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ARTICLE

Surgical Versus Percutaneous Stenting Treatment of Isolated Aortic Coarctation: Long-Term Follow-Up

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ABSTRACT

Background: In recent decades, aortic stenting has become a promising alternative to surgery for both native aortic coarctation and re-stenosis in children and adults. However, comparative long-term outcomes have poorly been investigated. **Methods:** We included 212 patients with previous aortic repair (19 ± 8.7 years) divided into 3 groups: 139 with single-time surgical repair (CoA-S group); 18 with single-time percutaneous stenting (CoA-PS group); and 55 hybrid patients with multiple aortic procedures because of re-coarctation occurrence (CoA-H group). All patients underwent 24-hour ambulatory blood pressure monitoring and trans-thoracic echocardiography. **Results:** After a median follow-up of 17 years after aortic repair, antihypertensive therapy was recorded in a significantly higher proportion of patients (83%) in CoA-PS group compared to 65% and 46% of CoA-H and CoA-S groups, respectively ($p = 0.002$). Pulse pressure values were higher in CoA-PS patients compared to the others ($p < 0.001$). Echocardiogram showed significant residual aortic gradient in 50% of CoA-PS and 73% of CoA-H patients compared to 33% of CoA-S patients ($p < 0.0001$). Indeed, stenting was associated to higher incidence of re-coartaction ($p < 0.0001$). At multivariate regression Cox analysis adjusted for age at repair and need for antihypertensive therapy, percutaneous stenting was an independent predictor of echocardiographic evidence of re-coarctation ($p \leq 0.001$). **Conclusion:** Aortic coarctation stenting was independently associated with re-coartaction occurrence during long-term follow up when compared to surgical procedures. Furthermore, patients with aortic stenting had lower blood pressure control at 24-hour ambulatory blood pressure monitoring and higher need for antihypertensive therapy.

KEYWORDS

Aortic coartaction; aortic stenting; arterial hypertension; aortic re-coarctation

1 Introduction

Coarctation of the aorta (CoA) is the sixth most common cardiovascular malformation, accounting for 5–8% of all congenital heart diseases, and is mostly diagnosed during infancy [1–3]. Since the first surgery performed in 1944 by Crawford [4], surgical repair has been the standard of care for isolated CoA for more than 50 years, via an evolution of approaches following the excision of the aortic coarcted segment, including subclavian flap repair, patch augmentation and, the most common used technique, the end-to-end anastomosis [5]. Despite excellent surgical results, patients still experience a reduced life expectancy and increased morbidity related to restenosis, aneurysm formation and most of all chronic arterial hypertension, left ventricular hypertrophy and dysfunction, and increased cardiovascular disease [6]. As an alternative to surgery, percutaneous CoA treatment came to light in the 1980s with balloon angioplasty and then in the early 1990s with CoA stenting, aiming at reducing surgical-related morbidity and acute complications [7,8]. Since then, advances in operator experience and stent technology have improved the success rate, the safety and thus the popularity of endovascular CoA treatment with stent placement for primary intervention and even for re-stenosis in both pediatric and adults ages [9,10]. However, long-term complications occur despite adequate and timely repair and re-coarctation (reCoA) is seen in 4–14% of patients, more frequently after stent placement or balloon angioplasty [6,11]. Moreover, hypertension is endemic in patients with aortic stenting, irrespective of the absence of residual obstruction [12]. Despite the large number of studies comparing outcomes of balloon angioplasty versus surgery for CoA repair, there is still a large debate about which technique could be best for the treatment of native CoA and mostly of reCoA [13,14]. The aim of this single-center retrospective study was to compare surgical and stenting effectiveness in terms of re-coartaction rate at trans-thoracic echocardiography and incidence of late arterial hypertension at 24-hour ambulatory blood pressure monitoring in the long-term follow up of a large cohort of pediatric and adult patients.

