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ORIGINAL ARTICLE

Intravascular Ultrasound for Assessment of Residual Coarctation of the Aorta after Balloon Angioplasty in Infants

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Abstract

Intravascular ultrasound (IVUS) has been introduced as an accurate and minimally invasive diagnostic technique for the assessment of vascular anatomy and its abnormalities. We believe that IVUS can be used for clarifying the reasons for failure of balloon angiography in infantile coarctation of the aorta (CoA), because post-balloon angioplasty tearing, intimal flap, thrombosis and pseudoaneurysm of the aorta can be evaluated by IVUS with greater sensitivity and specificity. We aimed to assess the outcome of balloon angioplasty of CoA using angiography as the gold standard and IVUS as a new method in infants, comparing the two techniques for the evaluation of the diameter and area of CoA segment pre- and post-procedure. This cross-sectional study was performed on 18 infants hospitalized with a final diagnosis of CoA. All the infants underwent angiography and were also assessed by IVUS to measure the preoperative and postoperative diameter of the narrow segment in the two anterior–posterior and lateral views. In assessment by IVUS, the mean diameter of the coarctation site increased from 2.10 ± 0.30 mm to 4.50 ± 0.94 mm ($P < 0.001$). Similarly, the average minimum area of the coarctation level increased from 5.26 ± 1.50 mm^2 to 13.77 ± 3.48 mm^2 after angioplasty ($P < 0.001$). Comparing these findings, angiography and IVUS showed a high level of agreement. In the assessment of a dissection flap, there was a high level of agreement between angioplasty and IVUS before the procedure, but IVUS had higher accuracy after the procedure. Our study showed that IVUS was more reliable than angiography in the assessment of residual coarctation. IVUS yielded high sensitivity (58.3%) and specificity (100%) for discriminating the presence and absence of residual coarctation as well as the need for repeating the procedure. The assessment of coarctation before and after angioplasty procedures in children is possible using the IVUS method, with high accuracy. IVUS can offer greater accuracy than angiography in the evaluation of the coarctation area, detecting tears, dissection and flaps, and assessment of residual coarctation.

Keywords Ultrasonography · Child · Aortic coarctation · Angiography

Introduction

Coarctation of the aorta (CoA) is a fairly common congenital heart disease that may appear as an isolated abnormality or concurrently with other cardiovascular malformations, including ventricular septal defect and bicuspid aortic valve [1]. Because of the progressively appearing clinical symptoms, particularly congestive heart failure, the diagnosis of CoA may be significantly delayed [2]. Theoretically, the occurrence of ectopic ductal tissue along with hemodynamic instability clarifies the precise pathophysiological mechanism of the disease [3]. Spontaneous closure of the ductus arteriosus in the postnatal stage may result in the progress of aortic arch obstruction [4]. Simultaneously, the occurrence of an abnormal preductal flow or an abnormal angle between the ductus and aorta can cause a lower isthmic flow and coarctation consequently [5]. Eventually, CoA can lead to a higher left ventricular afterload and pressure which may result in heart failure, severe aortic obstruction, and even cardiogenic shock in the unconditional situation [6]. Based on the pathophysiological fundamentals of CoA, achieving a beneficial prognosis depends on the appropriate diagnostic and therapeutic approaches. In other words, a good lifelong prognosis needs an early diagnosis of the defect and detection of its severity followed by relieving the

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obstruction, controlling the hypertension, and monitoring the risks of recurrent obstruction.

The early diagnosis and management of infantile CoA depends on a comprehensive clinical and laboratory assessment.

Electrocardiography in neonates with early onset of CoA may disclose right ventricular instead of left ventricular hypertrophy. The early signs of congestive heart failure, such as cardiomegaly and pulmonary edema, can be identified by using a chest radiography. Echocardiography can delineate intra-cardiac anatomy and the related major anomalies. In addition, Doppler examination can help in measurement of pressure gradients through the coarctation site [7]. Other imaging modalities, for instance computed tomography scanning, can also be used to evaluate the anatomic nature of the aortic obstruction and the related anomalies [8, 9].

