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Ability of noninvasive criteria to predict hemodynamically significant aortic obstruction in adults with coarctation of the aorta

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Abstract

Objective: Coarctation of the aorta (CoA) is a common condition. Adult patients with newly diagnosed CoA and patients with recurring or residual CoA require evaluation of the severity of aortic obstruction. Cardiac catheterization is considered the gold standard for the evaluation of hemodynamically significant CoA. The European Society of Cardiology (ESC) Guidelines for the management of grown-up congenital heart disease (GUCH) include noninvasive criteria for identifying significant CoA. Our aim was to investigate the ability of the Class I and Class IIa ESC recommendations to identify significant CoA at cardiac catheterization.

Design: Sixty-six adult patients with native or recurrent CoA underwent diagnostic cardiac catheterization at the GUCH unit at the Sahlgrenska University Hospital in Gothenburg from October 1998 to November 2013. Clinical and imaging data, as well as data about cardiac catheterization were retrospectively collected from patient records.

Results: The Class I ESC recommendations predicted significant CoA with a sensitivity of 0.57, a specificity of 0.63, a positive predictive value of 0.67, and a negative predictive value of 0.53. The combination of Class I and Class IIa recommendations predicted significant CoA with a sensitivity of 0.75, a specificity of 0.42, a positive predictive value of 0.66 and a negative predictive value of 0.52.

Conclusions: the noninvasive criteria proposed by the ESC guidelines to identify subjects with significant CoA performed poorly in our dataset. Further research is needed to develop more accurate, noninvasive criteria to evaluate CoA severity and thereby reduce the number of unnecessary cardiac catheterizations.

KEYWORDS

cardiac catheterization, coarctation of the aorta, congenital heart defects, decision support techniques, patient selection, practice guideline

1 | INTRODUCTION

Coarctation of the aorta (CoA) presents as a discrete stenosis or as a hypoplastic aortic segment, typically located in the area of the arterial duct or ligament. It may present as a single, isolated lesion or as part of a more complex congenital heart condition.

 * Both authors contributed equally to this article and should be considered first author.

CoA has a prevalence of 3-4 per 10 000 live births and is thus a relatively common condition. $^{1\mathchar`-3}$

Subjects with severe aortic obstruction exhibit signs and symptoms early in life and often undergo surgical correction during childhood, while mild cases may not become evident until adulthood, when hypertension is detected.⁴

The improvement in survival of patients with congenital heart disease has led to a growing number of patients with CoA living into adulthood and needing monitoring. Indeed, lifelong follow-up is crucial for the prompt recognition not only of hypertension, cardiovascular disease and postprocedural complications but also of recurring or residual CoA.^{4–7}

Conversely, adults with a newly diagnosed CoA need a de novo assessment of the severity of aortic obstruction. An evaluation of the hemodynamic severity of CoA is therefore necessary in a growing number of cases.

A set of noninvasive criteria to identify patients with significant CoA requiring intervention is provided in the European Society of Cardiology (ESC) Guidelines for the management of grown-up congenital heart disease (GUCH). The Class I recommendation is that all patients with a noninvasive blood pressure (BP) difference >20 mm Hg between upper and lower limbs in combination with arterial hypertension or pathological BP response during exercise or left ventricular hypertrophy should have intervention; the Class IIa recommendation is that hypertensive patients with \geq 50% aortic narrowing relative to the aortic diameter at the diaphragm level on imaging should be considered for intervention.⁴

However, cardiac catheterization is still regarded as the gold standard for the evaluation of hemodynamically significant CoA, defined as a peak-to-peak BP gradient \geq 20 mm Hg.

Despite its safety and reliability, cardiac catheterization is an invasive and costly procedure. Much effort has therefore been devoted to developing accurate noninvasive methods to evaluate CoA severity, thereby reducing the number of unnecessary diagnostic catheterizations.^{8,9}

The aim of this study is to investigate the ability of the noninvasive criteria proposed by the ESC to identify adults with a hemodynamically significant CoA, as compared to evaluation by cardiac catheterization.

2 | METHODS

Sixty-six adult patients with native or recurrent CoA underwent diagnostic cardiac catheterization at the GUCH unit at the Sahlgrenska University Hospital in Gothenburg from October 1998 to November 2013. All patients had been referred to our tertiary centre by their cardiologists, due to a clinical suspicion of significant CoA.

All study subjects were registered into the Swedish National Registry of Congenital Heart Disease (SWEDCON, www.ucr.uu.se/swedcon/), and had thus given their informed consent to the use of relevant personal and clinical data for projects aiming to improve local and national routines and guidelines for the diagnosis and treatment of congenital heart disease. Such projects do not need separate ethical approval, according to Swedish law.

