

Comparison Between Covered and Bare Cheatham-Platinum Stents for Endovascular Treatment of Patients With Native Post-Ductal Aortic Coarctation

Immediate and Intermediate-Term Results

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Objectives This study sought to evaluate the outcomes of endovascular treatment with covered versus bare Cheatham-platinum stents (NuMed, Hopkinton, New York) in coarctation of aorta (CoA) patients.

Background Covered stenting has been newly recognized as a useful therapeutic method for patients with native CoA, but there has been no study comparing the use of covered stents with bare stents for treating CoA.

Methods In this randomized clinical trial, 120 patients with a mean age of 23.60 ± 10.99 years (range 12 to 58 years, 79 men), with post-ductal, short-segment, severe native CoA underwent implantation of bare Cheatham-Platinum (bCP) ($n = 60$) or covered Cheatham-Platinum (cCP) ($n = 60$) stents. Patients were followed clinically at 1, 3, 6, and 12 months after the stenting and yearly thereafter. During follow-up, multislice computed tomography (64 slices) was scheduled to assess any complications.

Results The procedural success rate was 100% in both groups. Patients were followed for 31.1 ± 19.2 months. Although recoarctation was seen only in the bCP group during follow-up, the difference between groups did not reach statistical significance (6.7% vs. 0%; $p = \text{NS}$). Two cases of pseudoaneurysm (3.3%) occurred in the cCP group, but none was observed in the bCP group ($p = \text{NS}$). Normotensive status significantly increased during follow-up in both groups (from 15% to 73.3% in the bCP group and 16.7% to 78.3% in the cCP group, $p < 0.001$ for each group and not significant between groups).

Conclusions Implanting bCP and cCP stents have very high success rates with remarkable hemodynamic effects in severe native CoA patients. Patients undergoing cCP stent implantation experienced a nonsignificantly lower recoarctation rate and a higher occurrence of pseudoaneurysm formation with respect to bCP stenting during follow-up. These findings indicate that CoA stenting is a safe procedure. (Endovascular Stenting With Covered CP Stent Compared With Bare CP Stent for Adult Patients With Coarctation: The Initial and Intermediate-Term Follow-Up Results; [IRCT201012045311N1](https://doi.org/10.1016/j.jcin.2013.11.018)) (J Am Coll Cardiol Intv 2014;7:416–23) © 2014 by the American College of Cardiology Foundation

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Coarctation of the aorta (CoA) is a congenital cardiovascular malformation with relatively low prevalence and is characterized by a narrowing of the thoracic aorta mostly just distal to the left subclavian artery (1,2). CoA is normally detected and repaired surgically in childhood, but it occasionally recurs or presents de novo in adolescence or adulthood. If left untreated in childhood, CoA has a poor prognosis due to complications such as aneurysms, dissections, coronary artery disease, and intracranial hemorrhage. These complications mostly result from arterial hypertension secondary to the coarctation, and most patients die before reaching the age of 50 years from stroke, coronary heart disease, or sudden death (1–3).

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It has been documented that surgery, balloon dilation, and stent implantation are effective in the treatment of CoA in adults (4–6). Bare stent implantation in the treatment for native and recurrent CoA has become an excellent alternative to surgery and balloon angioplasty with better results (7–12). Although bare stents have considerable results, they are associated with some significant complications including aortic rupture, dissection, aneurysm formation, and even death (12–16). In such complicated patients, implanting a covered stent is commonly used as a rescue treatment.

Covered stents are widely used in the treatment of atherosclerotic abdominal and thoracic aneurysms in adults (17). There are limited data in the literature about the use of covered stents in patients with aortic coarctation (4,16,18–22) (Table 1), and there is no study comparing between covered and bare stents in this regard. We aimed to compare the immediate and intermediate-term outcomes of endovascular stenting with bare Cheatham-Platinum (bCP) versus covered Cheatham-Platinum stents (cCP) (NuMed, Hopkinton, New York) to find the best treatment method in patients with native CoA.

