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Long-term follow-up after endovascular treatment of aortic coarctation with bare and covered Cheatham platinum stents

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Abstract

Background: Endovascular treatment of aortic coarctation (CoA) in children and adults frequently requires stent implantation. The aim of this study was to analyze long-term results after CoA treatment with bare and covered Cheatham-Platinum™ (CP) stents in our institution and to derive recommendations for the differential use of these stent types.

Methods: In this retrospective single institution study, 212 patients received endovascular CoA treatment with bare ($n = 71$) and covered ($n = 141$) CP stents between September 1999 and July 2021, respectively. The indications for treatment were native CoA in 110/212 patients (51.9%) and re-coarctation after primary surgical or interventional treatment in 102/212 patients (48.1%). Median patient age at endovascular CoA treatment was 18.8 years [IQR 11.9; 35.8]. Long-term follow-up was available in 158/212 patients (74.5%) with a median follow-up of 7.3 years [IQR 4.3; 12.6].

Results: Procedural success was achieved in 187/212 (88.2%) patients. Survival rate was 98.1% after 5, and 95.6% after 10 and 15 years, respectively. The probability of freedom from re-intervention was 93.0% after 5, 82.3% after 10 and 77.8% after 15 years, respectively. Freedom from re-interventions (44/158, 27.8%) did not differ between patients who received bare or covered CP stents ($p = 0.715$). Multivariable risk factor analysis identified previous CoA surgery (HR: 2.0, 95% confidence interval (CI): 1.1–3,9, $p = 0.029$), postdilatation (HR: 2,9, 95% CI: 1.1–6.3, $p = 0.028$) and age at intervention (HR: 0.96, 95% CI: 0.94–0.99, $p = 0.002$) as independent risk factors for re-intervention. Peri-procedural complications occurred in 15/212 (7.1%) patients (dissection/thrombosis of vascular access vessel: $n = 9$; bleeding: $n = 1$; stent dislocation: $n = 2$; aortic dissection/aortic wall rupture: $n = 3$). Long-term complications were observed in 36 patients and included stent fracture ($n = 19$), aneurysm formation ($n = 14$), endoleak ($n = 1$) and subclavian artery stenosis ($n = 2$).

Abbreviations: BiB®, balloon-in-balloon catheter; CE, European conformity; CI, confidence interval; CoA, coarctation of the aorta; CP, Cheatham-Platinum™; CT, computed tomography; CW, continuous wave; FDA, United States Food and Drug Administration; HR, hazard ratio; IQR, interquartile range; MRI, magnetic resonance imaging.

Peri-procedural and long-term complications did not differ between patients who received CoA treatment with bare or covered CP stents (all $p > 0.05$).

Conclusion: Endovascular treatment of CoA using bare or covered CP stents can be performed safely and effectively with excellent long-term results. Survival, re-intervention and complication rate did not significantly differ between both stent types. However, individual stent selection is advisable with regard to CoA morphology and severity as well as patient age.

KEYWORDS

aortic coarctation, bare stent, Cheatham-Platinum stent, congenital heart disease, covered stent, endovascular treatment

1 | INTRODUCTION

Aortic coarctation (CoA) comprises 5% to 8% of all congenital heart disease.[1,2] After balloon angioplasty was introduced as a treatment option for patients with native or recurrent postsurgical CoA in the 1980s,[3,4] endovascular treatment has rapidly evolved and become a widely accepted alternative for surgery in patients beyond the neonatal period. Since the 1990s, bare balloon-expandable stent repair has replaced balloon angioplasty as the treatment of choice for adolescents and adults with CoA due to remarkable hemodynamic effects and lower complication rates.[5–7] Increased operator experience as well as refined balloon and stent technologies improved the safety and success of this procedure leading to excellent short- and long-term outcomes.[8,9]

The introduction of covered Chetham-Platinum™ (CP) stents in the late 1990s has substantially expanded the spectrum of endovascular CoA treatment including complex CoA anatomy with atretic or subatretic coarctation, severe aortic arch tortuosity, treatment of patients with CoA aneurysms or stent related complications such as fracture, endoleak or aortic wall injury.[10] Various stent types from a large number of manufactures have been reported to be employed for CoA treatment, however, the majority of these are being used off-label.[11,12] Bare or covered CP stents are specifically designed for endovascular CoA treatment and received CE mark in 2003 and FDA approval in 2016. However, long-term results comparing effectiveness and complications as well as recommendations concerning the use of bare or covered CP stents with regard to CoA anatomy are missing. In this study, we aimed to analyze long-term results after endovascular treatment of CoA with bare and covered CP stents by comparing procedural success, survival, re-intervention, and complication rates.

