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Balloon-expandable versus self-expanding stents in native coarctation of the aorta: three-year results of a randomised controlled trial

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The evidence regarding the mid- and long-term follow-up of transcatheter intervention for coarctation of aorta (CoA) is limited, with the majority of the relevant studies being retrospective in design with small study populations[1-3]. Previously, we reported the 1-year results of a randomised controlled trial comparing balloon-expandable stents (BES) and self-expanding stents (SES) in patients with *de novo* native CoA[4]. Herein, we have summarised the 3-year follow-up results (IRCT20181022041406N3).

Adult patients with *de novo* native CoA and no prior history of surgical or endovascular coarctoplasty were included **(Central illustration)**. A structural follow-up, encompassing transthoracic echocardiography and aortic computed tomography angiography was performed at 1- and 3-year follow-up. A supervised exercise test to detect masked hypertension was added to the 3-year follow-up. The main outcomes assessed were the 3-year rates of recoarctation, aortic injuries, and residual hypertension. A detailed description of the eligibility criteria, randomisation, procedural details, and study outcomes has been published previously[4] and is summarised in **Supplementary Appendix 1**, **Supplementary Appendix 2** and **Supplementary Appendix 3**.

Of 92 patients initially randomised, 71 patients (25 women [32.2%]), with a median age of 30 years (interquartile range 20-35), participated in the 3-year structural follow-up (2 patients passed away [1 COVID-19 infection and 1 car accident] and the others did not participate in the follow-up). Patient flow, baseline, and 3-year clinical and imaging characteristics are depicted in **Supplementary Figure 1**, **Supplementary Table 1**, **Supplementary Table 2** and **Supplementary Table 3**.

No new recoarctation was detected between the 1- and 3-year follow-up, and only 5 patients (with recoartation previously detected during the first year of follow-up) were identified as having recoarctation. Among those patients, 2 cases, both initially randomised into the BES group and treated for recoarctation during the first year, needed reballooning due to significant restenosis during the 3-year follow-up **(Table 1)**. Aortic wall injuries were detected in 6 patients (8.5%), all treated conservatively with no further endovascular/surgical intervention needed **(Supplementary Figure 2)**. The stenting procedure did not significantly impact aortic remodelling insofar as no substantial changes were noted in the diameter of the ascending and diaphragmatic aorta **(Table 1)**. A total of 42 out of the 71 patients (59.1%) had residual hypertension, detected more frequently in the BES group, with a trend existing towards a higher median number of antihypertensive drugs during the 3-year follow-up **(Table 1, Supplementary Figure 3, Supplementary Table 4)**. A detailed report of the 3-year results is presented in **Supplementary Appendix 2**.

A few prospective studies have elaborated the mid- to long-term outcomes of the endovascular treatment of CoA; however, most of these investigations had no integrated imaging protocol[2], or only a small proportion of their baseline population was finally monitored by approved imaging tests[3]. We followed up 77.1% (71 of 92) of our randomised population with the structural imaging protocol, and recoarctation occurred in 7.0% of the population with no new cases between the 1- and 3-year follow-up periods. This finding is in contrast with the major investigations focusing on long-term outcomes, in which a higher rate (~20%) of reintervention has been reported[2,3]. The inclusion of paediatric patients in the mentioned studies

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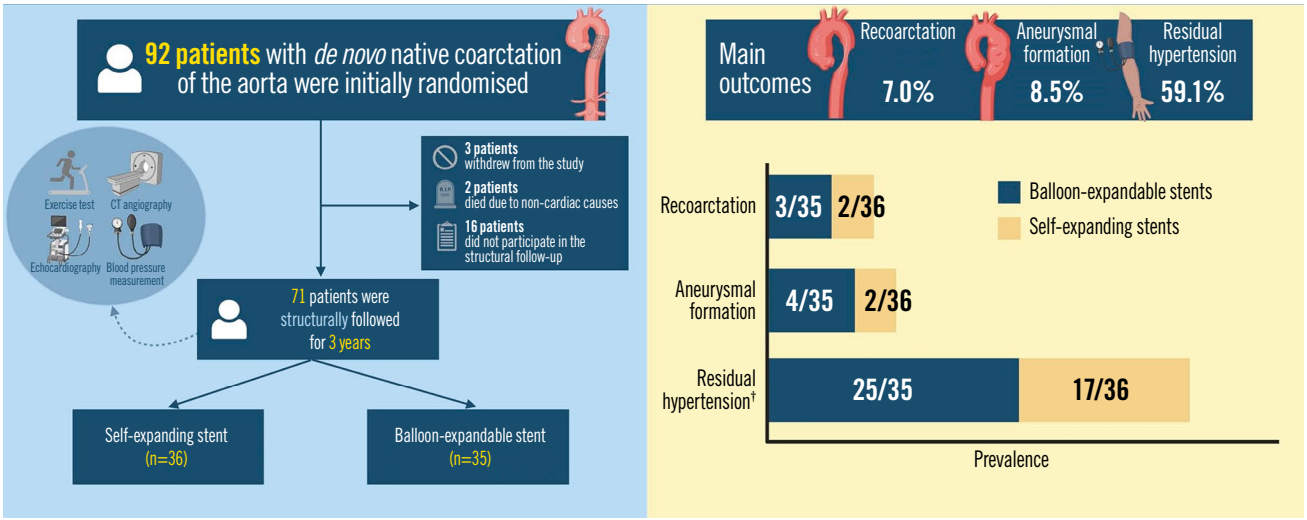

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A summary of patient flow, follow-up protocol and the main findings. † The hypothesis-generating difference in residual hypertension between the 2 stent types suggests a need for larger-scale studies. CT: computed tomography

Table 1. Three-year outcomes of the study patients.