Recently, intravascular ultrasound (IVUS) has been proposed as a precise and minimally invasive diagnostic technique for assessment of aortic anatomy and its abnormalities [10]. This modality safely allows one to assess the aortic lumen as well as to determine the patency of stents placed following angioplasty [11]. The main advantage of IVUS is that it visualizes the aortic lumen in cross-sectional view and thus determines the aortic diameter before and after balloon angioplasty of CoA [12]. The present study reveals the reasons for repeating angioplasty in infantile CoA. The authors aimed to assess the outcome of balloon angioplasty of CoA in infants using angiography as the gold standard and IVUS as a new method.

Material and Methods

The cross-sectional study was performed on 18 infants who were hospitalized with definite diagnosis of CoA. Patients with patent ductus arteriosus (PDA) and severe hypoplastic aortic arch were excluded from the study. All infants underwent angiography, and then IVUS (Ultra ICE™ 4Fr 40 MHz, Boston Scientific) was applied to measure the diameter of the narrow segment of CoA in the anteroposterior and lateral views.

Any changes in aortic wall diameter and also the existence of pseudoaneurysm and dissection of the aorta were evaluated using both methods. The decision for stenting was made based on the anatomy and its suitability by the attending interventional cardiologist. Informed consent was taken from the parents before the procedure. All of the patients underwent cardiac catheterization with monoplane aortography and IVUS study under general anesthesia. The results, after angioplasty, were assessed again using both diagnostic methods. All of patients were followed in an outpatient clinic by physical examination, electrocardiogram (ECG), chest X-ray (CXR) and transthoracic echocardiogram (TTE) 1, 3, 6 and 12 months after each procedure. The average follow-up period for patients was 5 ± 0.4 years.

Statistical Analysis

The results are presented as mean ± standard deviation (SD) in the case of quantitative variables and summarized by absolute frequencies and percentages for categorical variables. Normality of data was analyzed using the Kolmogorov–Smirnov test. Categorical variables were compared using the chi-square test or Fisher's exact test when more than 20% of cells with an expected count of less than five were observed. Quantitative variables were also compared with the *t* test or Mann–Whitney *U* test. The change in aortic parameters was assessed by the paired *t* test or Wilcoxon test. For the statistical analysis, SPSS version 16.0 statistical software for Windows (SPSS Inc., Chicago, IL, USA) was used (P value ≤ 0.05).

Results

A total of 18 patients were included in this study, and the majority of the cases were female ($n = 10$). Moreover, the mean age and body weight values were 79.72 ± 83.22 days (age range: 7–210 days) and 4.62 ± 1.75 kg (weight range: 2.7–7.8 kg), respectively. Table 1 demonstrates scheduled angioplasty performed in patients.

The overall prevalence of hypertension was reduced significantly after the procedure (27.8% versus 5.6%; $P < 0.001$). In the echocardiographic assessment, the mean pressure gradient through the coarctation position was obtained as 58.55 ± 14.04 mmHg, which decreased to 30.05 ± 14.69 mmHg after the procedure ($P < 0.001$). Additionally, the mean left ventricular ejection fraction increased significantly, from $24.72 \pm 12.30\%$ to $53.61 \pm 13.37\%$ ($P < 0.001$), as evaluated by TTE post-procedure.

Severe left ventricular dysfunction was found in 88% of the patients preoperatively, whereas 83.3% of the cases had increased left ventricular ejection fraction after the procedure. The present findings highlight the high efficacy of balloon angioplasty in newborns to improve left ventricular function.

The following results were obtained after the procedure: an increase in the mean diameter of the transverse aortic arch from 5.63 ± 0.83 to 6.34 ± 0.57 mm ($P = 0.002$), increase in the minimum diameter of the coarctation site from 1.56 ± 0.37 to 4.66 ± 1.18 mm ($P < 0.001$), and increase in the mean diameter of the descending aorta from 7.57 ± 0.91 to 7.98 ± 0.71 mm ($P < 0.001$). These values were acquired by TTE at the outpatient clinic after the procedure.