2 Methods

2.1 Patients

We included 212 patients with native or recurrent CoA corrected at our institution, the Bambino Gesù Children's Hospital, from 1983 to 2018 (with first stent positioning in 2002). We excluded patients with genetic syndromes (e.g., Turner syndrome) or associated significant congenital heart defects, except for bicuspid aortic valve, which was present in 82% of the study population and had normal function or only trivial regurgitation. We also excluded patients with aortic arch hypoplasia (any aortic segment with Z-score lower than −2 SD [15]) in order to avoid any bias in the analysis of long-term hypertension development. Approval from our Institutional Medical Ethics Committee was obtained and data were retrospectively analyzed in line with personal data protection policies (consent of patients was waived).

We divided patients into 3 groups depending on CoA treatment type:

1. The surgical group (CoA-S) included 139 patients who underwent one-time surgical aortic repair via patch aortoplasty, subclavian flap repair or end-to-end anastomosis;
2. The percutaneous stenting group (CoA-PS) included 18 patients with CoA repair by means of one-time endovascular aortic stent positioning;
3. The hybrid group (CoA-H) included 55 patients who underwent multiple aortic procedures (with or without balloon angioplasty) because of reCoA occurrence.

We collected demographic and clinical data including height, weight, body mass index (BMI) and anti-hypertensive (HTN) drugs at baseline and at the latest follow-up. All patients treated with aortic stenting performed the same percutaneous procedure with implantation of balloon-expandable Cheatham-Platinum (CP) stent (NuMED, Inc., Hopkinton, NY, USA) at the site of CoA. When appropriate, we also collected surgical data regarding age at first repair, correction repair technique and subsequent reinterventions and/or complications. All patients underwent clinical examination including blood pressure (BP) measurement using an OMRON oscillometric device placed on the right arm in the seated position. BP values were measured at rest according to pediatric guidelines recommendations [16]. BP was also measured in the supine position both at the right arm and right leg to determine any arm-to-leg gradient, defined as significant when ≥20 mmHg.

2.2 24-Hour Ambulatory Blood Pressure Monitoring (ABPM)

All patients performed ABPM (Spacelab 90207, Spacelab Inc., Redmond, Wash). We collected 24-hour mean systolic blood pressure (SBP) and pulse pressure (PP) values, as well as mean day-time and night-time SBP and percentage of dipping. Monitoring was considered reliable if at least 75% of readings were successful. Patients were defined as hypertensive if they had elevated BP values at rest according to hypertension pediatric guidelines or European Society of Hypertension guidelines for adults [17,18]; or if mean BP values at ABPM were above the 95^{th} percentile for height and gender; or, lastly, if they already receive HTN medications.

2.3 Trans-Thoracic Echocardiography (TTE)

TTE was performed in all patients by an expert sonographer according to standardized technical methods and reviewed off-line with computerized review stations by two independent echocardiographists (Intellispace, Philips, Andover, USA). We recorded aortic gradient at the site of intervention(s) as well as left ventricular internal dimensions and septal and posterior wall thickness measured at end-diastole and end-systole using American Society of Echocardiography recommendations on 3 cardiac cycles [19]. Standard formula was used to calculate left ventricular mass, which was then normalized both for body surface area and for an allometric power of height, as we have recently suggested [20].

2.4 End-Points

Primary end-point was to identify which aortic repair technique (CoA-S versus CoA-PS versus CoA-H) was predictive of re-coarctation during a long-term follow-up. Secondary end-point was to evaluate the incidence of late arterial hypertension at ABPM after different types of aortic repair.

2.5 Statistical Analysis

All continuous variables were assessed for normality with the Shapiro-Wilk test and by examination of their histogram. Variables with normal distribution were expressed as means and standard deviations and tested for differences using ANOVA with post-hoc Bonferroni correction and Student-T test, as appropriate. Non-parametric variables were expressed as median and interquartile range and differences tested using Kruskall-Wallis test and Mann-Whitney test, as appropriate. Categorical variables were expressed as percentages and analyzed by chi-squared test. Survival curves were estimated using the Kaplan-Meier product-limit estimator and compared using the log-rank test. Cox proportional hazards analysis was used to calculate the adjusted hazard ratios for each clinical variable. The final multivariable Cox regression model was selected via a stepwise approach based on minimization of Akaike Information Criterion. Only p values lower than 0.05 were considered statistically significant. All tests were 2-tailed and analyses were performed using computer software packages (SPSS-22.0, IBM, NY, USA).