Methods

In this randomized clinical trial, 120 patients with post-ductal, short-segment, near atretic, native CoA underwent treatment with bCP or cCP stent implantation between September 1, 2007, and February 1, 2011 at Madani Heart Center, the largest tertiary cardiac center in North West of Iran. CoA was defined as the presence of systemic hypertension with an upper- to lower-limb systolic blood pressure (BP) difference ≥ 20 mm Hg, which was confirmed by echocardiography, computed tomography (CT) angiography, or aortography. We enrolled only patients with native coarctation and those with recoarctation. Patients with long segmental coarctation, hypoplasia of aortic arch, or pre-ductal coarctation were excluded from the

study. Also patients under 10 years of age or those with a body weights <30 kg were excluded from the study.

Patients, who met the inclusion criteria, were randomly assigned to either the bCP or cCP groups. Computer-assisted randomization was performed. Numbered, sealed envelopes that contained the study group assignment were distributed among the subjects and were opened after informed, written consent had been obtained prior to the procedure. The study protocol was approved by the Ethics Committee of Tabriz University of Medical Sciences.

Study protocol. After randomization, all patients underwent stenting for CoA. All procedures were performed by 2 experienced interventionists under general anesthesia and fluoroscopic guidance in the cardiac catheterization laboratory.

Heparin sulfate (100 IU/kg; maximum, 10,000 IU) was given intravenously, after right femoral artery access was obtained and a 5-F sheath was inserted. Intravenous cefazolin (20 mg/kg) was also given during the procedure and at 6-h intervals (total of 6 doses). The lesion was crossed in a retrograde manner using a 5-F right coronary Judkins catheter (Cordis Corporation, Miami, Florida) with the aid of a flexible-tip guidewire, 0.035 inches in diameter. Standard left heart catheterization was carried out, and aortograms were taken in left lateral, left anterior oblique, and shallow right anterior oblique with mild caudal angulation views to best profile the lesion (Fig. 1). To help crossing the coarctation segment and for proper stent deployment, we used the radial approach in difficult cases. The first wire was exchanged for an Amplatz super-stiff, 0.035-inch, 260-cm wire (Cook Cardiology, Bloomington, Indiana), which was left in the right brachial artery, enabling the straightest course for subsequent stent deployment. Pre-dilation with a small balloon was strongly prohibited.

In all procedures, Cheatham-Platinum stents were used for both the covered and bare stents. The Cheatham-Platinum stent was hand-crimped down onto a balloon-in-balloon catheter (NuMed), which allows a precise and safe stent delivery. We used 12-F blue long sheaths (Cook Cardiology) for bCP stent and 14-F sheaths for cCP stent delivery. The balloon diameter was selected based on the proximal isthmus at the level of takeoff of the left subclavian artery, not exceeding the diameter of the aorta at the level of the diaphragm. The length of the chosen stent was based on the distance between the left subclavian artery and 15 mm beyond the site of the CoA. After proper balloon size selection, immediate full dilation of the stent beyond its nominal pressure was performed in 1 step to achieve complete or near complete disappearance of the waist. Hemodynamic data and

Abbreviations and Acronyms

bCP = bare Cheatham-Platinum stent

BP = blood pressure

cCP = covered Cheatham-Platinum stent

CoA = coarctation of the aorta

CT = computed tomography

Table 1. Studies Published on Stenting of CoA

First Author (Ref. #)	Year	n	Indications	Procedure Success Rate, %	Mean Age, yrs (Range)	Mean Follow-Up, Months (Range)	Stent(s)*
Pedra et al. (18)	2005	9	Severe native CoA Age >50 yrs Associated PDA Fracture within a previously implanted stent	100	31 (8–57)	12 s	CP stent Braile stent
Tzifa et al. (16)	2006	30	CoA associated with aneurysms or previous stent-related complications Complex CoA anatomy Advanced age	100	28 (8–65)	11 (0–40)	CP stent
Kenny et al. (19)	2006	37	Native CoA Recurrent CoA following surgical treatment Aneurysm following previous CoA surgery Aortobronchial fistula Stent fracture Associated PDA	97.29	29.6 (9–65)	11.5 (1–56)	CP stent Valiant stent graft Jostent stent graft Palmaz Genesis covered stent
Butera et al. (20)	2007	33	Complex CoA anatomy	100	13 (6–66)	12 (1–40)	CP stent
Tanous et al. (4)	2010	22	Native CoA Recurrent CoA or aneurysm following previous surgical repair	100	39 (19–67)	12 (9–15)	CP stent
Bruckheimer et al. (21)	2009	22	Native CoA	100	15.5 (7.8–38.6)	18.5 (1.6–31.4)	CP stent
Chang et al. (22)	2012	25	Native CoA Associated PDA	100	22.5 (14–44)	72	CP stent