The study protocol conforms to the ethical guidelines of the Declaration of Helsinki.

Demographics, upper and lower limb BP measurements, data on medications, exercise testing, transthoracic echocardiography, magnetic resonance imaging (MRI) or computed tomography (CT) and cardiac catheterization were retrospectively collected from patient records for all subjects. Congenital Heart Disease WILEY-

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Before catheterization, BP was measured in both upper limbs as well as in both lower limbs according to current guidelines.¹⁰ The highest readings for upper and lower limbs were used. Patients were classified as hypertensives if their BP at the upper limb was >140/90 mm Hg or if they were on antihypertensive medication at the time of catheterization.

Exercise testing was performed according to current guidelines.¹¹ As no formal definition is included in the ESC Guidelines for the management of GUCH, a pathological BP response during exercise was defined as a systolic BP \geq 210 mm Hg for men and \geq 190 mm Hg for women according to the 2013 ESH/ESC Guidelines for the management of hypertension.¹⁰

Echocardiography was performed by cardiologists specialized in the treatment of adult congenital heart disease. As no formal definition is included in the ESC Guidelines for the management of GUCH, left ventricular hypertrophy was defined according to the recommendations of the American Society of Echocardiography.¹² Left ventricular ejection fraction was estimated visually in most cases and determined according to the modified Simpson's rule only in a minority of cases.¹³ Echocardiography was always performed before cardiac catheterization; the ecocardiographists were thus blinded to the angiographic data, but not to the clinical data.

Preprocedural cardiovascular MRI or contrast-enhanced CT imaging data from multiple centers with equipment from different vendors could be retrieved in 59 (89%) patients (MRI n = 36; CT n = 23). Detailed information regarding the types of scanners was not obtained.

The examinations were reviewed by one radiologist with special interest in congenital heart disease. The radiologist was blinded to the clinical and angiographic data. The examinations were performed between 2001 and 2013, at a median of 8 months (range 1-36 months) prior to cardiac catheterization. Aortic measurements were performed at the narrowest site of the CoA and at the level of the diaphragm.¹⁴ Visually detectable collateral vessels, for example, enlarged intercostal or internal mammary arteries,15 or indirect signs of their presence as detected by phase contrast MRI were noted.^{16,17} In CT examinations including slice thickness of 3 mm or less (n = 13) and in contrastenhanced MR angiographies (n = 32), an Advantage Windows workstation 4.5 (GE Healthcare, Milwaukee, WI) was used to obtain multi-planar reconstructions to measure the narrowest aortic diameter and the severity of the CoA (45 subjects) (Figures 1-3). Most of the CT examinations where not ECG-gated (n = 15). The contrast-enhanced MR angiographies were non-ECG-gated, acquired during breath hold and had a reconstructed slice thickness of 0.7-1.2 mm. In six patients only CT images with a slice thickness of >3mm had been stored and in five patients contrast enhanced MRI angiography images had not been saved or were of modest quality and the severity of the CoA could not be measured accurately. In four patients there were no digital CT images available. In these 15 cases a visual evaluation of whether the CoA diameter was >50% of the aortic diameter at the level of the diaphragm was performed.

Cardiac catheterizations were performed by one of two interventional cardiologists specialized in the treatment of adult congenital ¹⁷⁶ WILEY Congenital Heart Disease



FIGURE 1 Contrast enhanced CT in left anterior oblique view of the thoracic aorta demonstrating the levels were measurements were made

heart disease. During the procedure, patients were not under general anaesthesia and only mild sedation was given if necessary. Vascular access was obtained via a femoral artery. In patients with severe coarctation, an approach from the left brachial artery was used if the coarctation site could not be crossed retrogradely. Biplane fluoroscopy was used to verify catheter position in all cases. BP was invasively measured in the aorta, proximally and distally to the coarctation site; the systolic peak-to-peak gradient across the coarctation site was thus obtained. A systolic peak-to-peak gradient across the coarctation site \geq 20 mm Hg was taken to indicate a significant CoA.



FIGURE 2 Contrast enhanced CT showing a double oblique true transverse image through the aorta at the level of the coarctation



FIGURE 3 Contrast enhanced CT showing a double oblique true transverse image through the aorta at the level of the diaphragm

Statistical analyses were performed using IBM SPSS Statistics for Windows, v.22 (IBM Corp., Armonk, NY). Data are presented as mean- \pm standard deviation, median (range), or number (%), as appropriate.