Figure 1 illustrates the aortogram of a 45-day neonate before angioplasty in the lateral view. It demonstrates a

Table 1 General characteristics of patients and evaluation diameter of CoA segment pre- and post-balloon

Code		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Sex		F	M	M	M	F	M	M	F	F	F	F	M	M	F	F	M	F	F
Age (age)		210	30	20	18	14	90	7	7	30	25	14	20	210	18	150	20	180	210
Weight (kg)		5.5	3.2	4	3.2	3.8	7	2.7	3.7	3.4	3.2	3	3.2	7	6.4	7.1	3.3	5.6	7.8
Left ventricular	Pre-balloon	30	20	20	30	25	55	20	10	20	55	20	20	25	15	15	30	20	15
Ejection fraction	Post-balloon	55	60	60	60	55	60	25	60	55	60	60	25	25	65	60	60	60	60
Minimal diameter of aorta at	Pre-balloon	1.5	1	1	1	1.5	1	2	1.5	1	2	1.2	1.2	2.5	1.8	2	1.2	1	1.3
CoA level with angiography	Post-balloon	4	5	4.5	4	4.8	6	2.5	2	3.4	5	3.8	2.8	8	4.2	6	4.4	3	4.6
Minimal diameter of aorta at	Pre-balloon	3	2	2	2.4	1.8	2.2	1.8	1.7	2.1	2.3	2	1.9	2.4	2	2.1	2.3	1.9	1.9
CoA level with IVUS	Post-balloon	4.5	4.8	5.1	4.9	4.2	5.8	2.8	2.7	4.2	4.8	3.8	2.8	5.8	4.8	5.6	4.8	4.8	4.8
Minimal area of	Pre-balloon	10	3.5	6	5.4	5.3	5.4	4.8	4.6	4.4	7.4	4.2	4.9	5.8	4.7	5.4	5.2	4.2	3.5
Aorta at CoA level with IVUS	Post-balloon	12	16	16.7	12.8	16.1	14.4	6.8	6.8	12.8	16.3	14.2	8.7	14.7	12.4	18.8	18.3	14.6	15.4

Fig. 1 Aortic arch injection in a 45-days infant, in lateral projection before balloon angioplasty, showing mild narrowing of the transverse aortic arch and a discrete-type CoA with length of less than 5 mm

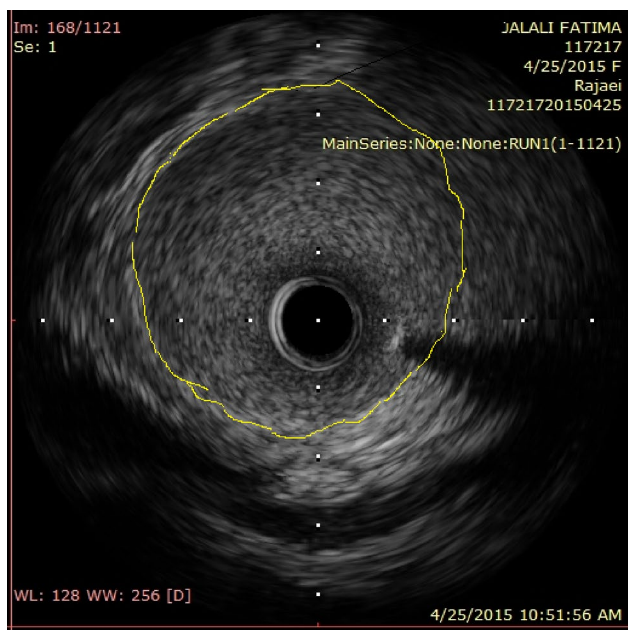

Fig. 2 IVUS image of descending aorta at the CoA level before balloon angioplasty in the same patient as Fig. 1 shows the circular appearance of the aorta at a horizontal view

discrete CoA with mild narrowing of the transverse aortic arch before the stenotic site without any tear or flap. Similarly, Figs. 2 and 3 show the intravascular ultrasound (IVUS) images of the same patient before angioplasty with no tear or flap. Moreover, the areas at pre-CoA and CoA levels were

Fig. 3 IVUS image of the aorta measuring areas at pre-CoA level, 23.3 mm^2 (5.1 mm × 5.9 mm), and at CoA level, 4.12 mm^2 (2.08 mm × 2.52 mm)