*1. CP stent (NuMED, Nicholville, New York); 2. Braile stent (Braile Biomedica, SJ Rio Preto, Sao Paulo, Brazil); 3. Valiant Thoracic Stent Graft (Medtronic Endovascular, Santa Rosa, California); 4. Jostent stent-graft (Jomed GmbH, Rangendingen, Germany); 5. Palmaz-Genesis stent (Cordis / Johnson and Johnson). There is no previous study comparing bare and covered CP stents, and we have only included studies with CP stents, mostly covered CP stents.
CoA = coarctation of aorta; CP = Cheatham-Platinum; PDA = patent ductus arteriosus.

angiographic measurements of the coarctation segment and other profiles were measured. A successful outcome was defined as a peak systolic pressure gradient after stent implantation of <15 mm Hg at the site of coarctation with no evidence of stent migration or aortic dissection. Hemostasis was achieved by manual compression. On discharge, aspirin 100 mg/day was prescribed for all patients for up to 6 months. Access site injury was assessed clinically immediately after the procedure and during follow-up.

Patients were followed at 1, 3, 6, and 12 months after stenting and yearly thereafter. Mean follow-up duration was 31.1 ± 19.2 months (range 12 to 60) months. During the follow-up, patients underwent physical examination including BP measurements and echocardiography. The routine chest x-ray, which was done on every follow-up visit, happened to be fairly useful in detecting stent migration. A multislice computed tomography (64 slices) was scheduled after 6 months to assess possible intimal hyperplasia, stent position, diameter at the dilated site, and the presence of an aneurysm (defined as >3 mm bulging) (Fig. 2). Routine survey for stent fractures was not done.

Our primary endpoint was recoarctation after the procedure, which was defined on the basis of a combination of clinical signs (arm-leg BP difference >20 mm Hg)

and noninvasive imaging by echocardiography (gradient >20 mm Hg) or invasive gradient measurements by catheterization and >10% of the stent lumen obstruction due to intimal proliferation within the stent. Secondary endpoints were mortality, pseudoaneurysm, obstruction of left subclavian artery, aortic dissection, migration of stent during procedure, post-CoA syndrome, hypertension, and need for antihypertensive drugs during follow-up period. Antihypertensive medications were discontinued or reduced, if possible, at the referring physician's discretion.

Statistical analysis. Statistical analyses were performed using the Statistical Package for Social Sciences (version 16.0, SPSS Inc., Chicago, Illinois). Quantitative data were presented as mean \pm SD, and qualitative data were demonstrated as frequency (percentage). The categorical parameters were compared by chi-square or 2-tailed Fisher exact tests when applicable, and the continuous variables were compared by Student *t* test for independent continuous scale data and Mann-Whitney *U* test for nonparametric data when appropriate. To compare values before and after the procedure, paired samples *t* tests for continuous variables and McNemar tests for categorical parameters were used. Repeated measure of analysis of variance was used to compare mean diastolic and mean systolic BP changes