	Balloon-expandable stents (n=35)	Self-expanding stents (n=36)	*p*-value	Risk ratio (95% CI)
Main outcomes				
Recoarctation of the aorta[a]	3 (8.5)	2 (5.5)	0.64	1.50 (0.26-8.68)
Thoracic aortic aneurysmal formation[b]	4 (11.4)	2 (5.6)	0.37	2.06 (0.40-10.52)
Residual hypertension[c]	25 (71.4)	17 (47.2)	0.03	1.51 (1.00-2.26)
Other outcomes				
Number of antihypertensive medications	2.0 (1.0 to 2.0)	1 (0.0 to 2.0)	0.06	
Difference in antihypertensive medications[d]	0.0 (0.0 to 1.0)	0.0 (0.0 to 0.75)	0.39	
Difference in the ascending aorta diameter[e], mm	0.3 (–1 to 1.6)	0.4 (–1.4 to 1)	0.60	
Difference in the diaphragmatic aorta diameter[e], mm	–1.1 (–2 to 0.4)	–0.85 (–2.1 to 0.4)	0.76	
Sizeable intrastent filling defect	N/A[f]	9 (25.0)		
Stent protrusion	0 (0)	1[g] (2.7)		

Data are presented as n (%) or median (interquartile range). [a] All the cases of recoarctation of the aorta were detected during the first year of follow-up, and no new cases were detected between the 1- and 3-year follow-up periods. [b] Detailed types of aortic injuries are summarised in **Supplementary Figure 4**; all were treated conservatively with no further endovascular/surgical therapies. [c] Residual hypertension was defined as a persistent need for antihypertensive drugs. [d] Median difference in the number of antihypertensive medications between the 1- and 3-year follow-up periods. [e] Changes in the aortic diameter between baseline and 3-year follow-up were analysed by the same operator with a similar methodology. [f] Due to considerable artefacts imposed by balloon-expandable stents, evaluation for the presence of filling defects was not feasible (**Supplementary Figure 4**). [g] The protrusion was minimal, with no apparent additional aortic injuries; it was treated conservatively. CI: confidence interval; N/A: not applicable

might explain the higher rates of reintervention. Recoarctation rates below 10% were reported when limiting their population to adult patients.

The rate of post-stenting aortic pathologies/injuries during the long-term follow-up was poorly reported with no clear consensus on their management; however, our data showed a low incidence and benign features with no need to intervene during the 3-year follow-up **(Supplementary Figure 2)**. Intrastent filling defect was detected in 25% of patients treated with SES **(Supplementary Figure 4)**. Although the clinical significance of the observed filling defects was not elaborated in the current study, it might challenge the short-term discontinuation of the antithrombotic regimen. Filling defects could not be analysed in patients with BES due to considerable artefacts.

Even though transcatheter intervention exerts a positive impact on reducing blood pressure, a considerable proportion

of patients might still suffer from residual hypertension, which predisposes patients to many acquired heart conditions, including coronary artery disease, persistent arrhythmia, stroke, and heart failure[2-4]. Holzer et al[3] and Eriksson et al[2] reported a downward trend in prolonged hypertension prevalence (42% and 34%, respectively) in patients treated endovascularly. The higher incidence of residual hypertension in the current study might result again from their inclusion of a paediatric population and better blood pressure response in this younger population. Additionally, we observed a higher residual hypertension in patients treated with BES. Although several explanations for this, such as less haemodynamic disturbance due to better flexibility of nitinol stents, could be suggested[5], the current finding is explanatory and hypothesis-generating and needs confirmation by future large-scale studies.

The small sample size, a 23% attrition rate, and the lack of ambulatory blood pressure monitoring for residual hypertension are among the major limitations of this study, which have been fully discussed in **Supplementary Appendix 3**, **Supplementary Table 5** and **Supplementary Table 6**.

In this 3-year follow-up, both BES and SES exhibited low rates of recoarctation, aortic wall injuries and remodelling, but still, more than half of the studied population suffered from residual hypertension. Larger-scale investigations are warranted to substantiate and validate these findings.

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Conflict of interest statement

The authors have no conflicts of interest to declare.

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Supplementary data

Supplementary Appendix 1. Methods.

The current open-label parallel-group blinded endpoint pilot randomized controlled trial (RCT) aimed to assess the efficacy and safety of the uncovered Cheatham-platinum Bare Metal Stent (BES) from NuMed, Hopkinton, NY, and the uncovered nitinol Self-Expanding Stent (SES) from Sinus-XL, Optimed Inc, Germany, in patients with native Coarctation of the Aorta (CoA) at Rajaie Cardiovascular Medical and Research Center, Tehran, Iran. Ethical approval for the study protocol was obtained from the institutional ethics committee, and written informed consent was secured from all participants. The study was registered in the Iranian Registry of Clinical Trials (IRCT20181022041406N3).

Adult patients with de novo native CoA, devoid of any history of surgical or endovascular coarctoplasty were included in the study. Exclusions comprised individuals with a circular-shaped aortic arch, interrupted aortic arch, preductal coarctation, hypoplastic aortic arch, right aberrant subclavian artery, coarctation with stenosis length exceeding 20 mm, aneurysms accompanying the coarctation, or common femoral and external iliac arteries measuring less than 7 mm in diameter. Utilizing an electronic web-based system employing permuted blocks of 4 and concealed allocation sequences, randomization assigned eligible patients in a 1:1 ratio to either the BES group or the SES group.

The study implemented two types of follow-up assessments: clinical and structural. Clinical follow-ups occurred at 6-month intervals, involving the identification of potential new complaints and blood pressure measurements. Any new findings were discussed with treating physicians, who determined the necessity for additional diagnostic procedures or therapeutic strategies. Patients declining on-site follow-ups underwent telephone interviews. Structural follow-ups occurred at 1 and 3-year intervals, encompassing clinical evaluation, blood pressure measurement, transthoracic echocardiography (TEE), and aortic coronary computed tomography angiography (CTA). Participants in the 3-year structural follow-up also underwent supervised exercise tests to detect masked hypertension.