2 | METHODS

2.1 | Study design and endpoints

From 1999 to 2021 a total of 212 consecutive patients underwent endovascular treatment of CoA by implantation of bare or covered CP stents in our institution. The study was approved by the institutional review board and ethics committee (decision number: EA2/009/21). Informed consent was not mandatory due to the retrospective character of this study. The term "native" CoA refers to patients who did not receive surgical or interventional treatment before CP stent implantation. Patients aging <18 years were defined as pediatric and ≥18 years as adult. Primary endpoints were defined as procedural success, survival and re-intervention rate. The procedure was considered successful with a peak systolic gradient ≤10 mmHg after intervention and the absence of a major complication such as aortic wall injury, stent dislocation or patient death. In-hospital mortality was classified as death before hospital discharge or within 30 days after an interventional treatment. Accordingly, late mortality was defined as occurring later than 30 days after endovascular CoA treatment. Re-interventions were defined as unplanned secondary interventional procedures performed to treat re-coarctation or long-term complications occurring after the primary endovascular treatment. Secondary end-points included peri-procedural and long-term complications. Peri-procedural complications comprised stent migration, dissection/thrombosis of the vascular access vessels, aortic wall injuries and bleeding. Long-term complications were characterized as stent fracture or aneurysm formation. Aneurysms were diagnosed by angiography during re-catheterization, computed tomography (CT) or magnetic resonance imaging (MRT) during follow-up. An aneurysm was defined as a secondary ≥10.0% expansion of the aortic diameter beyond the stent or native aortic diameter which was not present before or immediately after the intervention as proposed by the Congenital Cardiovascular Interventional Study Consortium.[13] Stent fractures were diagnosed during re-catheterization and/or CT and were subdivided into minor and major stent fractures. Minor stent fractures were defined as single or multiple strut fractures without structural consequences and major stent fractures as circumferential or longitudinal fractures causing restenosis or embolization of stent fragments. Postdilatation was performed immediately after stent implantation to achieve complete stent expansion using noncompliant balloons by applying inflation pressures up to 18 atmospheres. Arterial hypertension in adult patients was defined as a systolic blood

pressure ≥130 mmHg or diastolic blood pressure ≥90 mmHg. In pediatric patients arterial hypertension was defined as a systolic or diastolic blood pressure ≥the 95th percentile of the age-, gender-, and body dimensions-based reference values.

2.2 | Endovascular treatment of CoA

Indications for CoA treatment were based on the current guideline recommendations and included an upper extremity/lower extremity resting peak-to-peak systolic gradient or invasive peak-to-peak systolic gradient >20 mmHg, systemic arterial hypertension attributable to CoA, radiologic evidence of a moderate to severe CoA with significant collateral circulation or presentation with congestive heart failure with or without associated cardiac comorbidity.[2,14] Our institutional technique of endovascular CoA treatment has previously been described in detail.[10,15] Briefly, after retrograde placement of a long delivery sheat in the ascending aorta (10–16 F, Check-Flo Performer Introducer; Cook Medical Europe Ltd), a bare or covered CP stent (NuMED) was implanted. Stents were mounted on balloon-in-balloon catheters (BiB®; NuMED). The length of the stent was chosen based on the distance between the left subclavian artery and 10–15 mm below the CoA. Balloon diameter was selected based on the diameter or the transverse arch or the descending aorta at the level of the diaphragm. In some patients, additional postdilatation was performed to achieve complete stent expansion and stent apposition to the aortic wall (Atlas® Gold balloon, Bard Medical, USA or Z-MED™ II balloon; NuMED).

2.3 | Postprocedural follow-up

Before discharge, all patients underwent a detailed clinical examination, echocardiography and chest X-ray. Long-term follow-up was available in 158/212 patients (74.5%) and included serial clinical examinations, non-invasive blood pressure measurement and echocardiography. Echocardiographic peak systolic pressure gradient was determined by measuring the peak flow velocity with the CW Doppler and calculating the pressure gradient using the Bernoulli equation. Follow-up cross sectional imaging, such as magnetic resonance imaging (MRI) was available in 133/158 patients (84.2%). CT and re-catheterization imaging were accessible in 108/158 patients (68.4%). No follow-up data was available in 54 patients, who were excluded from long-term result analysis.

2.4 | Statistical analysis

Data were obtained from institutional electronic medical records. Patients' characteristics are expressed as median and interquartile range [IQR]. Survival and freedom from re-intervention were assessed using Kaplan–Meier survival analysis. Survival and re-intervention rates between groups were compared using the log rank test. Differences between groups were analyzed using the χ^2 test for categorical variables and the Wilcoxon rank sum test for continuous variables. Potential risk factors (anatomic, hemodynamic, and procedural parameters) for re-intervention were evaluated with univariate logistic and Cox regression analysis. Time-independent variables such as constant stent characteristics, procedural details and age at intervention were included in a multivariable model using the hazard ratio (HR) and additionally the accelerated failure time framework for time to event data, if the $p < 0.2$ in the univariate analysis. The final model was developed by a step-down procedure using likelihood ratio tests for model comparisons. Statistical analyses was performed using SPSS statistical software program (version 23, IBM Corp) and Stata 16.1 (Stata Corp). A $p < 0.05$ was considered statistically significant.

3 | RESULTS

3.1 | Patient characteristics

Patient characteristics of the entire cohort are listed in Table 1. Endovascular CoA treatment using bare CP stents was performed in 71 patients, whereas in 141 patients covered CP stents were implanted. Median patient age was 18.8 years [IQR 11.9; 35.8] and median patient weight 61.3 kg [IQR 43.3; 74.7]. The cohort consisted of 100 pediatric and 112 adult patients. Patient age significantly differed between patients receiving bare or covered CP stent (16.3 years [IQR 10.1;25.9] vs. 22.8 years [IQR 12.9;42.2], $p = 0.001$). The most frequent concomitant cardiac comorbidities and associated anomalies were arterial hypertension in 186/212 patients (87.7%), bicuspid aortic valve in 64/212 patients (30.2%), and aortic valve regurgitation in 40/212 patients (18.9%). Treatment of native CoA was performed in 110/212 patients (51.9%), whereas 71/212 patients (48.1%) received treatment of re-coartation after primary surgical repair. Previous transcatheter interventions had been performed in 54/212 patients (25.5%); 35/54 patients (64.8%) received a balloon dilatation and 19/54 patients (35.2%) a stent implantation. In 23/102 patients (22.5%) both, surgical and interventional treatment was performed before endovascular CoA treatment using a CP stent.