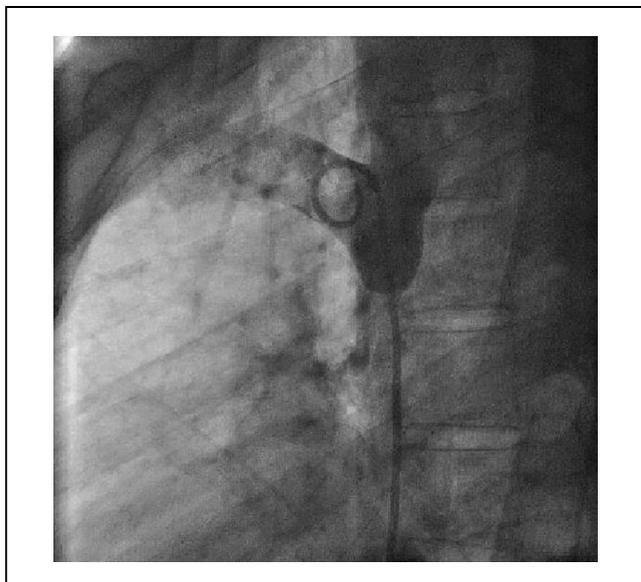


Figure 1. Baseline Descending Aortogram

Baseline descending aortogram in lateral view with pigtail catheter showing severe coarctation.



Figure 2. Multislice CT Angiography (64 Slices) During 8-Month Follow-Up in a Patient Who Underwent Covered CP Stent Implantation

Volume rendering techniques show good positioning of the stent without any complication. CP = Cheatham-Platinum; CT = computed tomography.

during the study in each group and between groups. A p value <0.05 was considered significant.

Results

During this study, 120 patients with a mean age of 23.60 ± 10.99 years (range 12 to 58 years; 79 men) underwent bCP (n = 60) and cCP (n = 60) stent implantation. Patients in both groups were matched for baseline characteristics (Table 2). There was no significant difference between groups in angiographic findings and stent characteristics (Table 3). The procedures were successful in all patients in both groups without any malposition, migration, or dissection. In 20 cases, a radial approach was required to cross the

stenotic segment, and after crossing and snaring the wire, the procedure was continued through the femoral approach.

Overall, the CoA diameter increased from 3.32 ± 0.65 mm to 15.94 ± 2.23 mm ($p < 0.001$) and the pressure gradient across the CoA site decreased from 54.6 ± 14.5 mm Hg to 3.38 ± 1.61 mm Hg ($p < 0.001$). There was no incidence of paraplegia, bleeding, vascular

	Bare CP (n = 60)	Covered CP (n = 60)	p Value
Age, yrs	24.66 ± 13.03	22.55 ± 8.48	NS
Male	40 (66.7)	40 (66.7)	NS
Associated cardiac findings	39 (65.0)	40 (66.7)	NS
Cardiac complication of aortic valve	12 (20.0)	27 (47.4)	
Coronary artery disease	2 (3.3)	1 (1.8)	
Aortic stenosis	5 (8.3)	3 (5.3)	
Aortic insufficiency	14 (23.3)	8 (14)	
Ventricular septal defect with/without repair	6 (10)	1 (1.8)	

Values are mean ± SD or n (%).
 CP = Cheatham-Platinum; NS = not significant.

	Bare CP (n = 60)	Covered CP (n = 60)	p Value
Mean systolic gradient before procedure, mm Hg	54.61 ± 15.05	54.42 ± 12.04	NS
Mean systolic gradient after procedure, mm Hg	3.47 ± 1.68	3.36 ± 1.65	NS
Mean length of coarctation, mm	16.52 ± 3.92	16.61 ± 3.31	NS
Mean diameter of coarctation segment before procedure, mm	3.34 ± 0.59	3.30 ± 0.70	NS
Mean diameter of coarctation segment after procedure, mm	16.07 ± 1.88	15.82 ± 2.51	NS
Mean diameter of diaphragmatic aorta, mm	16.71 ± 1.34	16.88 ± 1.80	NS
Mean diameter of the aorta after left subclavian artery, mm	16.64 ± 1.15	16.88 ± 1.72	NS
Mean length of the stent, mm	30.31 ± 7.24	28.94 ± 8.75	NS
Mean diameter of the stent, mm	16.56 ± 1.88	16.64 ± 1.89	NS

Values are mean ± SD.
 Abbreviations as in Table 2.

complication, post-CoA syndrome, or death during the procedure.

Mean systolic and diastolic BP were significantly reduced in both groups immediately after the procedure and at 1 month, 3 months, and the end of follow-up from values before intervention ($p < 0.001$) (Fig. 3). There were no significant differences between groups in the mean systolic and diastolic BP values before and during the follow-up period ($p = \text{NS}$).