Data were compared by t test when normally distributed and by Wilcoxon rank-sum test when not normally distributed. Frequencies were compared by Fisher's exact test. All tests were two-sided. Results with a probability value of P < .05 were considered significant.

3 | RESULTS

Demographic, anatomic, and functional data are listed in Table 1, with *P* values for the comparisons between subjects with and without a significant CoA at catheterization.

Of the 66 subjects who underwent cardiac catheterization under the study period, 22 (33%) were female; 40 (61%) had native CoA; 35 (53%) had bicuspid aortic valve; 53 (80%) had hypertension; 33 (50%) had left ventricular hypertrophy; three (5%) had a left ventricular ejection fraction <50% and 37 (56%) had a peak-to-peak pressure gradient \geq 20 mm Hg. Median age at the time of cardiac catheterization was 31.5 (range 18-71) years. Six patients were treated with angioplasty and stenting despite not having a peak-to-peak pressure gradient exceeding 20 mm Hg. Two patients had an in-stent stenosis, one of these also suffered from left ventricular dysfunction; one patient was stented to allow surgery of an ascending aortic aneurysm; three patients had associated aortic valve lesions and/or severe resistant hypertension. In our evaluation of the ability of the ESC Class I recommendations (noninvasive BP difference >20 mm Hg between upper and lower limbs in combination with arterial hypertension or pathological BP response during exercise or left ventricular hypertrophy) to identify subjects with a significant CoA at cardiac catheterization, four subjects (6%) were excluded from the analyses because of missing data required for the Class I recommendation: BP at the lower limbs (three

TABLE 1 Demographics, anatomic, and functional characteristics and catheterization data of patients by gradient at cardiac catheterization^a

	Gradient ≥20 mm Hg	Gradient <20 mm Hg	Р
Demographics			
Number	37	29	
Female, n (%)	16 (43)	6 (30)	0.13
Median age (range) at catheterization, years	34 (18-71)	29 (18-68)	0.38
Anatomic and functional characteristics			
Height, m	172 ± 11	175 ± 11	0.23
Weight, kg	76 ± 15	79 ± 17	0.43
Native coarctation, n (%)	27 (75)	13 (45)	0.02
Bicuspid aortic valve, n (%)	19 (51)	16 (59)	0.61
Aorta regurgitation, n (%)	12 (32)	8 (29)	0.79
Aorta stenosis, n (%)	4 (11)	4 (14)	0.72
Left ventricular ejection fraction $<50\%$, n (%)	2 (5)	1 (4)	1.00
Left ventricular hypertrophy, n (%)	19 (54)	14 (54)	1.00
Collateral vessels, n (%)	23 (74)	6 (25)	0.0004
Upper-lower limb blood pressure gradient, mm Hg	33 ± 26	15 ± 20	0.003
Hypertension, n (%)	33 (89)	20 (69)	0.061
Number (%) on antihypertensive medications	29 (78)	18 (62)	0.18
Catheterization data			
Peak systolic pressure gradient (range), mm Hg	31 (20-89)	11 (0-19)	
Number (%) treated with angioplasty and stenting	31 (84)	6 (21)	

 $^{
m a}$ Continuous data presented as mean \pm standard deviation or as median (range); dichotomous data presented as number (%).

subjects), exercise testing (three subjects), or BP at the upper limb (one subject).

The ESC Class I recommendations predicted a significant pressure gradient with a sensitivity of 0.57, a specificity of 0.63, a positive predictive value of 0.67, and a negative predictive value of 0.53. Overall diagnostic accuracy was 0.60 (Table 2).

TABLE 2 Performance of the ESC Class I recommendation in predicting hemodynamically significant coarctation of the aorta (peakto-peak pressure gradient at cardiac catheterization \geq 20 mm Hg)

	Peak-to-Peak pressure gradient, mm Hg		
	≥20	<20	
Class I ESC recommendation:	20	10	30
 Noninvasive blood pressure diff >20 mm Hg and 	20	10	
- Arterial hypertension or	20	9	
 Pathological blood pressure response during exercise or 	6	5	
- Left ventricular hypertrophy	11	5	
- None of the combinations above	15	17	32
Total	35	27	62

Sensitivity: 0.57, specificity: 0.63, positive predictive value: 0.67, negative predictive value: 0.53, diagnostic accuracy: 0.60.

In our evaluation of the ability of the combination of the ESC Class I and Class IIa recommendations (hypertension and \geq 50% aortic narrowing relative to the aortic diameter at the diaphragm level on imaging) to identify subjects with a peak-to-peak pressure gradient \geq 20 mm Hg at cardiac catheterization, six subjects (9%) were excluded from the analyses because of the following missing data: BP at the lower limbs (two subjects), exercise testing (three subjects), and cardiovascular imaging (six subjects).

