA or reCoA after surgical or transcatheter repair were included. Indications for stenting included hypertensive patients with an increased non-invasive gradient confirmed with invasive measurement (peak-to-peak $\geq$ 20 mmHg), when technically feasible [24]. Hypertension in children was defined as a systolic arterial pressure above the 95th percentile for their age and for adults the definition was in accordance to the ESC guidelines for the management of arterial hypertension [25]. Patients with associated congenital defects such as bicuspid or asymmetric tricuspid aortic valve and ventricular septum defect were included in the study, but patients with an associated more complex congenital cardiac anomaly were excluded. Hypoplastic arches were included. Transverse arch hypoplasia was defined as an arch index of less than 0.5 in which the arch index is the ratio of the transverse aortic arch diameter to the ascending and/or descending aorta diameter [26]. Clinical data, including age, sex, type and location of the coarctation and previous interventions were recorded at inclusion. The study was performed in accordance with the local ethics committee guidelines, University Hospitals Leuven, Belgium (S61175). Because of the retrospective design, informed consent was waived.

**Materials and stenting procedure**

All patients underwent a diagnostic catheterisation for invasive pressure gradient measurements, subsequently followed by covered stent implantation. The technique of stent implantation has been described before [27]. In summary, the aortic lumen at the narrowest part of the CoA was measured during angiography and compared to the descending part of the aorta, close to the diaphragm. The intention was to reach the same diameter as the descending aorta, although this diameter was not always exactly measured. The length of the stent was chosen to cover the length of the anomaly, ranging from a short focal narrowing to (in rare cases) a longer diffuse aortic arch hypoplasia. With growing experience, it was attempted to cover the whole lesion from proximal to distal, thereby barely positioning the distal zigs against the wall to avoid later aneurysm formation. All implants were done under general anaesthesia. The technical parameters (type and size of stent), hemodynamic parameters (peak-to-peak systolic gradient before and after stenting) and peri-procedural complications were recorded. Only 8-zig covered Cheatham Platinum (CCP) stents (Numed Inc., Hopkinton, NY, USA) were included in the study.
Blood pressure measurement and antihypertensive drugs

Blood pressure was measured by cuff sphygmomanometer on the right arm and left leg. No patients with an arteria lusoria were included and, as such, blood pressure was expected to be the highest in the right arm in all cases. Blood pressure in the lower limbs was mostly measured in the left leg and femoral pulsations were systemically examined. Only in-office measurements were analysed whereas ambulatory blood pressure measurements were not taken into account. When systemic hypertension was confirmed, medical treatment was started at the discretion of the treating physician. The numbers of antihypertensive medications prior to intervention and at each follow-up were systematically recorded.

Follow-up

Patients were followed after 1–3 months and thereafter every 6–12 months. Catheterisation, computed tomography or magnetic resonance imaging was repeated only in case of suspected complications.

Statistical analysis

Continuous variables are presented as mean plus minus standard deviation (range minimum–maximum). In case of an asymmetric distribution of data, results are reported as median (interquartile range (IQR)). Proportions are noted as number and percentage. Comparison of individual parameters before and after stenting was performed using the two-tailed paired t test. Categorical data were compared with a McNemar. A p value of less than 0.05 was considered statistically significant. Statistical analysis was done using the SPSS software version 26 package (SPSS Inc., Chicago, IL USA).

Results

Characteristics of the study population

A total of 89 patients (mean age 23.9 ± 15.8 years of which 35 patients <16 years and 54 patients ≥ 16 years, 67.4% male) underwent covered stent implantation. Table 1 summarises the demographic data including the operative and/or interventional history and indications for stenting.
Peri-procedural results

At the initial catheterisation, the mean diameter at the narrowest point of the coarctation prior to dilatation was 8 ± 3 (range 3–14) mm, corrected for body surface area 5 ± 2 (range 2–9) mm/m². The stent was inflated to a mean diameter of 16 ± 3 (range 10–30) mm, corrected for body surface area 10 ± 2 (range 6–20) mm/m². All implanted stents were covered Cheatham Platinum stents (CCP, Numed Inc., Hopkinton, NY, USA): 8z22 (1.1%), 8z28 (18.0%), 8z34 (25.8%), 8z39 (25.8%), 8z45 (28.1%) and 8z55 (1.1%).