Overall, 101 (84.16%) patients (51 in the bCP and 50 in the cCP group) were on antihypertensive medications before intervention; this was significantly reduced to 29 (24.16%) patients (16 in the bCP and 13 in the cCP group) during the follow-up ($p < 0.001$). There was no significant difference between bCP and cCP in normotensive patients before (15% vs. 16.7%) and after (73.3% vs. 78.3%) intervention ($p = \text{NS}$); however, in both groups, it was

significantly increased during follow-up (both $p < 0.001$). At the last assessment session, 6 patients continued their antihypertensive drugs with the same dosage; the dosage was reduced in 24 and discontinued in 50 patients due to the normalization of the BP.

There was no difference between groups in duration of hospitalization (3.44 ± 2.41 days in the bCP group vs. 3.05 ± 0.93 days in the cCP group; $p = \text{NS}$). Table 4 demonstrates the clinical findings during the follow-up in both groups. Occurrence of recoarctation was seen only in the bCP group during follow-up, but the difference between groups with respect to this complication was not statistically significant (6.7% vs. 0%; $p = \text{NS}$). The recoarctation cases included 2 female and 2 male patients (ages 12, 15, 30, and 48 years). All recoarctation cases occurred between 6 and 12 months after stent implantation. They were treated with covered stents and had no recurrence or complications during follow-up.

Although more pseudoaneurysm formation was seen with cCP stenting (0% vs. 3.3%), the difference between groups was not significant (Table 4). Pseudoaneurysms occurred in the 12- and 21-year-old patients, 30 and 40 days after initial stenting (Fig. 4). The presentation of both of these patients was severe back pain, and immediate CT angiography showed pseudoaneurysm formation just proximal to the implanted covered stent. Re-evaluation of the first procedure revealed prolonged and multiple attempts with different kinds of guidewires including Terumo hydrophilic wires, in both patients. The pseudoaneurysms were treated successfully with another cCP stent implantation along the previous stent. They had no other complaints during the follow-up.

Only 1 patient died during follow-up (Table 4), which was a 20-year-old woman in the bCP stent group, and her death was not related to the procedure. The patient became pregnant during follow-up and had successful delivery 12 months after initial stenting. The death occurred 3 months after delivery because of severe heart failure due to peripartum cardiomyopathy.

Our patients comprised 51 adolescents (≤ 18 years of age) and 69 adults (> 18 years of age). Comparing the clinical findings during the follow-up between the adolescents and adults (Table 5), there were no significant differences between groups.