3.2 | Procedural results

Median invasive peak systolic gradient before endovascular treatment was 30 mmHg [IQR 20; 40] and did not significantly differ between both subgroups ($p = 0.838$, Table 2). Additionally, the diameters of the transverse arch, the minimum CoA or the descending aorta did not diverge between patients who received endovascular treatment using bare or covered CP stents (all $p > 0.05$; Table 2). Procedural success was achieved in 187/212 (88.2%) patients. After endovascular treatment, invasive and non-invasive

TABLE 1 Patient characteristics.

Characteristic, *n* (%)/[IQR]	Entire cohort (*n* = 212)	Bare CP stent (*n* = 71)	Covered CP stent (*n* = 141)	*p* Value
Concomitant cardiac diagnoses				
Arterial Hypertension	186/212 (87.7%)	61/71 (85.9%)	125/141 (88.7%)	**0.357**
Bicuspid aortic valve	64/212 (30.2%)	19/71 (26.8%)	45/141 (31.9%)	0.527
Aortic valve regurgitation	40/212 (18.9%)	17/71 (23.9%)	23/141 (16.3%)	0.196
Ventricular septal defect	23/212 (10.8%)	7/71 (9.9%)	16/141 (11.3%)	0.819
Hypoplastic aortic arch	15/212 (7.1%)	7/71 (9.9%)	8/141 (5.7%)	0.801
Kinking of the aorta	17/212 (8.0%)	8/71 (11.3%)	9/141 (6.4%)	0.283
Aortic aneurysm	26/212 (12.3%)	8/71 (11.3%)	18/141 (12.8%)	0.828
Other	33/212 (15.6%)	13/71 (18.3%)	20/141 (14.2%)	0.430
Patient age at procedure (years)	18.8 [11.9; 35.8]	16.3 [10.3;25.9]	22.8 [12.9; 42.2]	**0.001**
Patient age <18 years	100/212 (47.2%)	43/71 (60.6%)	57/141 (40.4%)	**0.008**
Patient weight at procedure (kg)	61.3 [43.3; 74.7]	56.4 [40.0; 73.7]	62.4 [45.0; 75.4]	0.278
Sex (male)	146/212 (68.9%)	51/71 (71.8%)	95/141 (67.4%)	0.534
CoA morphology				
Native	110/212 (51.9%)	26/71 (36.6%)	84/141 (59.6%)	**0.002**
Postsurgical	48/212 (22.6%)	26/71 (36.6%)	22/141 (15.6%)	**<0.001**
Postinterventional	31/212 (14.6%)	10/71 (14.1%)	21/141 (14.9%)	0.356
Postsurgical and—Interventional	23/212 (10.8%)	9/71 (12.7%)	14/141 (9.9%)	0.641

Note: Data are expressed as median [interquartile range] or frequency (percentage). Statistical significant *p* values are labeled in bold.
Abbreviations: CoA, aortic coarctation; CP, Cheatham-Platinum™; IAA, interrupted aortic arch; IQR, interquartile range.

peak systolic gradient significantly decreased in both subgroups (Table 2). Additionally, after stent implantation a significant reduction of systolic blood pressure was achieved from a preinterventional median pressure of 145 mmHg [IQR 134; 157] to a postinterventional median pressure of 123 mmHg [IQR 112; 135] ($p < 0.001$, Table 2). In 25 patients the interventional procedure was not considered successful: In 22 of these patients a reduction of the peak systolic pressure ≤10 mmHg was not achieved. Fifteen of these patients were additionally diagnosed with a hypoplastic aortic arch with a remaining systolic ascending to descending aortic pressure difference >10 mmHg after successful implantation of the CP stent in the CoA region. In two patients with an unsuccessful procedure the stent migrated into the descending aorta immediately after placement. Both patients underwent subsequent surgical repair after fixation of the stent in the descending aorta by balloon dilatation. Another patient developed an aortic wall rupture immediately after stent implantation and died during extracorporal cardiopulmonary resuscitation. This 47-year-old patient received surgical CoA repair at the age of 12 years. During follow-up the patient developed a postsurgical aneurysm distal the CoA region, a moderate kinking of the CoA region and a re-coarctation. Immediately after placement of a bare 8-zig/45 mm CP stent the patient developed a cardiorespiratory arrest. In the angiogram a rupture of the posterior aortic wall proximal of the cranial stent end and below the origin of the left subclavian artery was detected. Despite immediate extracorporal cardiopulmonary resuscitation and implantation of four covered CP stents in aortic arch and CoA region a stable cardiopulmonary condition could not be achieved and the patient died from hemorrhagic shock.

3.3 | Survival rate

Survival rate was 98.1% after 5, and 95.6% after 10 and 15 years, respectively, and did not differ between patients who received bare or covered CP stents (Log Rank $p = 0.263$, Figure 1). In-hospital mortality occurred in 1/212 patients (0.5%) and late mortality in 8/158 patients (5.1%, Table 2). Late mortality was not attributable to previous CoA treatment; causes of late death were myocardial infarction ($n = 1$), progressive coronary artery disease ($n = 2$), septic shock ($n = 1$), cardiac arrest after mitral valve reconstruction ($n = 1$) or congestive heart failure ($n = 1$). In two patients, the cause of death was not identifiable. There was no difference in late mortality according to stent type ($p = 0.261$).

TABLE 2 Anatomic and hemodynamic characteristics.