The combination of Class I and Class IIa ESC recommendations predicted a significant pressure gradient with a sensitivity of 0.75, a specificity of 0.42, a positive predictive value of 0.66 and a negative predictive value of 0.52. Overall diagnostic accuracy was 0.62 (Table 3).

We also performed a post hoc analysis to assess the predictive value of individual criteria included in the ESC recommendations, as well as of the presence of directly visible collateral vessels on imaging, as compared to a peak-to-peak BP gradient \geq 20 mm Hg at cardiac catheterization. (The most interesting results are reported in Table 4).

4 | DISCUSSION

CoA is a relatively common condition requiring lifelong follow-up.^{6,7}

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TABLE 3 Performance of the combination of ESC Class I and Class Ila recommendations in predicting hemodynamically significant coarctation of the aorta (peak-to-peak pressure gradient at cardiac catheterization \geq 20 mm Hg)

	Peak-to- gradient	Peak pressure , mm Hg	
	≥20	<20	
Class I and/or IIa criteria met	27	14	41
None of the above criteria met	9	10	19
Total	36	24	60

Sensitivity: 0.75, specificity: 0.42, positive predictive value: 0.66, negative predictive value: 0.52, diagnostic accuracy: 0.62.

Class I and/or IIa criteria met: subjects meeting Class I and/or Class IIa recommendation for intervention on coarctation of the aorta according to the European Society of Cardiology guidelines for the management of grown-up congenital heart disease. The Class I recommendation is that all patients with a noninvasive pressure difference >20 mm Hg between upper and lower limbs in combination with arterial hypertension or pathological blood pressure response during exercise or left ventricular hypertrophy should have intervention; the Class IIa recommendation is that hypertensive patients with \geq 50% aortic narrowing relative to the aortic diameter at the diaphragm level on imaging should be considered for intervention.⁴

Adult patients with newly diagnosed CoA and patients with recurring or residual CoA require evaluation of the severity of aortic obstruction. Cardiac catheterization is considered the gold standard for the evaluation of hemodynamically significant CoA, but noninvasive criteria to identify significant CoA are proposed in the ESC guidelines for the management of GUCH.⁴ Class I recommendations are defined by the authors of the guidelines as beneficial, useful and effective as suggested by evidence or general agreement. In clinical practice, this translates into a rather imperative recommendation. We retrospectively investigated the ability of the ESC recommendations to identify hemodynamically significant aortic obstruction among adult CoA patients who had undergone diagnostic cardiac catheterization at our GUCH Unit.

The ESC Class I recommendations performed poorly and predicted a significant pressure gradient with a sensitivity of 0.57, a specificity of 0.63, a positive predictive value of 0.67, and a negative predictive value of 0.53.

When we combined Class I and Class IIa recommendations, overall diagnostic accuracy was modest: a significant pressure gradient could be predicted with a sensitivity of 0.75, a specificity of 0.42, a positive predictive value of 0.66, and a negative predictive value of 0.52.

Thus, relying on ESC recommendations to identify CoA patients who need to undergo cardiac catheterization might lead to both underand over-diagnosis. Many patients in need of intervention would be treated conservatively, while many others would undergo an unnecessary invasive procedure.

The accuracy of the ESC Class I recommendations directly depends on the sensitivity of noninvasive measurement of BP differences between upper and lower limbs to detect significant CoA. The relatively poor performance of this criterion may partly be explained by the presence of collateral circulation, mitigating the impact of the stenotic aortic region on BP differences between upper and lower limbs. Indeed, combining a noninvasive BP difference between upper and lower limbs and the presence of collateral vessels on imaging gives a higher sensitivity (0.80) (Table 4).

Additionally, the ESC Class I recommendations combine noninvasive BP differences between upper and lower limbs with either hypertension or left ventricular hypertrophy or pathological BP response during exercise to obtain a higher specificity. Hypertension may, even

TABLE 4 Post hoc analysis: performance of noninvasive blood pressure difference (BP diff) >20 mm Hg between upper and lower limbs, of the presence of directly visible collateral vessels on imaging, of the combination of these two criteria and of a \geq 50% aortic narrowing relative to the aortic diameter at the diaphragm level on imaging in predicting hemodynamically significant coarctation of the aorta (peak-to-peak pressure gradient at cardiac catheterization \geq 20 mm Hg)