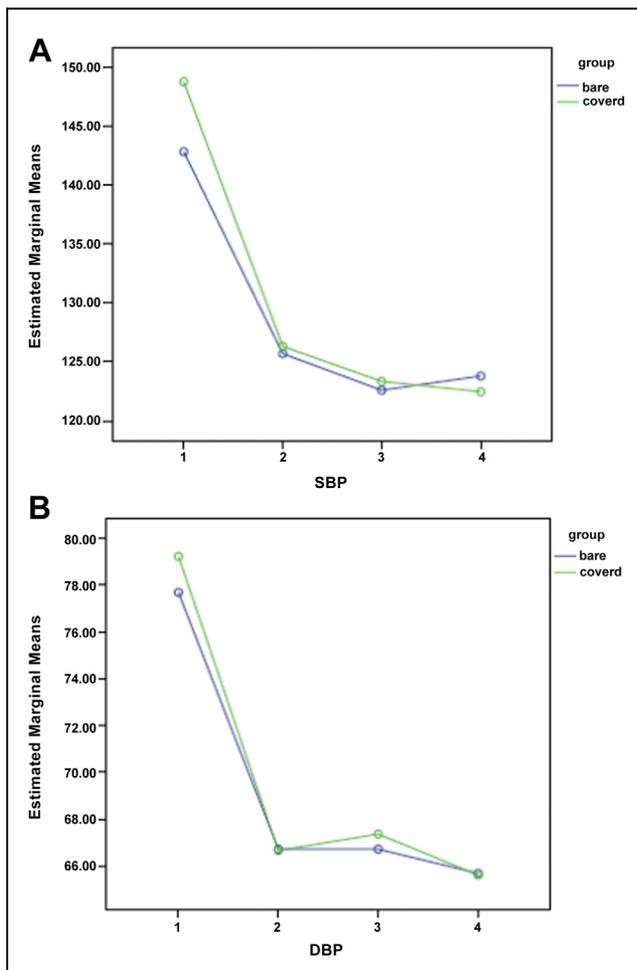


Figure 3. Significant Reduction in Mean SBP and DBP Immediately After the Procedure and at 1 and 3 Months and at the End of the Follow-Up

Significant reduction in mean systolic blood pressure (SBP) (A) and diastolic blood pressure (DBP) (B) immediately after and at 1 month, 3 months, and end of the follow-up period is shown. There is no significant difference between treatment groups.

Table 4. Clinical Findings During Follow-Up Between Groups

	Bare CP (n = 60)	Covered CP (n = 60)	p Value
Recurrent coarctation	4 (6.7)	0 (0)	NS
Pseudoaneurysm in aortic segment at 12-month follow-up	0	2 (3.3)	NS
Total mortality	1 (1.7)	0	NS

Values are n (%).
Abbreviations as in Table 2.



Figure 4. Pseudoaneurysm Formation Just Proximal to the Stent 30 Days After Covered CP Stent Implantation

(A) At 30-day follow-up, a pseudoaneurysm had formed proximal to the covered CP stent. (B) After implanting a second covered stent, the pseudoaneurysm was completely obliterated. CP = Cheatham-Platinum.

Discussion

The main findings of this study are that CP stent implantation in severe native CoA patients is highly successful and results in remarkable hemodynamic effects, with no significant complication during the procedure and hospitalization. During follow-up, patients undergoing cCP stent

Table 5. Clinical Findings During Follow-Up Between Adolescents and Adults

	Adolescents ≤ 18 yrs (n = 51)	Adults >18 yrs (n = 69)	p Value
Recurrent coarctation	2 (3.9)	2 (2.9)	NS
Pseudoaneurysm in aortic segment at 12-month follow-up	1 (2)	1 (1.4)	NS
Total mortality	0	1 (1.4)	NS

Values are n (%).
 NS = not significant.

implantation experienced a nonsignificantly lower recoarctation rate and a higher occurrence of pseudoaneurysm formation with respect to bCP stenting. In both groups, BP was significantly reduced after intervention.

Most available reports have evaluated only the outcome of cCP stents or overall CP stents with small numbers of patients, and no comparison has been made between bCP and cCP stents. To the best of our knowledge, this study is the first randomized clinical trial in a relatively large patient population with CoA comparing these 2 types of stents. In the technical point of view, performing the procedure in a high-volume referral center, use of CP stents and balloon-in-balloon catheter without pre-dilation, concurrent femoral and radial approaches, and wire positioning in right subclavian artery could be the reasons for the high success rate with no periprocedural complications in our study.

For the evaluation of late complications such as aneurysm formation and recoarctation, patients should be followed by magnetic resonance angiography or CT. In our study, all patients underwent 64-slice CT angiography for anatomic evaluation of stented and persistent segments. During the follow-up period, recoarctation occurred only in the bCP group. Use of covered stents for complex and very severe coarctations, especially in older patients with relatively less compliant aortic walls, have been associated with encouraging results (11,23-25). Limited data are available on the usefulness of covered stents in preventing recoarctation and stenosis. Our study shows encouraging results with covered stents for prevention of this complication in patients undergoing endovascular treatment of native CoA. Although recoarctation only occurred in the bCP group, the difference between groups with regard to this complication was statistically nonsignificant. Most likely, increasing the sample size of this study would have resulted in a significant difference between groups on the occurrence of recoarctation.