3 Results

3.1 Clinical Data

The study population included 212 CoA patients (male, 72%) with a median follow-up of 17 years (IQ range 11–24 years). Mean age at data collection was 19 ± 8.7 years with 47% patients in the pediatric age (<18 years). Baseline characteristics of the overall study population are shown in Tab. 1.

At last follow-up visit, only 5 patients (2%) had arm-to-leg gradient ≥20 mmHg (median 25 mmHg, IQ range 22–34 mmHg), 4 of which were children with previous aortic stenting. Conversely, at TTE 44.8% of the total cohort had an aortic gradient ≥20 mmHg; among those, a significant higher proportion of children had an ongoing HTN treatment compared to those without any medication (54% *vs.* 34%, $p = 0.003$).

Table 1: Characteristics of the study population

Patients, n	212
Male, n (%)	152 (72)
Follow-up, years (median, IQ range)	17 (11–24)
Age at follow-up, years (median, IQ range)	19 (12–26)
BMI, Kg/m^2 (mean ± SD)	22 ± 4
Total Surgical procedures, n (%)	153 (72)
End-to-end anastomosis, n (%)	85 (56)
Patch aortoplasty, n (%)	37 (24)
Subclavian Flap, n (%)	31 (20)
Total aortic stenting procedures, n (%)	39 (18)
HTN medications, n (%)	115 (54)
ACE-I/ARBs, n (%)	53 (46)
BBs, n (%)	12 (10)
Multiple therapy (ACE-I/ARBs +/- diuretics +/- BBs +/- CAs), n (%)	50 (44)
CoA-S group: single-time surgical repair, n (%)	139 (66)
End-to-end anastomosis, n (%)	83 (60)
Patch aortoplasty, n (%)	25 (18)
Subclavian Flap, n (%)	31 (22)
CoA-PS group: single-time aortic stenting, n (%)	18 (8)
CoA-H group: patients with reoperations, n (%)	55 (26)
Multiple surgical procedures, n (%)	4 (7)
Multiple percutaneous procedures, n (%)	5 (9)
Surgical and percutaneous procedures, n (%)	46 (84)

Note: ACE-I: Angiotensin Converting Enzyme Inhibitors. ARBs: Angiotensin II Receptor Blockers. BBs: Beta Blockers. BMI: Body Mass Index. CAs: Calcium Antagonists. HTN = anti-hypertensive. reCoA: reCoarctation of the Aorta.

Overall, 54% of the total population had anti-hypertensive therapy. Medical treatment was performed with single therapy in the majority of patients, using angiotensin converting enzyme inhibitors, angiotensin II receptor blockers or beta blockers. However, 44% of hypertensive patients needed multiple therapies with different drug combinations involving the above-mentioned ACE-I, ARBs and BBs with diuretics or calcium antagonists.

Age at first repair was higher in the CoA-PS group compared to both other 2 groups. Similarly, BMI was significantly higher in the CoA-PS group compared to the CoA-S group. Differences in the need of HTN therapy and type of medications are shown in Tab. 2.

3.2 ABPM

We observed 9% of the whole population with elevated 24-hour SBP values, 7.5% with elevated daily SBP values and 9% with elevated nocturnal SBP values. CoA-PS patients had a higher proportion of mean day-time SBP values exceeding the normal value compared to CoA-S patients (22% *vs.* 6%, respectively;

p = 0.045) (Tab. 3). Also, mean 24-hour PP values were significantly different in all study groups, as shown in Fig. 1. No significant difference in nocturnal dipping was recorded.