Primary outcomes in the follow-up study included 3-year recoarctation, aortic injuries, and residual hypertension. Recoarctation confirmation involved cardiac catheterization for

patients with suggestive findings in TTE or CTA. A pressure gradient exceeding 20 mm Hg was the diagnostic threshold for recoarctation. Residual hypertension was defined as a persistent need for antihypertensive medication. Blood pressure and medication needs were assessed at 6-month intervals during clinical visits. Masked hypertension was identified by an exaggerated blood pressure response during exercise treadmill tests. Additionally, aortic remodeling measurements between baseline and the 3-year follow-up were reported, encompassing ascending and diaphragmatic aorta diameters. Quantification of measurements was performed by a single expert radiologist using a unified standard protocol. Sizable intra-stent filling defects were also reported, with the evaluation for the presence of filling defects being unfeasible due to significant artifacts imposed by BES. Furthermore, changes in antihypertensive medications during follow-up were reported. To account for potential inconsistency and confounding factors in blood pressure management during the pre-trial phase, the 6-month data were used for comparison instead of baseline data.

Supplementary Appendix 2. Results.

3-year Recoarctation

No new recoarctation was detected between the 1 and 3-year follow-up periods, and only 5 patients previously detected during the first year of follow-up were recorded as recoarctation. Among those patients, 2 cases, both initially randomized into the BES group and treated for recoarctation during the first year needed re-ballooning because of significant restenosis during the 3-year follow-up (Table 1).

3-year Aneurysmal Formation

Aortic wall injuries were detected in 6 patients (8.5%) during the 3-year follow-up (Table 1). Three patients developed an aneurysmal formation at the origin of the intercostal artery (Figure S3). Outpouching at the proximal or distal ends of the stents, potentially due to aortic wall injuries, was detected in another 3 patients, with the outpouching in 1 patient being completely thrombosed (Figure S3).

3-year Hypertension

As mentioned in the main text 59.1% of the patients had residual hypertension (Table 1), detected more frequently in the BES group than the SES group (25 [71.4%] vs 17 [47.2%]: OR, 1.51; 95% CI, 1.00 to 2.26; *P* =0.03). A trend existed toward a higher median number of antihypertensive drugs during the 3-year follow-up in the BES group (2.0 [IQR =1.0 to 2.0] vs 1.0 [IQR =0.0 to 2.0]; *P* =0.06) (Figure 2). However, the median difference in the number of antihypertensive medications between the 1 and 3-year follow-up periods did not reach statistical significance between the 2 groups (*P* =0.39). In addition, an exaggerated blood pressure response during the exercise treadmill test was reported in 4 patients, only 1 of whom was normotensive at rest and considered to have masked hypertension.

3-year Stent protrusion

Stent protrusion in one SES-treated patient became apparent in the 3-year follow-up. However, since the protrusion was minimal, with no apparent additional aortic injuries, it was treated conservatively (Figure S3).

3-year Intra-stent filling defect

As mentioned in the main text, the intra-stent filling defect could only be evaluated in SES-treated patients, 9 of whom (25.0%) had a sizable defect (Figure S4).

3-year Aortic Characteristics

The stenting procedure did not significantly impact aortic remodeling insofar as no substantial changes were noted in the diameter of the ascending and diaphragmatic aorta (Table 1). The baseline evaluation detected 3 patients with an ascending aorta size exceeding 5.5 cm. All 3 patients underwent aortic root ± valve replacement after their coarctation repair. No new patients needed aortic surgery for a sizable ascending aorta during the 3-year follow-up. The 3-year echocardiographic characteristic of the patients is presented in Table S3.

Supplementary Appendix 3. Limitations.

The findings of this study must be interpreted within the context of certain limitations.

Sample Size

Firstly, the trial's ability to report outcomes may be limited by its small sample size, mainly influenced by the low prevalence of native Coarctation of the Aorta (CoA) and resource constraints. Despite this, the use of random assignment, blinded outcome assessment, and a well-defined structural follow-up program enhances the study's potential for providing a more impartial comparison of efficacy and safety between the two types of stents.

Attrition Rate

Secondly, attrition occurred during the 1 to 3-year follow-up period, leading to the non-assessment of 21 patients in the 3-year structural program. However, despite this drawback, the study achieved a 77% participation rate, which is comparable to participation rates in similar studies. Additionally, Tables S4 and S5 demonstrate a balance in baseline characteristics between patients lost to follow-up and those assessed in the follow-up.

Gold Standard Diagnostic Test

Thirdly, the study did not utilize ambulatory blood pressure monitoring to assess residual hypertension, which is considered the most accurate method for diagnosing and monitoring late hypertension. This decision was primarily due to resource limitations. To compensate for the absence of ambulatory blood pressure monitoring, exercise tests were employed to detect masked hypertension.

Supplementary Table 1. Baseline demographic and clinical characteristics of the study patients in the 3-year structural follow-up[a].