23.3 mm^2 (5.1 × 5.9 mm) and 4.12mm^2 (2.08 × 2.52 mm; Fig. 3), respectively. An aortogram in lateral view after balloon angioplasty is shown in Fig. 4. This image showed neither tear, flap or dissection nor significant residual CoA. On the other hand, Fig. 5 reveals an IVUS image of the patient, a tear spreading to the media layer of aorta, and pseudoaneurysm formation containing a clot. Also, Fig. 6 shows an increasing area of the aorta at the CoA level from 4.8 mm^2 (1.85 × 2.94 mm) to 16.09 mm^2 (4.11 × 4.78 mm) after the angioplasty. Furthermore, the prevalence rates of the anteroposterior and mediolateral shelves were 88.9% and 61.1%, respectively. The length of the coarctation site was less than 2 mm in 72.2% of the cases, and long-segment stenosis of 2–5 mm was observed in 27.8% of the cases. The mean size of the balloon used for angioplasty was 6.66 ± 0.82 mm ranging from 5.5 to 8 mm. Tyshak Mini balloons (NuMED Inc., Hopkinton, MA, USA) with a low profile and low-pressure quality were utilized for 61.1% of the patients. In addition, EverCross (Medtronic Co.) and Opta Pro PTA balloons with high profile and high-pressure quality were used in 38.9% of the patients (Figs. 7, 8, 9). The mean pressure gradient across the coarctation site was reduced from 40.05 ± 5.44 to 9.83 ± 5.37 mmHg ($P < 0.001$).

Fig. 4 Aortography in lateral projection after balloon angioplasty with a Tyshak-Mini balloon (7 × 20) in the same patient as Fig. 1. This image shows no tearing, flap formation, dissection or significant residual CoA

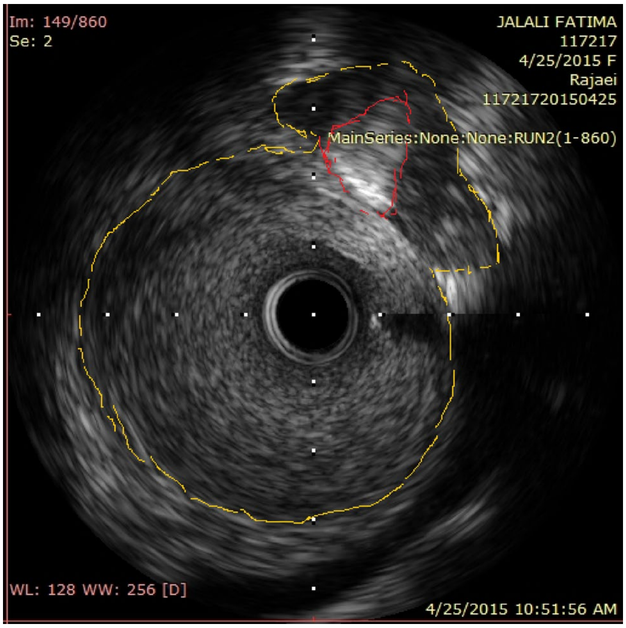

Fig. 5 IVUS image of the descending aorta at the CoA level after balloon angioplasty in the same patient as in Fig. 4. In this horizontal view and unlike Fig. 4 tearing, a line is spreading to the medial layer of the aorta. A pseudoaneurysm containing a clot is also shown

The occurrence rates of a tearing line after balloon angiography were 44.4% in anterior–posterior view and 27.8% in lateral view. The prevalence rate of flap formation after the procedure was 27.8% (Fig. 10). Stenting was performed in only one patient (5.6%), with a 16 × 8-mm Valeo balloon-expandable stent (Bard Co.). The need for repeated balloon angioplasty was negatively associated with the patients' age. In assessment by IVUS, the mean diameter of the coarctation site increased from 2.10 ± 0.30 mm to 4.50 ± 0.94 mm ($P < 0.001$).

Similarly, the average minimum area of the coarctation level increased from 5.26 ± 1.50 mm^2 to 13.77 ± 3.48 mm^2 after angioplasty ($P < 0.001$; Fig. 8).

Discussion

Despite the wide application of IVUS in the assessment of vascular stenosis and other malformations, its role is uncertain in the assessment of aortic coarctation in children. There are few studies on the evaluation of IVUS before and after balloon angioplasty of CoA, especially in infants. In our study, IVUS imaging was used to evaluate vessel wall morphology and revealed the diameter and area at different levels before and after balloon angioplasty of CoA in infants. To the best of our knowledge, this study is the first to estimate the value of different diagnostic methods in the assessment of vessels following aortic coarctation angiography.

Angiographic measurements were comparable with IVUS evaluation, and the results showed that the latter had more detailed information about the coarctation site, its proximal and distal portion areas, and also intimal and medial changes with no exposure to radiation or contrast media injection.