Table 2: Clinical variables of the three study groups

	CoA-S group (n = 139)	CoA-PS group (n = 18)	CoA-H group (n = 55)	p S *vs.* PS	p PS *vs.* H	p S *vs.* H
Age at repair, days/years (mean ± SD)	39 days (18 d–2.6 y)	12 years (9 y–16 y)	23 days (11 d–2 y)	**<0.001**[a]	**<0.001**[a]	0.07[a]
Male, n (%)	95 (68)	10 (55)	47 (85)	ns[b]	**0.018**[b]	**0.010**[b]
BMI, Kg/m^2 (mean ± SD)	21 ± 4	24 ± 3	23 ± 4	**0.025**[c]	ns[c]	ns[c]
Need of HTN therapy, n (%)	64 (46)	15 (83)	36 (65)	**0.009**[b]	ns[b]	**0.022**[b]
HTN therapy with ACE-inhibitors/ ARBs, n (%)	34 (64)	5 (9)	14 (26)	**<0.001**[b]	**0.428**[b]	**0.0002**[b]
HTN therapy with BBs, n (%)	7 (41)	5 (29)	5 (29)	ns[b]	ns[b]	ns[b]
Multiple HTN therapy, n (%)	23 (51)	5 (11)	17 (38)	**<0.001**[b]	**0.007**[b]	ns[b]

Note: ACE: Angiotensin Converting Enzyme. ARBs: Angiotensin II Receptor Blockers. BBs: Beta Blockers. BMI: Body Mass Index. HTN = anti-hypertensive. [a]Mann-Whitney test, [b]Chi square, [c]ANOVA with Bonferroni correction.

Table 3: ABPM variables of the 3 study groups

	CoA-S group (n = 139)	CoA-PS group (n = 18)	CoA-H group (n = 55)	p S *vs.* PS	p PS *vs.* H	p S *vs.* H
Mean 24hSBP, mmHg (mean ± SD)	116 ± 10	121 ± 8	118 ± 10	ns[b]	ns[b]	ns[b]
24h Pulse Pressure, mmHg (mean ± SD)	52 ± 11	58 ± 8	57 ± 11	0.085	ns	0.020
Day-time SBP, mmHg (mean ± SD)	120 ± 10	125 ± 8	121 ± 10	ns[b]	ns[b]	ns[b]
Number of mean daytime SBP values > 95th centile, n (%)	9 (6)	4 (22)	3 (5)	**0.045**[a]	ns[a]	ns[a]
Night-time SBP, mmHg (mean ± SD)	106 ± 10	112 ± 11	107 ± 10	0.075[b]	ns[b]	ns[b]
Nocturnal dipping, mmHg (mean ± SD)	11 ± 5	10 ± 7	11 ± 4	ns[b]	ns[b]	ns[b]

Note: PP: Pulse Pressure. SBP: Systolic Blood Pressure. [a]Chi square, [b]ANOVA with Bonferroni correction.

3.3 TTE

Echocardiography showed that the number of patients with significant aortic gradient was higher in CoA-PS (50%) and CoA-H (73%) groups compared to CoA-S (33%) group ($p < 0.0001$) and median 95% CI gradient was significantly different in all study groups (Fig. 2). Moreover, a correlation between aortic gradient and mean 24-hour PP values was found (rho: 0.399, $p < 0.0001$; Fig. 3). Besides, TTE evaluation of left ventricular mass did not show significant differences among the 3 study groups (Tab. 4). However, CoA-PS patients demonstrated a tendency to have higher relative wall thickness values compared to CoA-S patients (median 0.35 mm [IQ range 0.29–0.38] *vs.* 0.30 mm [IQ range 0.27–0.34], $p = 0.065$), which is consistent with a concentric left ventricular adaptation to pressure overload.

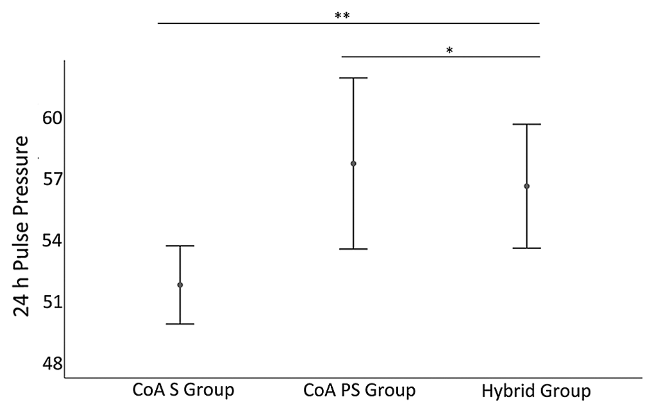

Figure 1: 24-hour Pulse pressure values at ABPM in the 3 study groups. * $p < 0.05$ obtained with student T test. **overall $p < 0.001$ obtained with ANOVA analysis