Baseline invasive pressure measurements are shown in Table 2. Overall, the mean ascending-descending pressure gradient across the coarctation decreased from 25 ± 16 mmHg to 4 ± 7 mmHg (*p < 0.001). All procedures were successful without any malposition, migration or dissection.

In our clinical practice, patients are followed within a time window of less than 3 months after the intervention. As such, we present peri-procedural complications as complications <3 months. This information was available for 88 of the 89 patients (98.9%). The peri-procedural complication rate was low (4.5%) and mostly due to vascular injuries at the access site: femoral artery pseudoaneurysm (n=1), access site bleeding (n=1) and femoral artery occlusion for which an aorto-femoral bypass was necessary (n=1). Pulsations of the femoral arteries were systematically examined, and ultrasound examinations were only done when clinical suspicion of a femoral artery injury. As such, subclinical injuries were not reported. One patient developed pericarditis without any pericardial effusion on transthoracic echocardiography and AWI was excluded by computed tomography (CT) scan. Because of the radiation load, patients did not undergo systematically a CT scan within 3 months after the procedure; however, there were no clinically apparent AWIs. There were no strokes or deaths and no immediate re-interventions. Median length of hospital stay after stent implantation was 1 (range 1–5) day. Longer hospital stay was related to access site complications.

Long-term follow-up

The mean systolic blood pressure (SBP) gradient between arm and leg before stent implantation was 38 ± 24 mmHg. There was a significant improvement of the mean SBP gradient at 3 months follow-up (10 ± 20 vs 38 ± 24 mmHg; *p < 0.001). Data on blood pressure differences were available in 49 (55.1%) of the original 89 patients. At 1-year follow-up, there was a persistent decrease of the SBP gradient (10 ± 17 vs 38 ± 24 mmHg; **p < 0.001), available in 58 (65.2%) of the patients. Finally, at latest follow-up, blood pressure (BP) measurements in upper and lower limbs could be retrieved from 56 patients (63.0%), where the SBP gradient was practically nonexistent, compared to pre-stent values (−7 ± 18 vs 38 ± 24 mmHg; *p < 0.001). Mean follow-up time was 6.6 ± 3.7 years (min max range 0.2–15.7 years).

Systemic arterial hypertension and antihypertensive drugs

Mean systolic and diastolic BP, measured at the right arm before stent implantation was 150 ± 19 mmHg and 82 ± 13 mmHg respectively. Criteria for systemic hypertension (>140/90 mmHg) were found in 70.8% of the patients. At three months follow-up, mean systolic

### Table 2. Invasive hemodynamic measures pre-/post stent implantation.

<table>
<thead>
<tr>
<th></th>
<th>Pre</th>
<th>Post</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAo SBP, mmHg</td>
<td>107 ± 22</td>
<td>106 ± 22</td>
<td>0.932</td>
</tr>
<tr>
<td>AAo DBP, mmHg</td>
<td>60 ± 14</td>
<td>63 ± 12</td>
<td>0.040</td>
</tr>
<tr>
<td>DAo SBP, mmHg</td>
<td>82 ± 17</td>
<td>102 ± 22</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>DAo DBP, mmHg</td>
<td>59 ± 12</td>
<td>63 ± 12</td>
<td>0.001</td>
</tr>
<tr>
<td>SPG AAo – Dao, mmHg</td>
<td>25 ± 16</td>
<td>4 ± 7</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Values are mean ± SD. AAo: ascending aorta; Dao: descending aorta; SBP: systolic blood pressure; DBP: diastolic blood pressure; SPG: systolic pressure gradient.