Harrison et al. reported on a 30-year-old man with aortic re-coarctation, who underwent balloon angioplasty. The IVUS images after the procedure showed significant intimal and medial dissection, as well as an intimal flap which was not demonstrated by angiography [1]. This result is consistent with the findings of the present study.

In another study, Xu et al. evaluated aortic parameters, such as aortic distensibility, aortic compliance and aortic wall stiffness by IVUS. They introduced the remaining aortic stiffness after balloon angioplasty as the main mechanism for future hypertension in coarctation patients [13]; however, the stiffness was not evaluated in our patients. According to the results of a study conducted by Tong et al., IVUS can successfully provide real-time data regarding aortic wall morphology and luminal diameter during balloon angioplasty of the CoA [14]. They demonstrated more detailed information about the intimal tearing after balloon angioplasty of aortic coarctation by performing IVUS during the procedure. It is worth mentioning that their findings were in line with the results obtained from the present study [3].

Pre- and post-angioplasty IVUS imaging has been employed as a standard method to evaluate the mechanism of dilatation and determine the success rate and complication rate after angiography. Vessel wall non-stretching was introduced as the probable cause, although the physiological changes were not evaluated in our study [4]. Consistent with the results of our study, the evaluation of 558 coarctation patients following stent implantation by Forbes et al. showed reduced follow-up complications by avoiding the use of oversized balloons and also angioplasty before stenting [5]. In the same vein, Shon et al. evaluated vascular wall changes with IVUS imaging after balloon angioplasty of CoA in 17 patients and introduced it as a significantly more reliable imaging method, compared to the angiography for detecting intimal tears, flaps or dissections [6]. Hernandez et al. applied IVUS before and after balloon angioplasty of CoA in 11 patients. They reported that IVUS imaging changed their treatment protocol as it was more informative than angiography alone; however, in our study, the patients were treated based on angiographic data [15].

In a study by Higashidate et al. on two infants with aortic re-coarctation and an another IVUS study, an abnormal area of localized density was demonstrated, which was diminished after balloon angioplasty. It should be noted that such a result was not observed in our study [16]. Along the same lines, John et al. performed IVUS during balloon angioplasty on animal models with CoA and demonstrated reduced radiation exposure and vessel wall damage during