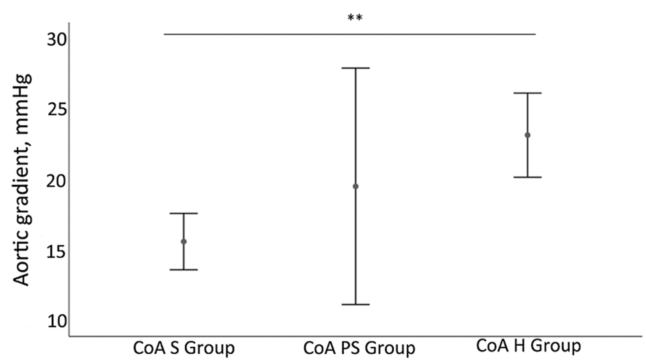

Figure 2: Aortic gradient at TTE in the 3 study groups **overall $p = < 0.0001$ obtained with Krurskall Wall test

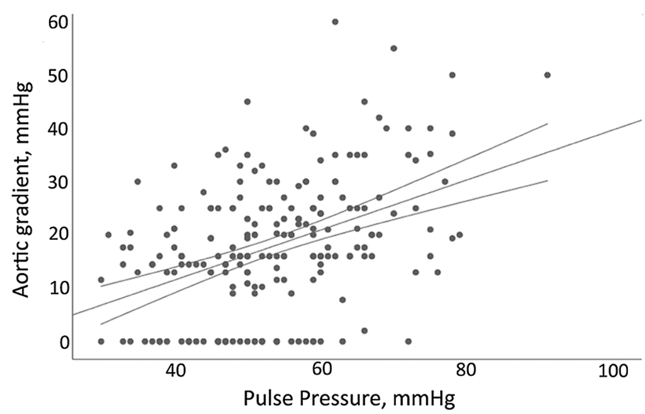

Figure 3: Correlation between aortic gradient at TTE and pulse pressure values at ABPM (obtained by Spearman bivariate correlation)

4 Survival and Multivariate Analysis

At Kaplan Meier survival analysis, CoA-PS group significantly showed a higher re-coartaction rate (log rank $p < 0.0001$) compared to CoA-S and CoA-H groups (Fig. 4). Finally, at multivariate regression Cox analysis adjusted for gender, age at first CoA repair, BMI > 90^{th} centile and HTN therapy, stenting treatment was the best independent predictor of echocardiographic evidence of re-coarctation during a long term follow up (H.R. 14.653, 95% CI 6.432–33.377; $p \leq 0.001$).

Table 4: Left ventricular values at TTE in the 3 study groups

	CoA-S group (n = 139)	CoA-PS group (n = 18)	CoA-H group (n = 55)	*p* value overall
IVSd, mm (mean ± SD)	7.9 ± 1.7	8.5 ± 1.2	8 ± 1.4	0.396
LVIDd, mm (mean ± SD)	48 ± 7	49 ± 6	49 ± 7	0.407
LVPWd, mm (mean ± SD)	7 ± 1.6	8 ± 1.2	8 ± 1.7	0.069
RWT, mm median (IQR)	0.30 (0.27–0.34)	0.35 (0.29–0.38)	0.32 (0.27–0.36)	0.065
LVMi (mean ± SD)	43 ± 11	47 ± 12	44 ± 12	0.190
LVM OBG (mean ± SD)	41.5 ± 14	42 ± 10	41 ± 12	0.948

Note: IVSd: end diastolic interventricular septum. LVIDd: end diastolic left ventricular internal diameter. LVPWd: end diastolic left ventricular posterior wall. RWT: relative wall thickness. LVMi: left ventricular mass index (normalized for body surface area). LVM OBG: left ventricular mass normalized for an allometric power of height using OBG-Ospedale Bambino Gesù formula (Chinali et al. [20]).

