ORIGINAL ARTICLE

Short-term clinical follow-up of the treatment of aortic coarctation with a new generation of device

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INTRODUCTION

Coarctation of the aorta is a congenital heart anomaly involving constriction of an aortic segment, associated with wall thickening of media and the formation of overlapping infolding of neointimal tissue. For the first time it was described by Morgagni in 1760. This pathology represents 5% -7% of all congenital heart diseases, with an incidence of approximately 3 cases to 10 000 neonates[1]. The typical location of the coarctation of the aorta is distal to the origin of the left subclavian artery, yet it can be found and at the level of the thoracic or abdominal segment. Coarctation can be observed in isolation or associated with other congenital heart malformations.

Patients with less severe coarctation are usually diagnosed later with clinical signs of high blood pressure, decreased or delayed pulse in lower limb arteries, difference in upper and lower limb systolic pressure and uncontrollable tension. Another common sign is systolic murmur, more evident in the thoracic and abdominal levels[5].

Without surgery, prognosis for patients with aortic coarctation is unfavorable. In 1970, Campbell examined autopsy results and clinical records of 465 patients with coarctation who survived one year after intervention. The mean age of death was 34 years, with a mortality of 75% at 43 years. Causes of death include congestive heart failure (26%), aortic rupture (21%), bacterial endocarditis (18%) and intracranial hemorrhage (12%)[8].

TREATMENT METHODS

The American College of Cardiology and the *American Heart Association* (ACC / AHA) guidelines developed guidelines for surgical or endovascular surgery in patients with aortic coarctation as follows: 1. Peak cutoff gradient ≥20 mmHg – the difference between the proximal and distal peak pressure of the stenosed segment; 2. Coarctation gradient on the peak <20 mmHg, and radiological evidence of secondary collateral flow; 3. The rest gradient alone may be an unsafe indicator of severity when there is significant collateral circulation.

Infants with “critical” coarctation are at risk for heart failure and death after closing the arterial duct. The identification of these patients is essential and therapeutic measures include the maintenance of duct permeability and continuous intravenous infusion of prostaglandin E[8,9].

Correction of aortic coarctation is preferred to be performed at pre-school age, with the goal of preventing the development of chronic systemic arterial hypertension. At the same time, surgical intervention in mature is associated with a much higher rate of postoperative complications and even the risk of perioperative death than in children or adolescents[8,9].

The first method of surgical treatment of aortic coarctation described by Crafoord in 1944 consisted in the resection of the coarctation area with termino-terminal anastomosis. Early studies showed a high rate of re-coarctation in over 50% of patients[10]. The

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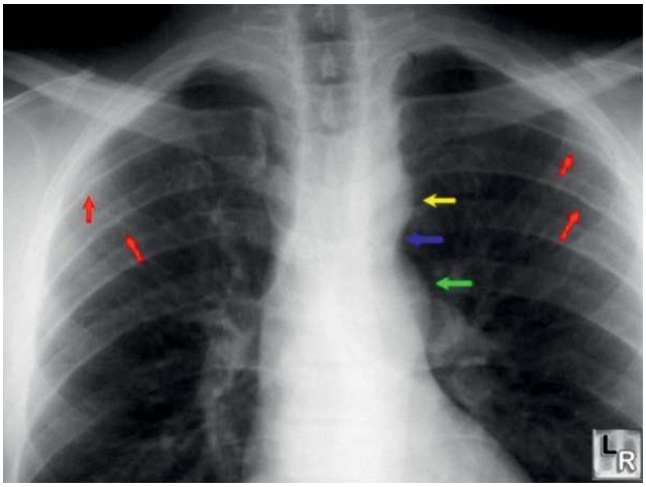

Figure 1. Thoracic radiography in the Aortic Coarctation. Yellow - Ao arch; blue - coarctation; red-thinned rib areas (collateral network); green - the post-stenotic area.

Figure 3. MSCT - aortic narrowing distal to the left subclavicular artery origin.

decision to refer for surgical approach for coarctation correction should be considered and seems to be more grounded when during a single thoracotomy other malformations are being approached. In the case of open-heart surgery for the coarctation, one should estimate all the risks associated with a general intervention as well as the ones that could appear in the perspective. It should be mentioned that interventions at a higher age are also associated with difficulty of approaching the coarctation area, due to the presence of numerous collateral originating from the subclavicular artery and the left mammary artery.

Initially, surgical therapy was the only treatment option for aortic coarctation. In 1982, the first case of balloon transluminal angioplasty was reported by Lock. Subsequent studies have shown the effectiveness of endovascular treatment, reporting a reduced rate of recoarction - from 8% to 32%.

First for angioplasty, standard Mansfield Inc. and Meditech Inc. balloons were used. The size of the balloon was selected so that the diameter of the inflated balloon to be 0 to 2 mm greater than the aortic isthmus at the base of the left subclavian artery. The effectiveness of this method is controversial due to the high incidence of forward-looking recurrence with the frequent need for reintervention[10].