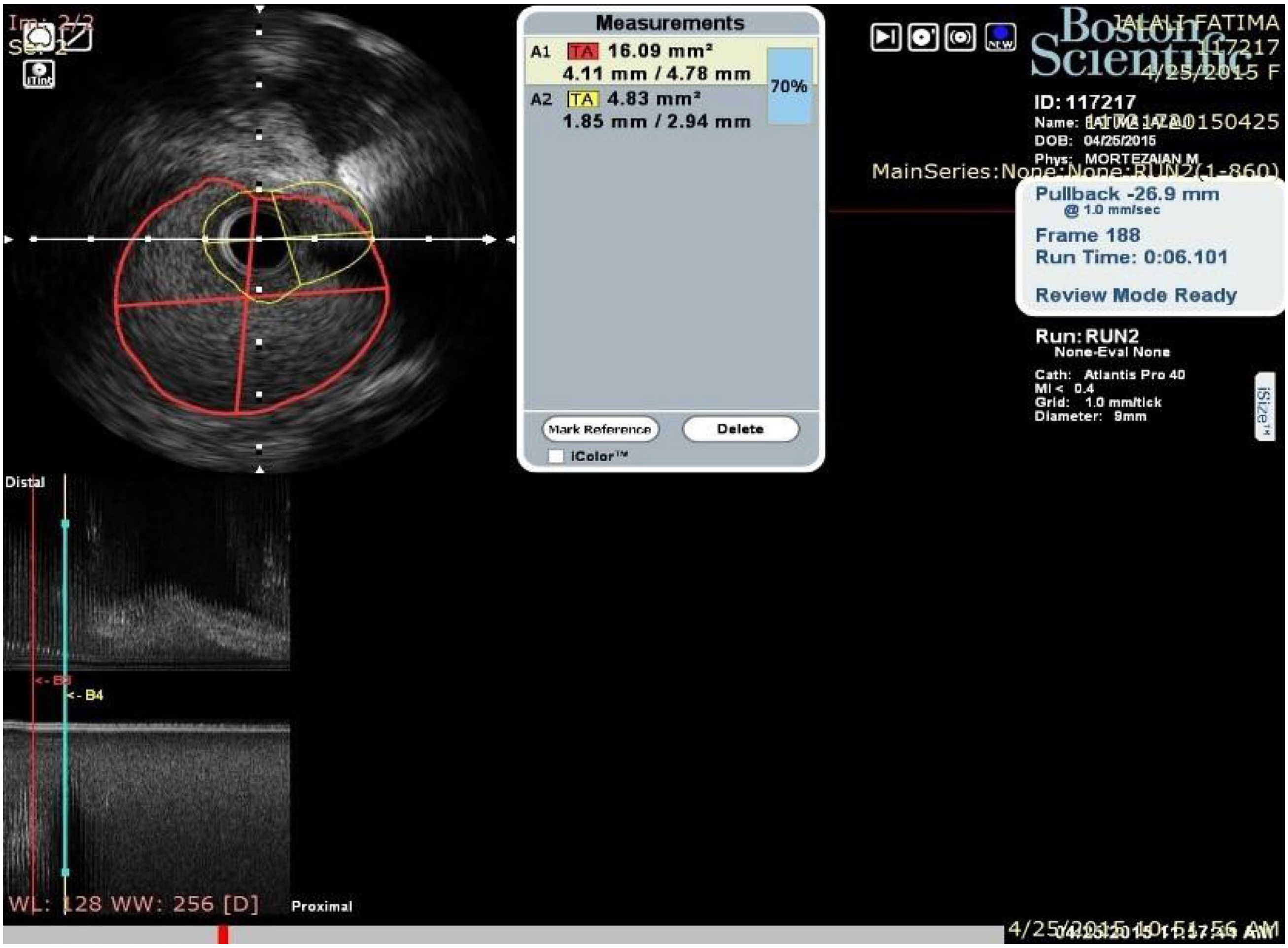

Fig. 6 IVUS image of aorta at CoA level shows an increase in the area from 4.8 mm^2 (1.85 mm × 2.94 mm) before to 16.09 mm^2 (4.11 mm × 4.78 mm) after balloon angioplasty

Fig. 7 Minimal diameter of the aorta at CoA level before and after balloon angioplasty measured during angiography

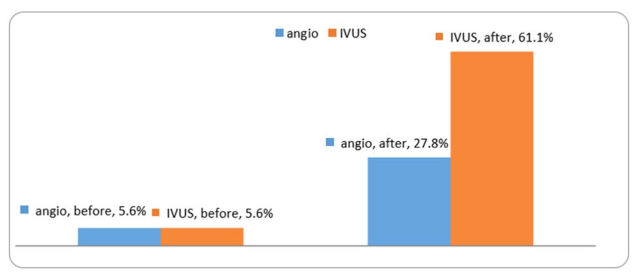

Fig. 8 Assessment of medial flap formation before and after balloon angioplasty during angiography and IVUS (%)

the procedure. This finding is consistent with the results of our study [7]. In a study carried out by Panten et al., an iatrogenic dissection of the descending aorta was described that occurred during balloon angioplasty and stenting of a recurrent coarctation [17]. Although the dissection was not discovered by transesophageal echocardiography, IVUS successfully identified the dissection and guided further

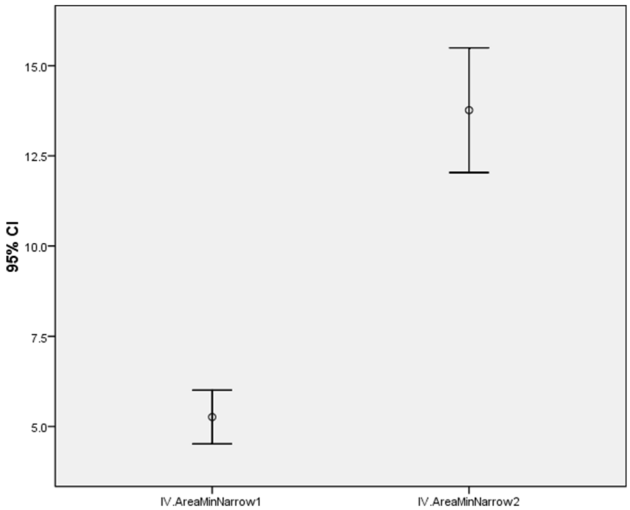

Fig. 9 Minimal area of the aorta at CoA level before and after angioplasty measured during IVUS