Parameter, *n* (%)/[IQR]	Entire cohort (*n* = 212)	Bare CP stent (*n* = 71)	Covered CP stent (*n* = 141)	*p* Value
Anatomic measurements/diameters				
Transverse arch (mm)	16.0 [12.2; 18.6]	15.3 [11.8; 18.2]	16.1 [12.5; 18.8]	0.273
CoA diameter (mm)	8.0 [6.0; 10.9]	8.9 [6.9; 10.9]	7.7 [5.4; 10.9]	0.124
Descending aorta (mm)	17.2 [13.5; 22.0]	17.0 [13.1; 20.5]	17.5 [13.7; 22.3]	0.259
Predilatation	24/212 (11.3%)	14/71 (19.7%)	10/141 (7.1%)	**0.010**
Postdilatation	149/212 (70.3%)	49/71 (69.0%)	100/141 (70.9%)	0.874
Diameter of BiB® catheter (mm)	16.0 [14.0; 20.0]	16.0 [14.0; 18.0]	16.0 [14.0; 20.0]	0.870
Full expansion of BiB® catheter	171/212 (80.7%)	53/71 (74.6%)	118/141 (83.7%)	0.141
Stent dimensions after implantation				
Minimum diameter (mm)	13.3 [10.8; 16.2]	13.2 [10.9; 16.2]	13.7 [10.8; 16.2]	0.732
Length (mm)	30.6 [24.9; 36.0]	26.0 [22.0; 32.4]	32.6 [26.7; 36.7]	**<0.001**
Maximum peak-to-peak systolic gradient (invasive)				
Preinterventional (mmHg)	30 [20; 40]	30 [20; 40]	30 [20; 40]	0.838
Postinterventional (mmHg)	0 [0; 7]	0 [0; 10]	0 [0; 5]	**0.037**
Maximum systolic blood pressure (non-invasive)				
Preinterventional (mmHg)	145 [134;157]	142 [133;153]	147 [135;160]	0.077
Postinterventional (mmHg)	123 [112;135]	124 [113;135]	123 [113;135]	0.9
Last follow-up (mmHg)	130 [119;140]	131 [119:140]	130 [120:140]	0.953
Upper extremity/lower extremity resting peak-to-peak systolic gradient (non-invasive)				
Preinterventional (mmHg)	29 [15;44]	25 [17;39]	30 [14;45]	0.36
Postinterventional (mmHg)	0 [0;6]	0 [0;7]	0 [0;6]	0.869
Last follow-up (mmHg)	0 [0; 7]	2 [0;8]	0 [0;6]	**0.018**
Maximum peak pressure gradient (echocardiography)				
Preinterventional (mmHg)	46 [34;60]	45 [30;60]	48 [35;62]	0.489
Postinterventional (mmHg)	15 [10; 20]	12 [9;17]	15 [10;20]	**0.026**
Last follow-up (mmHg)	19 [12,25]	20 [12;25]	19 [13;25]	0.895
Duration of follow-up (years)[a]	7.3 [4.3; 12.6]	9.5 [5.1; 15.1]	6.6 [3.6; 10.4]	**<0.001**
Mortality				
In-hospital	1/212 (0.5%)	1/71 (1.4%)	0/141 (0.0%)	0.317
Long-term	8/158 (5.1%)	5/60 (8.3%)	3/98 (3.1%)	0.261
Re-interventions				
Planned	33/158 (20.9%)	13/60 (21.7%)	20/98 (20.4%)	0.843
Unplanned	44/158 (27.8%)	18/60 (30.0%)	26/98 (26.5%)	0.715
Peri-procedural complications				
Injury/thrombosis of the vascular access vessel	9/212 (4.2%)	3/71 (4.2%)	6/141 (4.3%)	1.000
Bleeding of vascular access vessel	1/212 (0.5%)	0/71 (0.0%)	1/141 (0.7%)	0.665
Stent dislocation	2/212 (0.9%)	2/71 (2.8%)	0/141 (0.0%)	0.111
Aortic dissection/aortic wall rupture	3/212 (1.4%)	2/71 (2.8%)	1/141 (0.7%)	0.260

TABLE 2 (Continued)

Parameter, *n* (%)/[IQR]	Entire cohort (*n* = 212)	Bare CP stent (*n* = 71)	Covered CP stent (*n* = 141)	*p* Value
Long-term complications				
Aneurysm formation	14/133 (10.5%)	5/50 (10.0%)	9/83 (10.8%)	1.000
Stent fracture	19/108 (17.6%)	10/39 (25.6%)	9/69 (13.0%)	0.092
Minor	15/19 (78.9%)	9/9 (100.0%)	6/7 (85.7%)	
Major	4/19 (21.1%)	1/9 (11.1%)	3/9 (33.3%)	
Endoleak	-	-	1/98 (1.0%)	-

Note: Data are expressed as median [interquartile range] or frequency (percentage). Statistical significant *p* values are labeled in bold.
Abbreviations: BiB®, balloon-in-balloon; CoA, aortic coarctation; CP, Cheatham-Platinum™; IQR, interquartile range.
[a]Fifty-three patients with no available follow-up data were excluded from long-term result analysis.

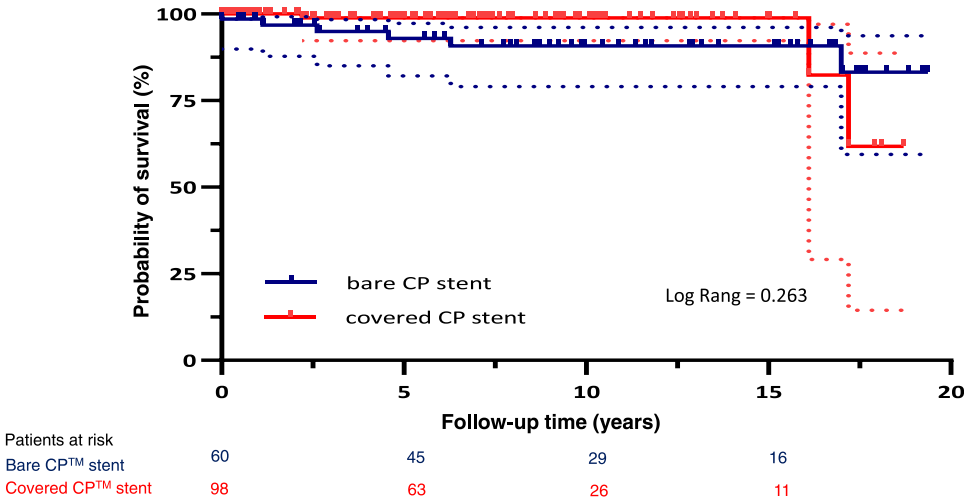

FIGURE 1 Kaplan–Meier curve analysis comparing survival after endovascular CoA treatment with bare (*n* = 60) and covered CP (*n* = 98) stents. [Color figure can be viewed at wileyonlinelibrary.com]