	Balloon-Expandable Stents (n = 35)	Self-Expandable Stents (n =36)	*P* value
Age, y	31.0 (20.0 – 36.0)	25.5 (19.0 – 33.0)	0.23
Female sex	11 (31.4)	14 (38.9)	0.51
Family history of coarctation	2 (5.7)	0 (0.0)	0.15
Hypertension	34 (97.1)	35 (97.2)	0.98
Cigarette smoking	3 (8.6)	3 (8.3)	0.97
Coronary artery disease	2 (5.7)	4 (11.1)	0.41
Diabetes mellitus	1 (2.9)	0 (0.0)	0.31
Hyperlipidemia	1 (2.9)	0 (0.0)	0.31
Presenting Symptoms			
Hypertension	20 (57.1)	17 (47.2)	0.40
Claudication	2 (5.7)	2 (5.6)	0.98
Chest pain	4 (11.4)	1 (2.8)	0.15
Dyspnea on exertion	2 (5.7)	1 (2.8)	0.54
Palpitation	0 (0.0)	1 (2.8)	0.32
Duration of Symptoms			0.56
< 6 months	12 (34.3)	16 (44.4)	
6–12 months	5 (14.3)	6 (16.7)	
> 12 months	18 (51.4)	14 (38.9)	
Number of antihypertensive medications[b]	3.0 (2.0 – 4.0)	3.0 (1.0 – 3.0)	0.03
Type of antihypertensive medications			
ARB	19 (54.3)	19 (52.8)	0.90
Beta-blocker	16 (45.7)	18 (50.0)	0.72
Diuretics	15 (42.9)	8 (22.2)	0.06
CCB	16 (45.7)	7 (19.4)	0.02
ACEI	7 (20)	1 (2.8)	0.02
Hemoglobin, mg/dL	13.7 ± 1.7	13.7 ± 1.5	0.92
Creatinine, mg/dL	0.9 (0.8 – 1.0)	0.8 (0.8 – 1.0)	0.25

Data are presented in n (%), mean ± standard deviation (SD), and median (interquartile range [IQR]).

[a] Of 92 patients initially allocated to the 2 study groups, 71 patients accepted to participate in the 3-year structural follow-up, composed of transthoracic echocardiography and aortic computed tomography angiography. Among the remaining 21 patients, 16 were followed up through phone interviews, 3 withdrew from the study, and 2 died (a car accident and complications of COVID-19 infection, respectively). The baseline demographic, clinical, and imaging characteristics of the 21 patients are presented in **Supplementary Tables 1 and 3**.

[b] These medications were taken by the patients in the pre-trial phase.

ACEI = angiotensin-converting enzyme inhibitor; ARB = angiotensin receptor blocker; CCB = calcium channel blocker

Supplementary Table 2. Baseline imaging characteristics of the study patients in the 3-year structural follow-up[a].

	Balloon-Expandable Stents (n =35)	Self-Expandable Stents (n =36)	*P* value
TTE Parameters			
Bicuspid aortic valve	23 (65.7)	19 (52.8)	0.27
Moderate to severe AI	4 (12.1)	3 (8.6)	0.63
Moderate to severe AS	0 (0.0)	0 (0.0)	
Moderate to severe MR	2 (6.1)	3 (8.6)	0.69
LVEF, %	55.0 (50.0 – 55.0)	55.0 (50.0 – 55.0)	0.39
PWd, cm	0.9 (0.8 – 1.0)	0.9 (0.9 – 1.0)	0.53
LVIDd, cm	5.1 (4.7 – 5.4)	5.0 (4.3 – 5.1)	0.13
Peak systolic PG, mm Hg	63.4 ± 12.1	66.9 ± 19.6	0.45
Mitral E/e'	8.0 (7.0 – 10.0)	8.0 (7.0 – 8.0)	0.59
AV Annulus, cm	2.2 (2.0 – 2.4)	2.1 (2.0 – 2.3)	0.46
Sinus of Valsalva, cm	3.2 (2.8 – 3.6)	3.2 (2.8 – 3.6)	0.52
LV diastolic grading			
Moderate	0 (0.0)	0 (0.0)	
Severe	0 (0.0)	0 (0.0)	
IVSd, cm	0.9 (0.8 – 1.1)	1.0 (0.9 – 1.1)	0.55
CTA Parameters			
Aortic diameter before CoA, mm	15.2 ± 3.2	14.6 ± 3.8	0.67
Aortic diameter after CoA, mm	19.6 ± 4.7	18.7 ± 6.2	0.64
Ascending aorta diameter, mm	33.0 ± 4.7	32.6 ± 6.5	0.79
Distance between the LSCA and CoA, mm	21.4 ± 10.6	18.7 ± 6.0	0.27
Proximal descending aorta diameter, mm	21.7 ± 4.0	20.9 ± 4.8	0.52
Aortic diameter at the diaphragmatic level, mm	15.8 ± 1.9	15.6 ± 2.8	0.77

Data are presented in n (%), mean ± standard deviation (SD), and median (interquartile range [IQR]). [a] Of 92 patients initially allocated to the 2 study groups, 71 patients accepted to participate in the 3-year structural follow-up, composed of TTE and aortic CTA. Among the remaining 21 patients, 16 were followed up through phone interviews, 3 withdrew from the study, and 2 died (a car accident and complications of COVID-19 infection, respectively).

AI = aortic insufficiency; AS = aortic stenosis; AV = aortic valve; CoA = coarctation of the aorta; CTA = computed tomography angiography; E/e = the ratio of the mitral peak velocity of early filling (E) to early diastolic mitral annular velocity (E'); IVSd = interventricular septal thickness at diastole; LSCA = left subclavian artery; LV = left ventricle; LVEF = left ventricular ejection fraction; LVIDd = left ventricular internal diameter at end-diastole; MR = mitral regurgitation; PG = peak gradient; PWd = posterior wall diameter; TTE = transthoracic echocardiography

Supplementary Table 3. Three-year imaging characteristics of the study patients in the 3-year structural follow-up[a].