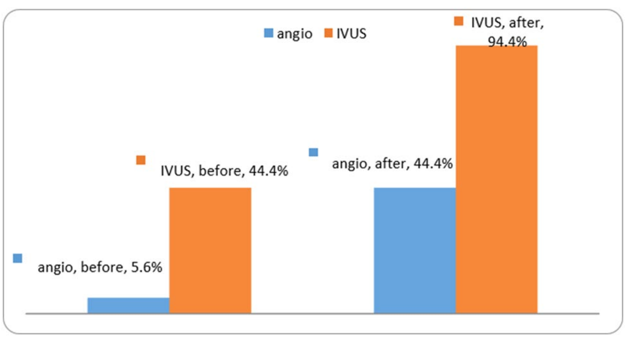

Fig. 10 Comparing intimal tearing before and after balloon angioplasty during angiography and IVUS (%)

therapeutic stent placement. The comparison of the findings of angiography and IVUS showed no significant difference between the two procedures in terms of the minimum diameter of the aorta before ($P = 0.63$) and after the procedure ($P = 0.92$). This indicates a high agreement between the two procedures. However, there was a poor agreement between the two procedures regarding the assessment of aortic tearing both before (agreement value of 0.137, $P = 0.25$) and after the procedure (agreement value of 0.095, $P = 0.35$).

Concerning the assessment of flaps, a high agreement was found between angioplasty and IVUS before the procedure (agreement value of 0.393, $P = 0.036$); however, this was not the case after the procedure (agreement value of 0.059, $P = 0.803$). It seems that IVUS has high accuracy in the assessment of postoperative flaps, compared to angiography. The results showed that IVUS was more reliable than angiography in the evaluation of residual coarctation ($P < 0.01$). After making a comparison between IVUS and angiography as the gold-standard procedure, higher sensitivity (58.3%, 95% CI: 27.67–84.83%) and specificity (100%, 95% CI: 54–100%) were obtained to determine the presence or absence of residual coarctation and the need for repeating the procedure.

It is believed that IVUS can be used to clarify the reasons for failure of balloon angiography in infantile CoA since the severity of tearing, flap formation, thrombosis and pseudoaneurysm is the most important reason for recurrent CoA that should be evaluated by IVUS with more sensitivity and specificity. Another reason for comparing IVUS with angiography is the evaluation of area pre- and post-procedure in the narrowest and proximal segments. Furthermore, greater accuracy can be observed in an area, compared to the diameter, for predicting recurrent CoA that was made by IVUS. This indicates the high efficacy of balloon angioplasty in infants to improve left ventricular function status and future prognosis. According to the results of our study, a comparison between the areas of transverse aorta (TAO) and the site of CoA post-angiography for the evaluation of residual CoA is more reliable than the diameter of the segment post-angiography.

Limitation of the Study

Regarding the limitations of our study, one can name the sample size; however, the data for making a comparison between two-dimensional angiography and IVUS were significant in this study. It is believed that further multicenter studies will be capable of investigating the reasons for the recurrence post-balloon angioplasty in infantile CoA.

Conclusion

IVUS imaging can provide important data about the aortic wall morphology before and after balloon angioplasty of aortic coarctation, such as stenosis severity, intimal or medial tearing, flap or aneurysm formation, and dissection. Such data enables practitioners to select the most appropriate device to evaluate the probable mechanism of restenosis. The results showed that tearing in the medial layer and flap formation may be associated with clot establishment, which results in fibrosis. In the case of newborn infants, this fibrosis may progress to restenosis, which needs re-intervention. IVUS imaging also generates further and more detailed information, compared to angiography, along with less risk of radiation or contrast media exposure. Application of this procedure for children, especially infants, is reasonable and should be encouraged in pediatric angioplasty procedures for understanding the mechanisms of good results and complications.

Authors Contributions HM, FA and ASM: data acquisition, drafting the manuscripts in Persian and revising the manuscript in English; YK: project design and supervision; AF, FA and AV: data acquisition and revising the manuscript in English; HM, YK, MFG and ST: data acquisition, quality control of data, designing the project in the statistical analysis section, data analysis and preparation of results; HM, ST and SAQ: editing and revising the manuscripts in English; MF, YK and SAQ: project design, checking quality of final data; HM and YK: data analysis, preparation of tables).

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This study meets criteria for waver by the ethics committee of Iran University of Medical Sciences (IR.IUMS.REC.1394.9211169204).

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