3.4 | Re-intervention rate

Planned re-interventions were performed in 33/158 patients (20.9%) who received an intended two-staged endovascular CoA treatment with primary stent implantation and secondary post-dilatation of the remaining central narrowing after a period of 6 to 12 months. Seven of these patients (21.2%) received a secondary unplanned reintervention for treatment of re-coarctation. In 44/158 patients (27.8%), unplanned re-interventions were performed to treat re-stenosis or aortic wall injuries, and included secondary balloon dilatation in 27/44 patients (61.4%) and secondary stent implantation in 17/44 patients (38.6%) after a median follow-up duration of 4.2 years [IQR 2.2; 6.5]. In 12/44 patients (27.3%) two re-interventions were performed, whereas 5/44 patients (11.4%) received equal or more than three re-interventions after CP stent implantation. The probability of freedom from re-intervention in the entire cohort was 81.0% after 5, 64.0% after 10 and 62.0% after 15 years, respectively. Re-intervention rate did not differ between patients who received endovascular CoA treatment with bare or covered CP stents ($p = 0.50$; Figure 2). Re-interventions were performed more frequently in patients who received an endovascular CoA treatment before CP stent implantation compared to those who received a CP stent as primary endovascular treatment (Log Rank $p = 0.003$). Moreover, re-intervention rate was significantly higher in pediatric compared to adult patients ($p < 0.001$, Figure 3). Multivariable risk factor analysis revealed previous CoA surgery (HR: 2.0, 95% confidence interval [CI]): 1.1–3,9, $p = 0.029$), postdilatation (HR: 2,9, 95% CI: 1.1–6.3, $p = 0.028$) and age at intervention (HR: 0.96, 95% CI: 0.94–0.99, $p = 0.002$) as independent risk factors for re-intervention. The accelerated time failure (AFT)-model suggests that prior CoA surgery shortens the time to re-intervention by a factor of 0.48 ($p = 0.016$; 95% CI: 0.26–0.87), postdilatation by a factor of 0.44 ($p = 0.048$; 95% CI: 0.20–0.99), whereas increasing the age at intervention leads to a prolongation of the time to re-intervention by a factor of 1.04 ($p = 0,002$; 95% CI: 1.01–1.07) per year.

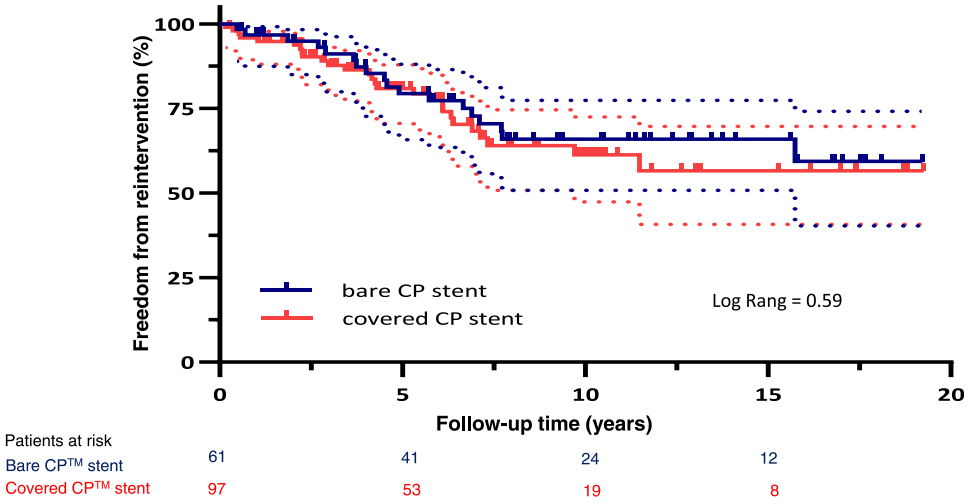

FIGURE 2 Kaplan–Meier curve analysis comparing freedom from reintervention after endovascular CoA treatment with bare ($n = 61$) and covered CP (n = 97) stents. [Color figure can be viewed at wileyonlinelibrary.com]