	Balloon-Expandable Stents (n =35)	Self-Expandable Stents (n =36)	*P* value
TTE Parameters			
Bicuspid aortic valve	21 (60.0)	19 (52.8)	0.54
Moderate to severe AI	7 (20.0)	3 (8.3)	0.16
Moderate to severe AS	0 (0.0)	2 (5.6)	0.16
Moderate to severe LVH	0 (0.0)	1 (2.8)	0.32
LVEF, %	55.0 (55.0 – 55.0)	55.0 (55.0 – 55.0)	0.84
PWd, cm	0.9 (0.8 – 1.0)	0.9 (0.7 – 1.0)	0.84
Peak systolic PG, mm Hg	19.8 ± 8.7	21.4 ± 12.6	0.54
LV Diastolic Function			0.73
Normal	17 (48.6)	16 (44.4)	
Grade I	18 (51.4)	20 (55.8)	
CTA Parameters			
Ascending aorta diameter, mm	33.3 ± 6.3	32.2 ± 6.9	0.48
Aortic diameter at the diaphragmatic level, mm	16.8 ± 2.8	16.5 ± 2.3	0.71

Data are presented in n (%), mean ± standard deviation (SD), and median (interquartile range [IQR]).

[a] Of 92 patients initially allocated to the 2 study groups, 71 patients accepted to participate in the 3-year structural follow-up, composed of transthoracic echocardiography and CTA. Among the remaining 21 patients, 16 were followed up through phone interviews, 3 withdrew from the study, and 2 died (a car accident and complications of COVID-19 infection, respectively).

AI = aortic insufficiency; AS = aortic stenosis; AV = aortic valve; CTA = computed tomography angiography; LSCA = left subclavian artery; LV = left ventricle; LVEF = left ventricular ejection fraction; LVH = left ventricular hypertrophy; PG = pressure gradient; PWd = posterior wall diameter; TTE = transthoracic echocardiography

Supplementary Table 4. Type of antihypertensive medication use in the study population at baseline and 3-year follow-up.

Type of Stent	Baseline		3-year	
	BES (n =35)	SES (n =36)	BES (n =35)	SES (n =36)
Type of anti-hypertensive medication				
ACEI	7 (20)	1 (2.8)	2 (5.7)	0 (0.0)
ARB	19 (54.3)	19 (52.8)	15 (42.9)	10 (27.8)
Beta-blocker	16 (45.7)	18 (50.0)	18 (51.4)	16 (44.4)
Diuretics	15 (42.9)	8 (22.2)	4 (11.4)	1 (2.8)
CCB	16 (45.7)	7 (19.4)	0 (0.0)	2 (5.6)

Data are presented in n (%); ACEI = angiotensin-converting enzyme inhibitor; ARB = angiotensin receptor blocker; BES = balloon-expandable stent; CCB = calcium channel blocker; SES = self-expandable stent

Supplementary Table 5. Baseline demographic and clinical characteristics of the study patients with and without the 3-year structural follow-up[a].

	Structural Follow-up (n =71)	No Structural Follow-up (n =21)	*P* value
Age, y	30.0 (20.0 – 35.0)	29.0 (21.0 – 37.0)	1.00
Female sex	25 (35.2)	7 (33.3)	0.87
Family history of coarctation	2 (2.8)	0 (0.0)	0.44
Hypertension	69 (97.2)	21 (100)	0.60
Cigarette smoking	6 (8.5)	0 (0.0)	0.17
Coronary artery disease	6 (8.5)	2 (9.5)	0.88
Diabetes mellitus	1 (1.4)	0 (0.0)	0.58
Hyperlipidemia	1 (1.4)	1 (4.8)	0.35
Presenting Symptoms			
Hypertension	37 (52.1)	8 (38.0)	0.26
Claudication	4 (5.6)	0 (0.0)	0.27
Chest pain	5 (7.0)	5 (24.0)	0.03
Dyspnea on exertion	3 (4.2)	4 (19.0)	0.23
Palpitation	1 (1.4)	0 (0.0)	0.58
Duration of Symptoms			0.55
< 6 months	28 (39.4)	11 (52.4)	
6–12 months	11 (15.5)	3 (14.3)	
> 12 months	32 (45.1)	7 (33.3)	
Number of hypertension medications	3.0 (2.0 – 4.0)	3.0 (2.0 – 4.0)	0.44
Type of hypertension medication			
ARB	38 (53.5)	12 (57.1)	0.77
Beta-blocker	34 (47.9)	13 (61.9)	0.26
Diuretics	23 (32.4)	5 (23.8)	0.45
CCB	23 (32.4)	8 (38.1)	0.63
ACEI	8 (11.3)	4 (19.0)	0.35
Hemoglobin, mg/dL	13.7 ± 1.6	12.6 ± 2.2	0.06
Creatinine, mg/dL	0.9 (0.8 – 1.0)	0.9 (0.8 – 0.9)	0.75

Data are presented in n (%), mean ± standard deviation (SD), and median (interquartile range [IQR]). [a] Of 92 patients initially allocated to the 2 study groups, 71 patients accepted to

participate in the 3-year structural follow-up, composed of transthoracic echocardiography and aortic computed tomography angiography. Among the remaining 21 patients, 16 were followed up through phone interviews, 3 withdrew from the study, and 2 died (a car accident and complications of COVID-19 infection, respectively).