Figure 1. Central illustration. Change in blood pressure and proportion of coarctation patients with antihypertensive treatment. Decrease in systolic blood pressure after stenting persists during follow-up (values are mean ± SD), but the proportion of patients needing antihypertensive treatment increases over time (values are percentages). SBP = systolic blood pressure. * Paired t test and ** McNemar test.
and diastolic BP, available for 84 patients (94.4%) was $133 \pm 6$ mmHg and $72 \pm 11$ mmHg, respectively ($p < 0.001$ vs pre-stent, for both). The criteria for systemic hypertension were met in 27.4% of the cases. At one-year follow-up, with a systolic upper-to-lower BP gradient of $10 \pm 17$ mmHg, mean systolic and diastolic BP, available in 83 patients (93.3%), was $132 \pm 19$ mmHg and $71 \pm 11$ mmHg, respectively ($p < 0.001$ vs pre-stent, for both). The criteria for systemic hypertension were met in 22.9% of the patients.

At latest follow-up, with a systolic upper-to-lower BP gradient of $-7 \pm 18$ mmHg, mean systolic and diastolic BP, available in 88 patients (98.9%), was $134 \pm 16$ mmHg and $73 \pm 12$ mmHg respectively ($p < 0.001$ vs pre-stent, for both). At latest follow-up, 31.8% of the patients remained hypertensive. Data on SBP at different time points are plotted in Figure 1.

Of the 30 patients receiving antihypertensive treatment before intervention, less medication could be applied in 13 patients (43.3%) after intervention. Of note, the first data on the use of antihypertensive treatment were collected 1 year after stenting. The proportion of patients who had hypertension but received no antihypertensive treatment before the stenting was 39.3% ($n = 35$). Of this proportion, 26 patients (74.3%) were normotensive at 3-months follow-up without any additional antihypertensive drug. Although blood pressures immediately after general anaesthesia and the day after the stenting were systematically recorded, these measurements were not analysed and considered too short after intervention to adapt already treatment.

At latest follow-up, 13 patients (50%) were diagnosed with hypertension, meaning that they received at least 1 antihypertensive drug ($n = 9$, 34.6%) or had a clinical diagnosis of hypertension (BP $> 140/90$ mmHg) but did not receive any treatment yet ($n = 4$, 15.4%). We did not have data on long-term follow-up in 1 patient (Figure 2).

Overall, 30 of the 89 patients (33.7%) were on antihypertensive medication before intervention, of which 18 (20.2%) were receiving $\geq 2$ medications to control BP. At latest follow-up, there were more patients on antihypertensive medication (42 of 84 patients (50%)), as well as a larger proportion (23 of 84 patients (27.4%)) requiring $\geq 2$ antihypertensive drugs to control blood pressure ($p = 0.017$ and $p = 0.066$). Five patients were lost to follow-up. Proportions of patients with antihypertensive treatment before stenting and at latest follow-up are plotted in Figure 1.

**Adverse events and reintervention**

Since the development of aortic aneurysms or pseudo-aneurysms is rarely clinical apparent, it is important to systematically survey for these adverse events during long-term follow-up. In our study, we did not have any follow-up data regarding imaging in 14 of the 89 patients (15.7%). Of the remaining 75 patients, 47 patients (62.7%) had follow-up imaging within the first five years of follow-up. Different imaging modalities were used during follow-up: CT scan was performed in 18 patients (38.3%), cardiac magnetic resonance (CMR) in 13 patients (27.7%) and both CT and CMR in 4 patients (8.5%). A second angiography was performed in 12 patients (25.5%) that did not have a CT or CMR during follow-up and reflected for a large part the expected reinterventions due to further dilatation to account for somatic growth. Of the 28 patients that did not have follow-up imaging within the first five years, 14 patients had a follow-up time of less than five years (Figure 3).