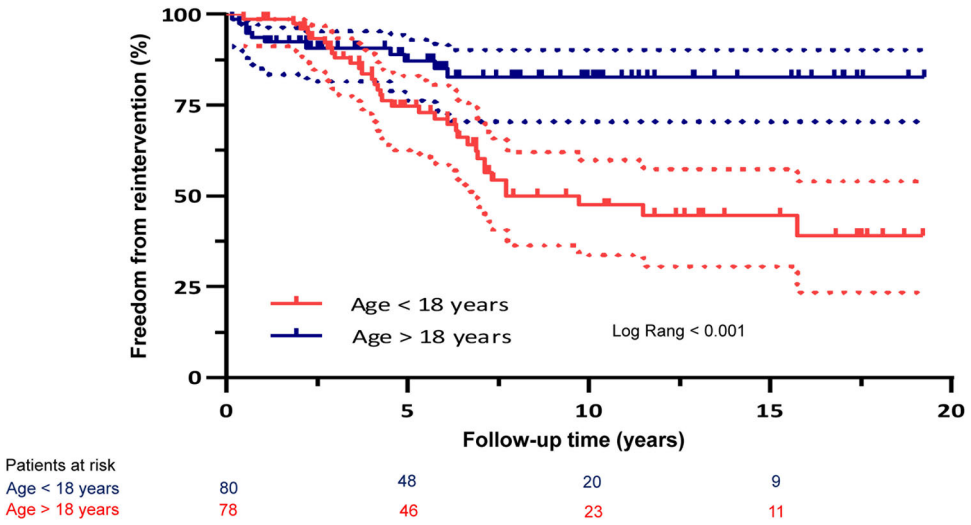

FIGURE 3 Kaplan–Meier curve analysis comparing freedom from reintervention after endovascular CoA treatment in pediatric ($n = 79$) and adult patients ($n = 79$). [Color figure can be viewed at wileyonlinelibrary.com]

3.5 | Complication rate

Peri-procedural complications occurred in 15/212 patients (7.1%, Table 2) and included dissection/thrombosis of vascular access vessel ($n = 9$), postinterventional bleeding of access vessel requiring surgical treatment ($n = 1$), stent dislocation ($n = 2$), aortic dissection/aortic wall rupture ($n = 3$). Long-term complications were observed in 36 patients and included stent fracture (19/108; 17.6%, Figure 4), aneurysm formation ($n = 14/133$; 10.5%, Figure 4), endoleak ($n = 1/133$; 0.8%, Figure 4) and subclavian artery stenosis requiring treatment ($n = 2/133$; 1.5%). In the majority of patients whith stent fractures, only minor stent fractures were observed ($n = 15$), whereas in four patients the secondary placement of a covered CP stent was indicated to provide further embolization of stent fragments (Figure 4). The incidence of stent fracture was not associated with patient age ($p = 0.383$), stent diameter ($p = 0.187$), stent length ($p = 0.513$), treatment of native or postsurgical CoA ($p = 0.346$), or the performance of postdilatation after stent placement ($p = 0.499$). Peri-procedural and long-term complications did not significantly differ between patients who received bare or covered CP stents (all $p > 0.05$; Table 2).

3.6 | Long-term follow-up

Long-term follow-up was available in 158/212 patients (74.5%) with a median follow-up of 7.3 years [IQR 4.3; 12.6], which significantly differed between patients who received endovascular treatment with