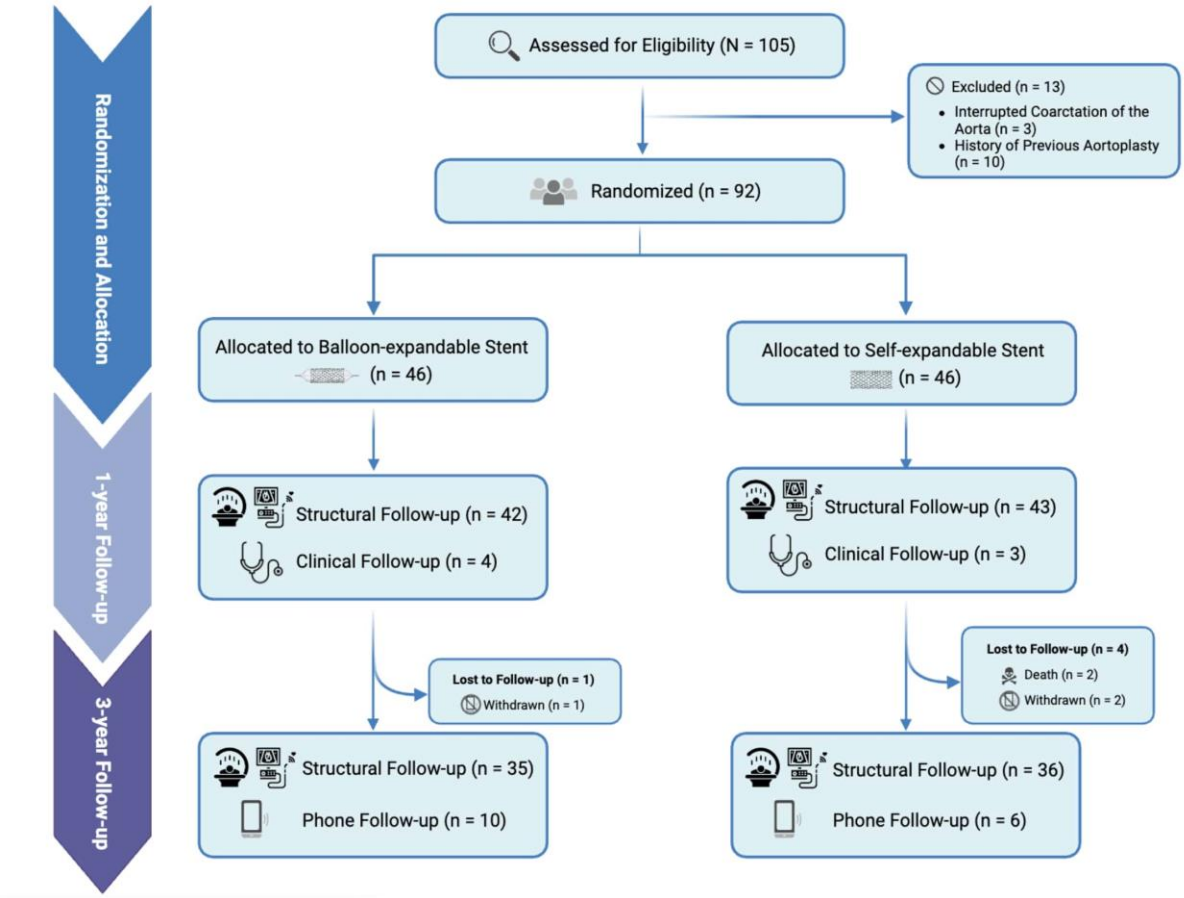
ACEI = angiotensin-converting enzyme inhibitor; ARB = angiotensin receptor blocker; CCB = calcium channel blocker

Supplementary Table 6. Baseline imaging characteristics of the study patients with and without the 3-year structural follow-up[a].

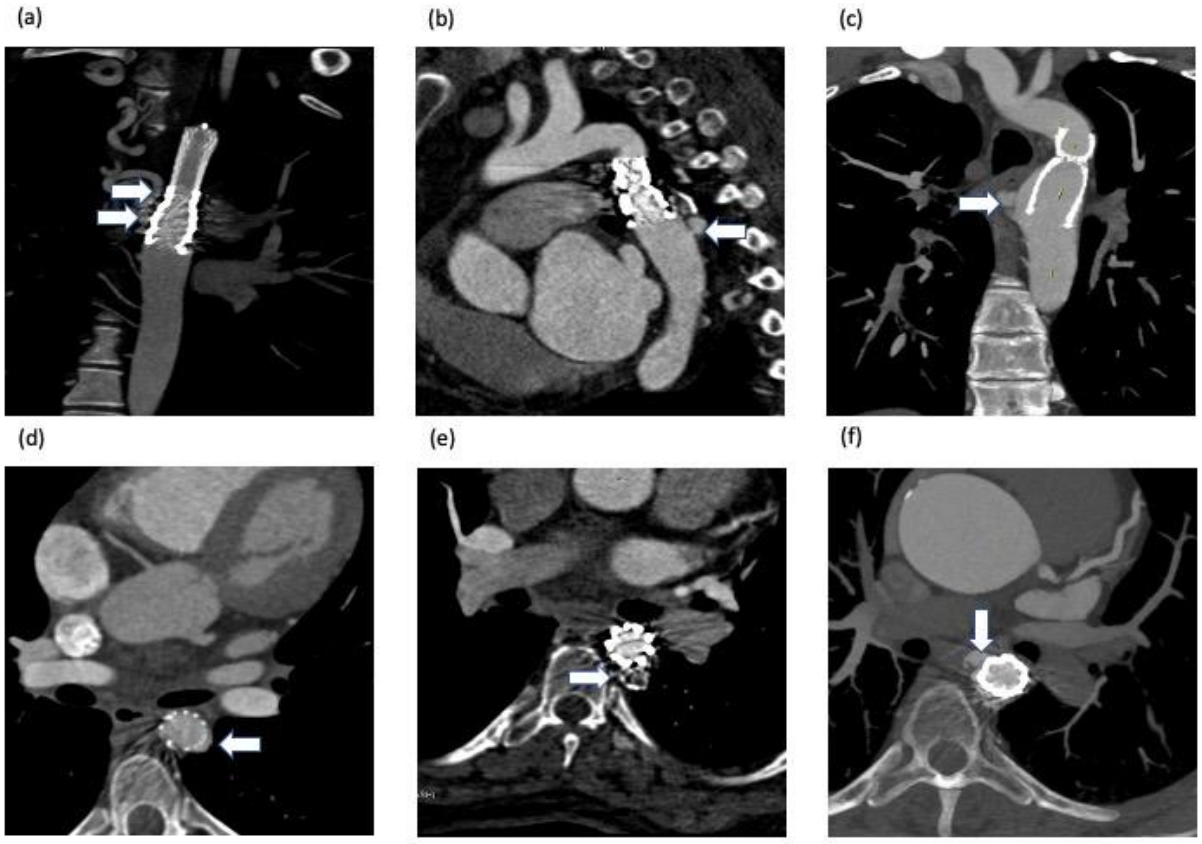
	Structural Follow-up (n =71)	No Structural Follow-up (n =21)	*P* value
TTE Parameters			
Bicuspid aortic valve	42 (59.2)	12 (57.1)	0.87
Moderate to severe AI	7 (10.3)	3 (15.0)	0.56
Moderate to severe AS	0 (0.0)	4 (20.0)	0.00
Moderate to severe MR	5 (7.4)	0 (0.0)	0.21
LVEF, %	55.0 (50.0 – 55.0)	52.5 (50.0 – 55.0)	0.10
PWd, cm	0.9 (0.8 – 1.0)	1.0 (1.0 – 1.1)	0.07
LVIDd, cm	5.0 (4.6 – 5.3)	4.9 (4.4 – 5.1)	0.57
Peak systolic PG, mm Hg	65.0 ± 16.0	64.8 ± 17.2	0.97
Mitral E/e'	8.0 (7.0 – 9.0)	11.5 (10.0 – 12.5)	0.02
AV Annulus, cm	2.2 (2.0 – 2.3)	2.2 (2.0 – 2.3)	0.50
Sinus of Valsalva, cm	3.2 (2.8 – 3.6)	3.2 (3.0 – 3.7)	0.65
LV Diastolic Grading			0.03
Moderate	0 (0.0)	1 (5.3)	
Severe	0 (0.0)	1 (5.3)	
IVSd, cm	1.0 (0.8 – 1.1)	1.0 (0.9 – 1.2)	0.19
CTA Parameters			
Aortic diameter before CoA, mm	14.9 ± 3.5	14.5 ± 5.9	0.81
Aortic diameter after CoA, mm	19.1 ± 5.5	18.3 ± 4.8	0.67
Ascending aorta diameter, mm	32.8 ± 5.6	32.3 ± 6.1	0.79
Distance between the LSCA and CoA, mm	19.9 ± 8.5	16.3 ± 9.0	0.17
Proximal descending aorta diameter, mm	21.3 ± 4.4	21.2 ± 4.8	0.95
Aortic diameter at the diaphragmatic level, mm	15.7 ± 2.4	15.9 ± 3.7	0.75