	Peak-to-peak pressure gradient, mm Hg				
	≥20	<20			
Noninvasive BP diff >20 mm Hg	21	11	32		
Noninvasive BP diff \leq 20 mm Hg	14	17	31		
Total	35	28	63		
Sensitivity: 0.60; specificity: 0.61; positive predictive value: 0.66; negative predictive value: 0.55; diagnostic accuracy: 0.60					
Collateral vessels	22	4	26		
No collateral vessels	9	20	29		
Total	31	24	55		
Sensitivity: 0.71; specificity: 0.83; positive predictive value: 0.85; negative predictive value: 0.69; diagnostic accuracy: 0.76					
Noninvasive BP diff >20 or Collateral vessels	28	11	39		
None of the above	7	13	20		
Total	35	24	59		
Sensitivity: 0.80; specificity: 0.54; positive predictive value: 0.72; negative predictive value: 0.65; diagnostic accuracy: 0.69					
≥50% aortic narrowing	12	16	28		
<50% aortic narrowing	22	9	31		
Total	34	25	59		
Sensitivity: 0.35; specificity: 0.36; positive predictive value: 0.43; negative predictive value: 0.29; diagnostic accuracy: 0.36					

in the presence of coarctation, have causes other than CoA. Indeed, as many as 80% of the included subjects met the diagnostic criteria for hypertension, which was of limited help in refining the identification of patients with significant CoA. Likewise, left ventricular hypertrophy can have causes other than CoA and had the same prevalence among patients with and without significant CoA in our dataset (54%).

A commonly used semiquantitative imaging measurement, for example, the ratio of the diameter of the aorta at the level of the diaphragm, in comparison to the diameter at the site of coarctation, did not perform well in our study (Table 4). One could speculate that the ratio relies on simple morphological measurements, without taking into account any haemodynamical parameters, which may play a greater role in the development of a significant pressure gradient across the CoA.

Previous studies have shown encouraging results on the ability of phase contrast MRI^{8,18} and noninvasive 4D pressure difference mapping derived from 4D flow MRI¹⁹ to detect recurring or residual CoA. The method is constantly developing and may in the future help to select patients eligible for cardiac catheterization. Unfortunately, phase contrast MRI was available only in 22 study subjects (33%), making it impossible to draw any valuable conclusions from our dataset.

Conversely, the presence of visually detectable collateral vessels is a known indicator of the severity of aortic obstruction in subjects with CoA²⁰ and, as a single factor, performed well in our dataset (Table 4).

5 | LIMITATIONS

The relatively small size of our study sample results in some uncertainty as to the reproducibility of our observations.

The heterogeneity of our sample, including both young and older adults as well as patients with newly diagnosed, residual and recurrent CoA, makes it difficult to generalize our results.

As echocardiography was performed by different cardiologists and CT and MRI examinations were reviewed by a single radiologist inter- and intra-observer variability have to be considered a limitation of our dataset.

Furthermore preprocedural imaging was performed at multiple centers, with equipment from different vendors, which should also be accounted for as a limitation of our study.

Selection bias might also have affected our observations: the enrolled patients were referred to our tertiary centre by their cardiologists because of a clinical suspicion of significant aortic obstruction. This might explain why as many as 37 of the 66 included patients (56%) had a hemodynamically significant CoA. Positive and negative predictive values depend not only on the properties of the diagnostic test, but also on the prevalence of the outcome. In a sample with fewer patients with hemodynamically significant CoA, the negative predictive value of the ESC recommendations would have been higher, possibly making them a more acceptable screening tool. Furthermore, because of selection bias, an important subgroup of subjects with CoA, for example those patients with significant CoA that were not referred to our center because of low clinical suspicion, is not represented in our study.

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6 | CONCLUSION

This is, to the best of our knowledge, the first study to investigate the ability of the ESC guidelines for the management of GUCH to identify hemodynamically significant CoA. Our results suggest that neither the Class I recommendations nor the combination of Class I and Class II recommendations can be safely used to identify patients needing to undergo cardiac catheterization. Further research is needed to develop a more accurate set of noninvasive criteria to evaluate the severity of aortic obstruction in adults with CoA.

CONFLICT OF INTERESTS

None of the authors has any conflict of interest to declare.

AUTHOR CONTRIBUTIONS

M Astengo and C Berntsson contributed to the data collection, drafting and revision of the article.

Å A Johnsson contributed to critical revision and approval of the article.

P Eriksson contributed to the design of the study, critical revision, and approval of the article.

M Dellborg secured funding, contributed to the design of the study, critical revision, and approval of the article.

All authors contributed to interpretation of data.

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