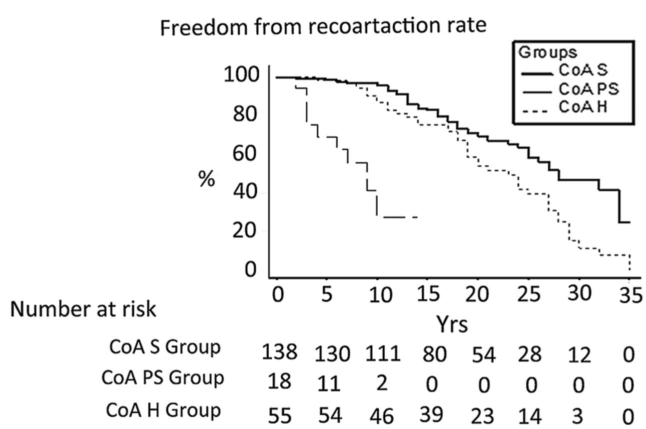

Figure 4: Freedom from re-coarctation rate: Kaplan-Meier Survival Estimates

5 Discussion

Coarctation of the aorta is a common congenital cardiac malformation mainly diagnosed in infancy and early childhood and surgical repair has been for many years the treatment of choice in neonates, infants and young children [11]. However, surgery entails procedural risks potentially leading to early o mid-term complications and also long-term complications may occur despite successful repair [14]. Particularly, hypertension is known to persist after intervention in 1/3 of patients irrespective of the absence of re-coarctation [21]. Hence, as an alternative, endovascular treatment (balloon angioplasty and/or percutaneous stenting) has recently emerged as a promising technique both for primary CoA repair and correction of secondary restenosis [22–24]. However, some concerns must be pointed out regarding percutaneous stenting in the pediatric age, for example radiation exposure, age/weight limitations, major complications (mostly aneurysm formation, aortic dissection and stent migration or fracture) and failure to adapt to the growing aorta during childhood [25].

In this heated debate about which technique could be best for isolated CoA treatment, literature lacks of long-term results after different repair techniques, particularly for percutaneous stent positioning in the pediatric age. Previous studies showed that surgical repair is associated to lower incidence of reCoA, lower need of re-intervention and lower residual aortic gradient compared to balloon angioplasty [25]. Others describe the excellent results of aortic stenting in the acute and mid-term, which are superior to balloon angioplasty and comparable to surgery [3,8]; particularly, stenting is preferred over balloon angioplasty alone because of the superior immediate relief of a relevant pressure gradient [26] and the lower risk of restenosis and aneurysm formation [11]. Forbes et al. [8] designed a multicenter observational study showing that aortic stenting had lower acute complications than surgery and balloon angioplasty, and both stenting and surgery achieved superior hemodynamic outcomes compared to percutaneous angioplasty alone in a short-term follow-up. Similarly, in a recent review of the literature evaluating different CoA repair strategies' outcomes, re-intervention rates and vascular complications were lower for patients treated with surgical repair, whereas both balloon angioplasty and stenting were related to excellent rates of residual aortic gradient <20 mmHg [25].

As far as we know, this retrospective study for the first time directly compares long-term effects of aortic surgery versus aortic stenting in a large cohort of children and adults, focusing on blood pressure control and freedom from re-coarctation. We only included isolated forms of CoA as we recently demonstrated that the presence of associated cardiac anomalies results in a significantly lower incidence of late-onset arterial hypertension [27]. During a median follow-up of 17 years after successful aortic repair, reCoA was observed in 25% of the total cohort, similar to what reported in the literature [11]. We found 44.8% of patients with aortic gradient ≥20 mmHg at TTE despite the absence of significant arm-to-leg gradient at clinical evaluation. This is also consistent with literature [28] and confirms the low diagnostic value of the arm-to-leg gradient in the diagnosis of significant aortic re-stenosis.