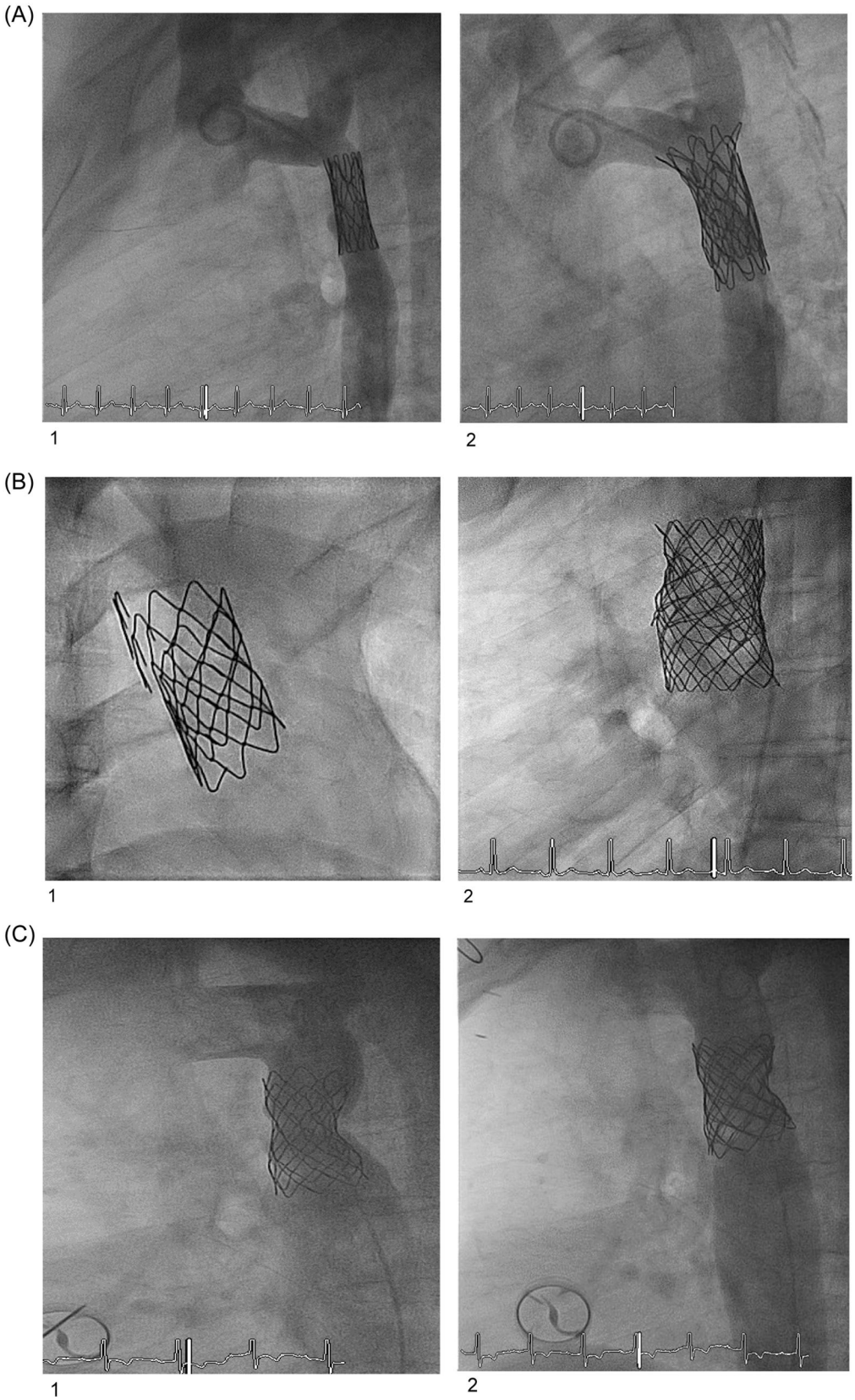

FIGURE 4 Images of long-term complications after CoA treatment with bare or covered CP stent. (A1) Pseudoaneurysm formation 7 years after primary implantation of a bare CP stent (8-zig; 22 mm) to treat a native CoA in a 6-year-old patient. (A2) Result after implantation of a covered CP stent (8-zig/34 mm). (B1) Stent fracture at the proximal stent end with multiple embolized struts 9 years after implantation of a covered CP stent (8-zig/34 mm) to treat native CoA in a 11-year-old patient. (B2) Result after implantation of a covered CP stent (10-zig/50 mm). (C1) Endoleak formation 1 year after implantation of a covered CP stent (8-zig/34 mm) to treat native CoA in a 54-year-old patient. (C2) Result after implantation of a covered CP stent (8-zig/45 mm) and postdilatation with a 28 mm Z-med II balloon.

bare or covered CP stent (9.5 years [IQR 5.1; 15.1] vs. 6.6 years [IQR 3.6; 10.4], $p < 0.001$). Non-invasive peak systolic blood pressure significantly decreased from a median of 145 mmHg [IQR 134; 157] to 123 mmHg [IQR 112; 135] after stent implantation and remained at 130 mmHg [IQR 119; 140] at last follow-up (Table 2, $p < 0.001$). In analogy, upper extremity/lower extremity resting peak-to-peak blood pressure gradient was significantly reduced from 29 mmHg [IQR 15; 44] to 0 mmHg [IQR 0; 7] at last follow-up (Table 2, $p < 0.001$). Echocardiographycally measured median peak systolic gradient at last follow-up was 16 mmHg [IQR 6; 24] and did not significantly differ between patients with bare or covered CP stent (20 mmHg [IQR 10; 25] vs. 16 mmHg [IQR 9; 25], $p = 0.211$). Residual arterial hypertension was present in 53/158 patients (33.5%); 23 of these patients were adult and 30 patients pediatric ($p = 0.173$). Before endovascular treatment with bare or covered CP stent 114 patients received no medical antihypertensive therapy, 44 patients received monotherapy, 30 patients dual therapy, and 24 patients triple or quadruple therapy. In 76/158 patients (48.1%) the number of antihypertensive medication did not change during follow-up, whereas in 57/158 patients (36.1%) the number of antihypertensive medication was increased and in 25/158 patients (15.8%) decreased.

4 | DISCUSSION

In this study, long-term outcomes after endovascular treatment of native, postsurgical or postinterventional CoA using bare and covered CP stents were analyzed. Our study demonstrates that transcatheter implantation of both CP stent types is effective and associated with excellent procedural and long-term results. Neither survival nor re-intervention rate significantly differed between bare and covered CP stents. Additionally, no differences concerning peri-procedural and long-term complications, in particular stent fracture or aneurysm formation were detected. These results contradict to findings of previous studies, which described a trend toward a lower re-coarctation and a higher aneurysm formation rate in patients who received CoA treatment with covered CP stents[16] or identified the use of bare CP stents as an independent predictor for stent fractures.[17] In our cohort, implantation of both, bare and covered CP stents effectively reduced peak systolic gradient immediately after endovascular CoA treatment. Additionally, no statistically significant differences of peak systolic gradient were detected during long-term follow-up comparing both CP stent types.

4.1 | Aortic wall injury

In our study, peri-procedural mortality occurred in one case after treatment of a postsurgical re-coarctation by implantation of a bare CP stent. Bare CP stent implantation caused an acute aortic rupture, which immediately lead to patient death. Severe aortic wall complications such as dissection and aortic wall rupture are predominantly reported after the use of bare CP stents.[18,19] Considering that in adult and elderly patients calcifications, wall thinning, increased aortic wall stiffness and cystic medial necrosis proximal and distal to the CoA segment are frequently present, endovascular CoA treatment with covered CP stents should be preferred to minimize or avoid aortic wall injuries.[17–19] After introduction of covered CP stents in the late 1990s, they have rapidly become the treatment of choice for patients with severe or complex CoA anatomy.[10,20] The sealant effect of the ePFTE cover prevents acute aortic wall injuries and enables the treatment of severe and complex CoA morphologies with low peri-procedural risk. Only a few patient-specific risk factors such as patient age, bicuspid aortic valve, systemic arterial hypertension or the presence of Turner syndrome have been associated with an increased risk for aortic wall injuries.[21–23] Additional associations with technical aspects of endovascular treatment (balloon oversizing, manipulation of guide wires and catheters in the CoA region before and after the intervention) are not unlikely but remain speculative. In our study, no association between anatomic and hemodynamic characteristics (e.g., minimal CoA diameter, maximal peak-to-peak systolic gradient) or technical procedural details (BiB® catheter diameter, achieved nominal pressure, postdilatation) and the occurrence of aortic wall injuries was detected. Whereas some institutions prefer balloon dilatation of the CoA region before stent placement to identify patients with a noncompliant CoA, our favored institutional approach is primary stent implantation to avoid dissection or aneurysm formation from a therapeutic tear of the intima and media. However, in our cohort, predilatation was performed in 24/212 (11.3%); the incidence of aortic wall injuries was not significantly increased in this subgroup ($p = 0.545$).