Data are presented in n (%), mean ± standard deviation (SD), and median (interquartile range [IQR]). [a] Of 92 patients initially allocated to the 2 study groups, 71 patients accepted to participate in the 3-year structural follow-up, composed of TTE and aortic CTA. Among the remaining 21 patients, 16 were followed up through phone interviews, 3 withdrew from the study, and 2 died (a car accident and complications of COVID-19 infection, respectively).

AI = aortic insufficiency; AS = aortic stenosis; AV = aortic valve; CoA = coarctation of the aorta; CTA = computed tomography angiography; E/e = the ratio of the mitral peak velocity of early filling (E) to early diastolic mitral annular velocity (E'); IVSd = interventricular septal thickness at diastole; LSCA = left subclavian artery; LV = left ventricle; LVEF = left ventricular ejection fraction; LVIDd = left ventricular internal diameter at end-diastole; MR = mitral regurgitation; PG = peak gradient; PWd = posterior wall diameter; TTE = transthoracic echocardiography

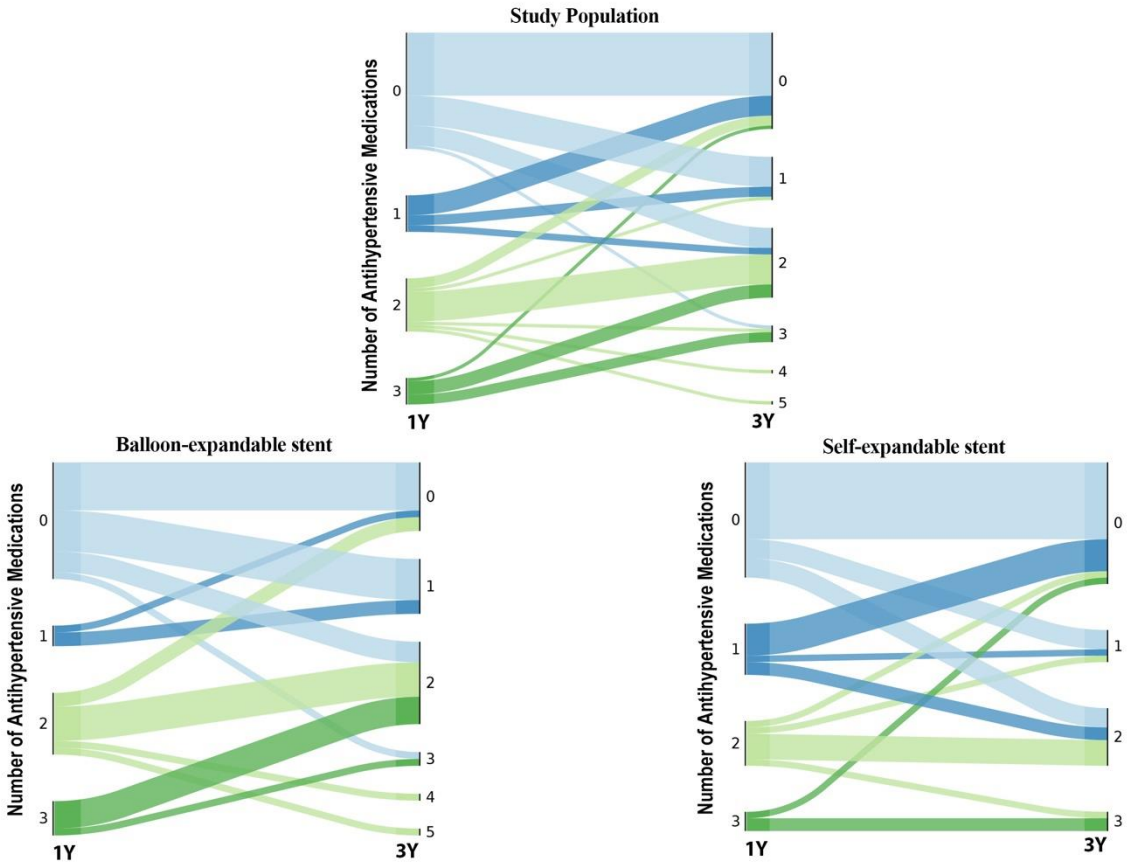


Supplementary Figure 1. Detailed patients' flow diagram during the 3-year follow-up period.