During follow-up, long-term adverse events related to stent implantation were found in 4 patients (4.5%). Two patients had a covered stent fracture for which an additional stent was implanted. New aneurysms were observed in another 2 patients: one aneurysm was located at the proximal part of the covered stent and treated with a second covered stent. One patient experienced a stent fracture with rupture of the membrane causing a posteriorly located aneurysm, which could also be treated with a covered stent. Of note, in 22 patients (29.3%) no follow-up imaging was performed.
Expected aortic re-interventions for reCoA were performed in 24 patients (27.0%) with more than 1 intervention in 4 patients (4.5%) and 5 interventions (5.6%) within the year. These expected re-interventions reflected the practice of staged therapy for severe obstructions in the entire cohort and elective further dilatation of stents to account for somatic growth. Further dilatation of the existing stent in 22 patients and additional stents were implanted in 6. Of the 4 patients with more than 1 intervention, 2 patients had further dilatation at two different time points and 2 patients had further dilatation and additional stenting during longer follow-up. No acute AWIs have been noted in relation to these re-interventions.

Four patients died during follow-up. A 21-year-old woman died 6 years after stent implantation due to a malignant melanoma. A 71-year-old woman died 2 years after stent implantation because of septic shock, which was of respiratory origin. The cause of death of a 59-year-old man who died 2 years after stent implantation and a 48-year-old man who died 4 years after stent implantation could not be retrieved from the patients’ records.

**Discussion**

Covered stents are increasingly used in severe and complex coarctations of the aorta, mainly to avoid the risk of aortic wall injuries, such as local aneurysm formation, dissection and aortic rupture [19–21,28–30]. Nevertheless, the aorta can still rupture with a covered stent, but no unlimited bleeding will occur, unless there was insufficient sealing, the covering was torn or in case of vessel tear with retrograde bleeding from collaterals. Most of the data on the use of covered stents in CoA is limited to immediate and intermediate outcome, whereas results on long-term outcome are sparse. In this retrospective study, patients were followed for a mean period of 6.6 ± 3.7 years (maximum follow-up time 15.7 years). To our knowledge, this is the largest study with the longest follow-up of the use of covered stents in (re)CoA.

In our study, covered stent implantation was highly effective for acute relief of an aortic obstruction, supporting prior reports in which stenting with a covered stent consistently reduced invasive measured gradients [23,31]. The in-hospital rate of complications was low and exclusively due to access site vascular injuries. Relatively large sheaths are used (up to 14 Fr in the femoral artery) for these procedures. The ease to puncture the femoral artery, the degree of temporarily prolonged anticoagulation immediately after removing the sheath, and the effectiveness of the local compression technique all play a substantial role in avoiding vascular complications. In our series, the number of events was too low for a valid statistical analysis. Although there is concern of potential, clinically significant, occlusion of an aortic side branch [32], this was not observed in our study. Furthermore, there were no aortic wall injuries, strokes or deaths, which further emphasises the short-term safety of covered stent implantation in patients with CoA.

Although there is an improvement in systemic hypertension, the blood pressure profile is not normalised, and residual systemic arterial hypertension is a common complication after CoA repair. The prevalence varies between 25 and 45% [4,33,34]. As a consequence, these patients remain to be exposed to increased cardiovascular risk with premature morbidity and mortality [3,35]. Therefore, identifying elevated blood pressures is important for long-term follow-up.

In this study, patients had an excellent immediate hemodynamic effect after stenting, which persisted at 3-month follow-up with a permanent reduction of
their mean blood pressure gradient compared to the pre-stent values. This beneficial result persisted also at one year and at long-term follow-up.