4.2 | Stent fracture

In contrast to findings of other investigators,[16–18] the incidence of stent fractures did not significantly differ between patients who received bare or covered CP stents. In our cohort, the most frequent fractures observed were single or multiple strut fractures with no structural or hemodynamic consequences. In 4/19 patients (21.1%) a secondary covered CP stent was implanted to prevent further embolization of stent fragments. Although major biomechanics of stent fracture, such as overloading beyond the tensile stress limit of the material and fatigue, have been investigated,[24] the particular risk factors of stent fractures in the aorta are unclear. Additional force added by somatic growth or cyclic stress to the stent struts transmitted by aortic pulsatily are discussed as possible mechanisms.[24] In our cohort, patient age, native or recurrent CoA, diameter or length of the implanted stent or postdilatation were not associated with the incidence of stent fracture (all $p > 0.05$).

4.3 | Re-intervention rate

In 33/158 patients (20.9%) with moderate or severe CoA, a two-staged approach was favored to avoid acute wall injury at the proximal and distal stent end during balloon expansion. During primary stent implantation, an incomplete stent expansion with a remaining central narrowing was preferred to reduce aortic wall shear stress. A balloon dilatation was

TABLE 3 Considerations for transcatheter CoA treatment with bare versus coved CP stent.

Bare CP stent	Covered CP stent
Mild but hemodynamically relevant CoA	Moderate and severe CoA
Unfavorable anatomic proximity of the left subclavian artery to the CoA segment	Adult and elderly patients
	Turner syndrome
	Complex CoA anatomy • Subatretic or atretic CoA • Presence of an aneurysm or pseusoaneurysm • Postsurgical CoA • Postinterventional CoA (especially after previous stent placement) • Presence of a stent fracture

Abbreviations: CoA, aortic coarctation; CP, Cheatham-Platinum™.

electively scheduled 6 to 12 months after primary stent implantation to perform secondary complete stent expansion. In 44/158 patients (27.8%), unplanned re-interventions were indicated to treat re-obstruction related to somatic growth or neointimal proliferation. Multivariable analysis revealed prior CoA surgery, postdilatation after stent implantation and patient age as independent risk factors for unplanned re-interventions. Anatomic and hemodynamic parameters such as minimal CoA diameter, peak-to-peak systolic gradient or minimal stent diameter after implantation were not associated with re-intervention.

4.4 | Residual arterial hypertension

Residual arterial hypertension was present at last follow-up in 53/158 patients (33.5%), which corresponds to findings of other investigators.[25,26] Suggested underlying pathomechanisms for residual arterial hypertension are abnormal vascular biomechanics, such as increased stiffness of the ascending aorta causing interference with the *Windkessel* effect, and impaired ventricular-arterial coupling.[25,26] The high number of patients with residual arterial hypertension despite sufficient obstruction relief and antihypertensive medication underlines aortic coarctation to be a systemic arterial disease with the indespensible need for constant follow-up and consequent medical and interventional treatment.

Our findings suggest that endovascular CoAo treatment using bare or covered CP stents is safe and effective with excellent long-term results. However, transcatheter CoA treatment might cause short-and long-term complications and might require multiple reintervetions. Since no statistically significant differences concerning mortality, re-intervention rate and peri-procedural or long-term complications were detected between both stent types, recommendations concerning the preferred stent type are debatable. However, based on our institutional experience we would recommend the use of covered CP stents in adolescent and elderly patients, patients with a complex CoA anatomy, such as atretic or severe CoA, presence of aneurysms, fractures of previously implanted stents or postsurgical or postinterventional re-coarctation to avoid aortic wall complications (Table 3). The use of bare CP stents should be preferred in patients with mild but hemodynamically relevant CoA or in patients characterized by an unfavorable anatomic proximity of the left subclavian artery and the CoA segment to avoid obstruction. However, according to individual morphology, a hybrid approach with debranching of the left subclavian artery by surgical implantation of a left carotid artery left subclavian artery bypass and secondary covered stent implantation in the CoA segment may be considered alternatively in these patients.[15]

5 | CONCLUSION

In conclusion, our study documents excellent long-term results after CoA treatment with bare and covered CP stents. In our cohort, mortality, re-intervention and complication rate did not significantly differ between both stent types.

6 | LIMITATIONS

There are several limitations to this study. First, the subgroups are not distributed equally with more patients receiving covered CP stents due to institutional preference. Additionally, based on different time points of availability and product approval of bare and covered CP stents, follow-up duration differs between both subgroups, which might skew the results of this study. Moreover, 54 patients were lost to follow-up and could not be considered in long-term result analysis. The incidence of major complications such as aortic dissection, stent fracture or aneurysm formation was favorably low in the entire cohort, however, this low event rate in in relation to the long follow-up time might limit the statistic comparison of event rates between groups. Since re-catheterization or cross-sectional imaging were not available in all patients, the incidence of long-term aortic wall complications such as aneurysm formation or stent fracture might be underestimated. Additionally, based on the retrospective character of the study, non-invasive blood pressure measurement during exercise

or 24-h blood pressure measurements were not available to reveal unmasked arterial hypertension being a common long-term complication after CoA treatment. The number of antihypertensive medications before endovascular CoA treatment and at last follow-up might be affected by cofounders such as patient compliance, concomitant diseases (such as chronic heart failure) or practice variability among institutions.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author, (A. S). The data are not publicly available due to privacy and ethical restrictions. The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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