In theory, the covered stent can protect the post-stenotic area by redirecting the flow away from the dilated areas and more centrally into the descending aortic lumen. Nevertheless, no previous report has been issued on aneurysm or pseudoaneurysm formation after covered stent placement. However, we observed pseudoaneurysm formation in 2 patients in the cCP group, 30 and 40 days after initial

stenting just proximal to the stent; the pseudoaneurysms were managed with implantation of another cCP stent in both patients with no other complication during the long-term follow-up. Re-evaluation of the first procedure revealed a severe coarctation segment with prolonged and multiple attempts with different kinds of guidewires, including Terumo hydrophilic wires, in both patients. These frequent attempts to cross the subtotal segment may traumatize the aortic wall and play a role in the occurrence of this delayed major complication. It appears that Terumo hydrophilic wires could easily pass to the subintima in severe coarctation, leading to this delayed complication, and should be used with extreme caution or not at all during the procedure. We believe that in such cases with difficulties in crossing the stenotic segment with hydrophilic wires and higher probability of aortic wall trauma, implanting a covered stent might be useful to reduce associated complications. This needs to be confirmed in future larger multicenter studies.

Some investigators propose to perform dilation and coarctation stenting in 3 separate sessions with slow and progressive dilation of the stent. However, our study showed that the 1-step approach is highly successful and effective and reduces the need for further admissions.

BP control can be improved in adult patients after relieving the stenosis of coarctation (26). Like other studies (27), we showed that the systolic gradient across the CoA and mean systolic and diastolic BP were reduced after both types of CP stent implantation. Our results are in accordance with others (22,26) that implantation of the cCP stent is associated with significantly improved hemodynamic status and reduced number of cases in need of antihypertensive medication. Chang et al. (22) reported normotensive status after cCP stent implantation in 84% of cases. In our study, normotensive cases increased from 14% to 77.2% after procedure. These findings are indicative of the effectiveness of covered stents on improvement of patient's hemodynamics.

Bare stent implantation also has a considerable effect on hemodynamic status. In previous studies, it was accompanied by improvement in the systolic BP control and also resulted in left ventricular mass reduction and improvement in its long-axis function, which could reduce the incidence of morbidity and mortality (4,28,29). In our study, patients with bare stent implantation also had significant improvements in BP control after the procedure and during follow-up (from 15% pre-intervention to 73.3% in the last assessment).

In previous studies, reduction or discontinuation of antihypertensive medication following stent implantation was achieved in 18% to 88% of the patients (16,20,30-32). Overall, in our study, antihypertensive therapy was reduced or discontinued in 95.72% of the patients. However, the improvement in hypertension control was not different between groups.

As there were no in-hospital complications, patients were discharged in a mean of 3 days after the procedure with no difference between groups. In the study of Erdem et al. (33), which evaluated 16 covered and 31 bCP stents, there was an acute aortic wall rupture at the distal end of the implanted bCP stent, which was successfully managed immediately in the same session with the implantation of a second covered stent. Also among cCP stents implanted in the study by Tanous et al. (4), 1 patient required a second covered stent for aortic wall rupture. It is notable that there is no report of any procedure-related mortality in covered or bCP stenting in the literature, whereas it is reported that death may occur in 0% to 1.4% of cases after non-CP bare stenting (34). We found no in-hospital complications in our study, which is in favor of the safety of CP stent implantation in CoA patients. Although in our study there was 1 death in a 20-year-old female patient after bCP stenting, it was not related to the procedure and occurred after pregnancy and was presumed to be due to peripartum cardiomyopathy.

Study limitations. Although the first randomized clinical trial in this respect, our study was limited in some aspects. First, during follow-up, patients did not undergo 24-h ambulatory BP monitoring, which could have diagnosed the normotensive state more accurately. Second, evaluation of the BP response during exercise testing could have been more valuable in defining the procedure outcome.

Conclusions

Implanting bCP and cCP stents have very high success rates with remarkable hemodynamic effects in patients with severe, native, post-ductal CoA. Patients undergoing cCP stent implantation experience a nonsignificantly lower re-coarctation rate and higher occurrence of pseudoaneurysm formation with respect to bCP stenting during follow-up. These findings indicate that CoA stenting is a safe procedure. However, these findings may not be applicable to other anatomical variants of coarctation.

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Key Words: aortic coarctation ■ bare stent ■ Cheatham-platinum stent ■ covered stent.