As mentioned above, chronic arterial hypertension is known to be the major long-term morbidity even after successful aortic repair and in the absence of aortic re-obstruction [11]. Similarly, we also found an elevated incidence of hypertension as more than 50% patients of our total cohort were treated with HTN medications. Although the underlying pathophysiology is not yet fully understood, different factors such as age and weight at initial repair (especially when first repair is performed after 1 year of age), pre-operative aortic gradient, arch hypoplasia, impaired baroreceptor reflex or abnormal renal perfusion have been advocated to influence reCoA rate and hypertension development [8,29–31]. Moreover, as CoA is considered a general arteriopathy with increased stiffness of the aortic wall, concerns have been raised regarding the eventual worsening of hypertension when a stent is placed in this context. In fact, in our cohort CoA-PS patients not only had significant higher age at first repair but also higher BMI values compared to the others, and both factors may contribute to the onset hypertension. In addition, Maschietto et al. [1] found in animal models elevated markers of oxidative stress and endothelial damage within the aortic wall proximal to a stent, supposing a higher cardiovascular risk in patients after aortic stenting with premature development of arterial hypertension.

Consistent with this, our data showed that patients with aortic stenting have a higher need for HTN therapy compared to those with previous surgical or hybrid CoA repair. Moreover, we observed at ABPM significantly higher PP values in CoA-PS and CoA-H groups compared to CoA-S group. PP is a simple surrogate of arterial stiffness measure and it has been reported to be abnormally elevated in patients with repaired CoA [32] and associated to a higher risk of hypertension [33]. Indeed, stent may reduce aortic compliance, increase impedance to blood flow causing a loss of pulsatile energy; this could explain the lowest PP values in patients with one-time surgical aortic repair compared to those with aortic stent implantation. This is also confirmed by TTE: CoA-PS and CoA-H patients had the highest mean aortic gradient compared to CoA-S group ($p < 0.0001$), and a significant correlation between aortic gradient and PP was found. Not least, patients with aortic stenting had higher relative wall thickness values compared to CoA-S group as an expression of concentric left ventricular adaptation to pressure overload; this might be an early sign of hypertension development in these patients.

Finally, in order to avoid bias between surgery and percutaneous stenting (mostly due to significant difference in age at first repair), we demonstrated at multivariate Cox regression analysis that stenting was the strongest predictor of reCoA in the long-term follow up, irrespective from age at first aortic repair, gender, HTN medications and elevated BMI.

In conclusion, this study evaluated the long-term ABPM and TTE outcomes in a large cohort of children and adults with previous isolated CoA treated with surgery, stent implantation or both. We demonstrated that patients with aortic stenting had higher prevalence of late arterial hypertension with higher need for HTN therapy and higher rate of significant aortic gradient. Much more, aortic stenting emerged as the best independent predictor of re-coartaction, irrespective from age at repair, need and type of antihypertensive therapy or other CoA repair techniques.

Although being yet far from the solution of the problem (i.e., which technique is best for isolated CoA repair), our data suggest that surgery may probably be still the best option for native CoA in the pediatric age. On the other hand, looking at recoarctation scenarios, treatment should be probably tailored to each patient. Children and adolescents before puberty may experience the cons of stent positioning for reCoa treatment (need of multiple dilation procedures with multiple radiation exposures, stent's failure to adapt to a growing aorta, hypertensive burden as suggested by our data). Instead, patients after pubertal development may be akin to adults and stenting procedure may be the best choice for reCoa correction in this context.

6 Limitations

The main limitation of our study is the heterogeneity of groups, mostly regarding age at first repair, which is higher in patients with aortic stenting. This is not perfectible because percutaneous treatment needs by definition higher age and weight of patients, compared to surgery. Thus, age-matched groups are not feasible. As much as possible, we reduced this discrepancy by applying multivariate Cox regression analysis, and primary end-point proved to be irrespective of age at repair.

Ethical Approval and Consent: Approval from Ethics Committee of Bambino Gesù Chidren's Hospital, IRCCS, Rome (Approval No. 2427) was obtained and data were retrospectively analyzed in line with personal data protection policies (consent of patients was waived).

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Conflicts of Interest: The authors declare that they have no conflicts of interest to report regarding the present study.

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