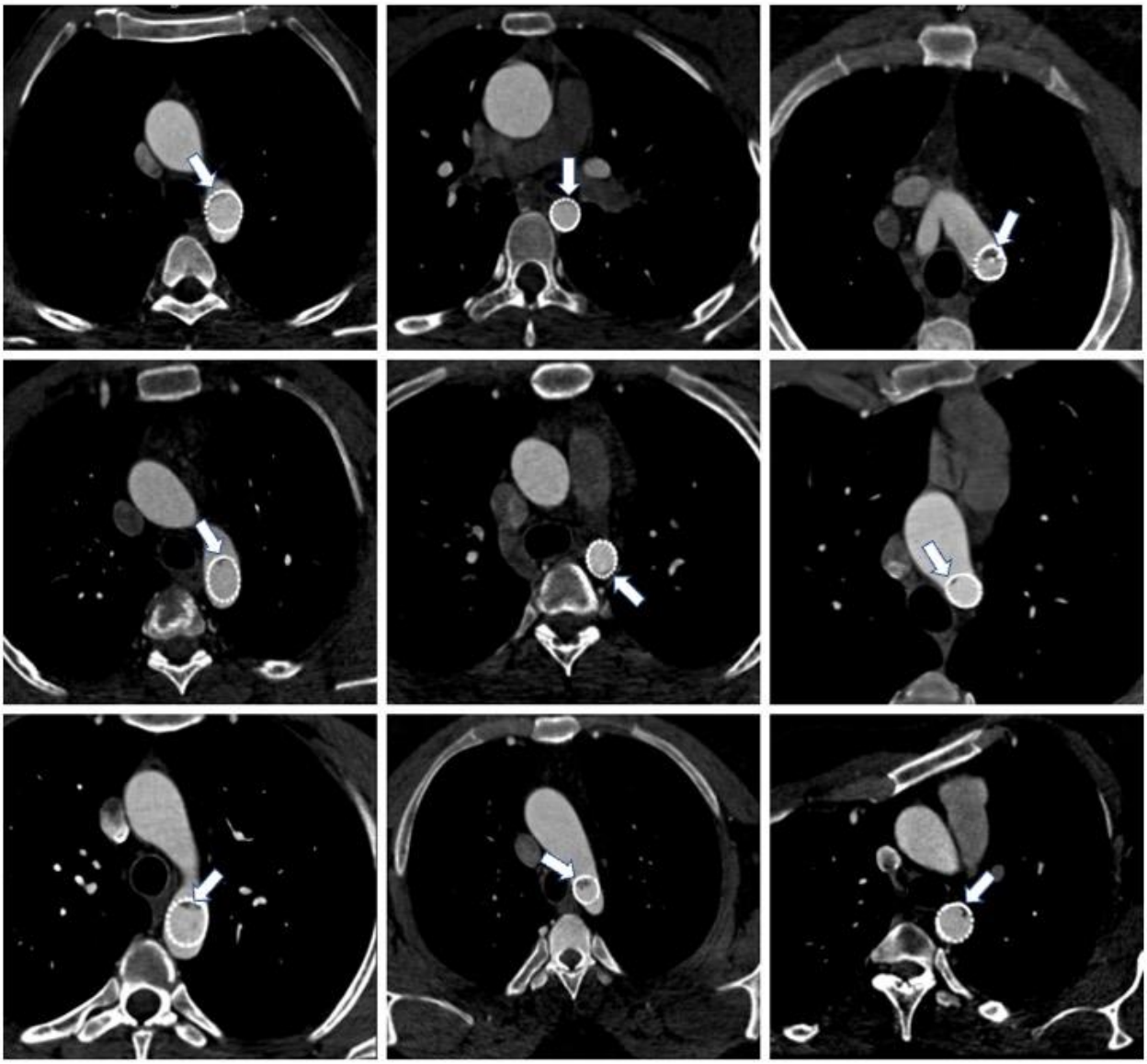
Supplementary Figure 2. Aortic computed tomography angiography of patients complicated with aortic wall injuries.

Figure 2 Legend: Aortic wall injuries (arrows) comprised aneurysmal formation at the origin of the intercostal artery (a, b, and c) and outpouching in the proximal/distal end of the deployed stents (d, e, and f).



Supplementary Figure 3. Alluvial plot of changes in the number of antihypertensive medications between the 1- and 3-year follow-up periods.

The figure demonstrates the flow of drug usage in the total study population and each study group (balloon-expandable and self-expandable stents) throughout the 1 and 3-year follow-up period. The width of the flows represents the proportion of participants using different drugs at each time point. The left side of the plot represents the drug usage at the 1-year follow-up, while the right side represents the drug usage at the 3-year follow-up.



Supplementary Figure 4. Aortic computed tomography angiography of the studied patients with filling defects.

The images show 3-year intra-stent filling defects (arrows) in patients with coarctation of the aorta treated with self-expandable stents. Due to the artifacts in the computed tomography angiography of the patients treated with balloon-expandable stents, similar filling defects cannot be accurately detected.