These results are in accordance with other studies, showing that the blood pressure profile can improve immediately and during mid- and long-term follow-up, after relieving the stenosis of the coarctation [33,36–38]. However, in contrast to other studies using a covered stent to repair CoA [19,23], antihypertensive therapy could not be permanently reduced or discontinued in our series. We rather noticed an increase in antihypertensive drugs requirement to achieve rigorous BP control at later follow-up. One-third of the patients was still hypertensive at latest follow-up. This number is probably overestimated because the blood pressures refer to in-office measurements. In case of elevated blood pressures in-office, the patient is instructed to measure the home blood pressure and to mail the results to the congenital heart disease team of the hospital. As such, it is confirmed that there is sometimes a discrepancy between in-office and ambulatory blood pressure recordings. Treatment is only adapted to achieve normal blood pressures at home (<135/85 mmHg). Because of the retrospective design, ambulatory blood pressure measurements were not systematically performed in all patients. Only when home blood pressure measurements were unreliable, ambulatory blood pressure measurements were performed. This occurred only in a minority of cases. Although most studies on covered stent implantation do no report exact percentages of patients with residual systemic hypertension, the percentage of short-term residual hypertension in our study was in line with the study of Sohrabi et al [23]. Also for longer-term hypertension, the percentage of patients with residual hypertension was comparable to the percentage mentioned in other studies [4,5,33,34].

The fact that a significant number of patients with hypertension after CoA repair do not have residual obstruction, underlines the complexity of the pathophysiology of residual hypertension. The latter has been linked to several mechanisms, including abnormal geometry of the aortic arch, changes in arterial function, attenuation of baroreflexes or hyperactivation of the renin angiotensin system [33,38–43]. As such, lifelong follow-up of these patients remains mandatory. An open vessel does not equal a normal blood pressure.

Despite early and successful anatomic repair, patients with CoA may still develop aneurysm formation during long-term follow-up due to the associated abnormal vascular phenotype. Also therefore, lifelong follow-up with routine imaging surveillance should be performed in these patients, even when asymptomatic.

Long-term adverse events due to stent implantation were seen in four patients (stent fracture and aneurysm formation). Although no previous reports have been issued specifically on aneurysm formation after covered stent placement and the interpretation of data is confounded by mostly heterogeneous subject populations and incomplete follow-up, a covered stent might protect the post-stenotic area by diverging the flow from the dilated areas and more centrally into the descending aortic lumen. This favourable hemo-dynamic effect could explain the lack of aneurysm formation during the first years of follow-up. However, since we did not perform routine routine imaging late after stenting, we cannot compare our results with the existing literature on bare stents.

Limited data are available on the usefulness of covered stents in preventing reCoA [44]. Although aortic reinterventions were common in our study (31.5%), and notably higher than in most surgical series, this reflected for the most part our initial practice of staged therapy for severe obstructions in children and adults. A higher number of reinterventions reflect elective further dilatation of stents to account for somatic growth in children. Regardless of the indication, reintervention seemed in general efficient and safe with no immediate or long-term procedural complications. The latter demonstrates the relative ease in redilating these covered stents.

There were 4 deaths in our series during follow-up. None of them, however, could be linked directly to the covered stent implantation.

**Study limitations**

Our study has some limitations. The most important limitation is the retrospective, single-centre design and the incomplete follow-up achieved. We acknowledge that especially follow-up data on SBP gradients between right arm and leg was incomplete. Furthermore, because our study only included patients with covered stents, we cannot compare our results regarding short- and long-term complications and blood pressure regulation to other endovascular or surgical options in the management of CoA. Patient groups would have no similar baseline characteristics and as a consequence difficult to compare. Patients did not undergo 24 h blood pressure measurements, which could have studied the normotensive state more accurately. Also, blood pressure response during
exercise testing could have been more valuable to define procedure outcome. We did not present BP data as Z-values in the young population and, as such, we may have underestimated hypertension in a proportion of these young patients. Since data on follow-up imaging was incomplete, we cannot exclude that the rate of adverse events was higher than described in our study. Finally, the ultimate goal of these procedures is to prolong survival without vascular complications in patients with CoA. Only long-term follow-up will determine whether this objective will be met.

**Conclusion**

The main findings of this study show that covered stent implantation in patients with severe coarctation of the aorta is highly successful, safe and results in permanent positive hemodynamic effects during long term follow-up.

However, to achieve these long-term results, many patients require additional drug treatment to control blood pressure and as such a lifelong follow-up of these patients, encompasses a rigorous control of cardiovascular risk factors.

**Disclosure statement**

MG is proctor for Numed; WB is proctor for Occlutech and Abbott.

**References**