The main complications that arise from balloon angioplasty include: aortic recoarctation, aortic aneurysms, aortic dissection or rupture. Histological and

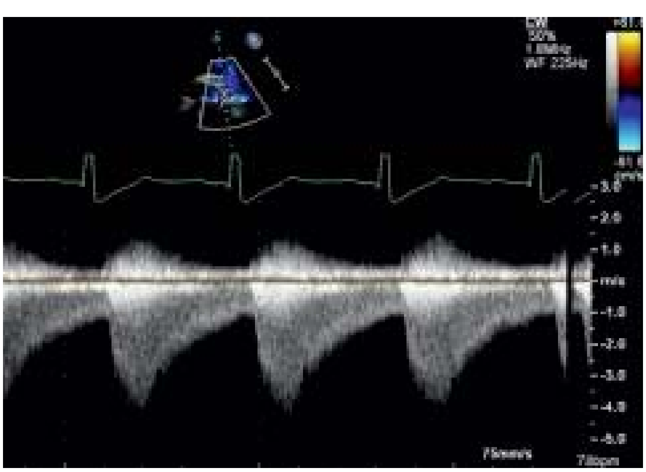

Figure 2. Transthoracic echocardiography of aortic coarctation in suprasternal position, Doppler regimen. High velocity systolic jet and slow diastolic jet.

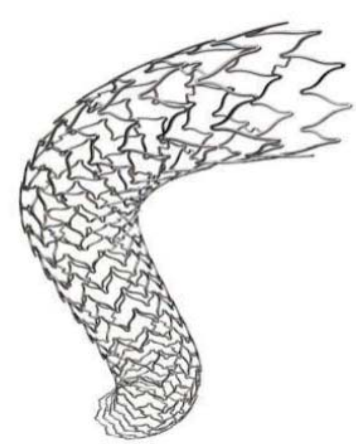

Figure 4. Virtual visualization of an aortic graft-stent Bentley. The reticulated framework of the stent can be selected from three designs proposed by the manufacturer.

intravascular ultrasound studies have demonstrated that frequent angioplasty is associated with rupture of vessel intima and media. Although some of these may spontaneously heal, disruption of vascular integrity contributes to a relatively increased incidence of aneurysm formation. The CCISC observational study during 2004-2012 has showed that 24% of patients with native coarctation developed aortic aneurysm in echocardiographic monitoring after balloon angioplasty[11].

The use of stents in the treatment of aortic coarctation was first proposed in 1992. Unlike balloon angioplasty, in the case of implantation of the stent it does not require the supradilation of the aorta. Thus, the pressure applied to the aortic wall is smaller and more evenly distributed, resulting in a lower rate of complications such as dissection and aneurysm formation. The stents provide better structural support, thus reducing the incidence of aortic wall lesions and restenosis, often in the case of balloon angioplasty[12].

A retrospective analysis after stenting in 17 institutions (565 patients) from 1989 to 2005 have demonstrated a procedural success rate of 97.9% with no significant residual gradient or serious complication. A 5-year follow-up confirmed the efficacy of this method. At the same time, the re- coarctation was confirmed in 20% of patients, and 4% required repeated interventions. Other major aortic wall complications - aneurysm or dissection, have been reported in 1% of cases[13].

Table 1. Characteristics of patients included in the study. Periprocedural data

Characteristics	N
Age, mean	12,5 (8)
Sex	
M	5
F	3
Comorbidities	
HTN	8
DM type I	1
CRF	1
Obesity	2
Valvular cardiopathy	4
BAV	1
Mitral valve prolapse	2
Aortic stenosis	1
Assosciated congenital malformations	
PDA	2
ASD	1

PDA - persistent ductus arteriosus; ASD – atrial septal defect; BAV - bicuspid aortic valve. Out of all solved cases of CoA - 5 patients were male and 3 were female. Of 4 cases of associated valvulopathies - 2 were MVP (mitral valve prolapse), 1 case of aortic valve stenosis, 1 case of BAV. 2 patients were with PDA, another one-with ASD.

The stents have been shown to be more effective in preventing vascular recoil, and if this complication occurs, subsequent redilation is relatively simple and safe. The neointimal growth and remodeling of the aortic wall is more controllable and prevents the formation of pseudoaneurism[14].

Initially, the stents that were used in aortic coarctation, could be adjusted to the size of the aortic segment (bilio-hepatic, Palmaz XL, etc.)[16]. Another attempt was to use self-expanding stents. Their advantage is good compliance with the vascular lumen, thus reducing the risk of malposition, and from the drawbacks the permanent trauma of this type of device to the aortic wall can be mentioned.

The use of endovascular stents in small children remains a problem because repeated adjustments due to the child's growth[17].

Another "ideal" stent concept would involve a device that can be adjusted from large diameters to small diameters covered with a synthetic material to prevent mechanical complications (dissection or aortic rupture) with a "delicate" delivery system, and simple to use[18,19].

MATERIALS AND METHODS

In this study were analyzed short-term results of the implantation of the graft-stent "BeGraft aortic Bentley", a relatively new device, officially announced in 2016. It was designed to solve stenoses both on the aorta and on the peripheral vessels.

Stent-graft structure is made up of a metallic cobalt-chromium (CoCr) alloy; a synthetic polytetrafluoroethylene (ePTFE) graft with multiple micropores and an expandable semicompliant balloon, with platinum or iridium markers. The advantages of this type of construction is the maximum compliance of the device and the synthetic graft wich it is covered with.

The BeGraft Bentley aortic stent is available in 3 base diameters, with a variable diameter of 12 to 24 mm, which can be brought up to 30 mm. The recommended applied pressure of the BeGraft aortic balloon

Table 2. Stent details

Stent parameters	N
Aortic stent BeGraft Bentley	8
Mean stent length	29,3 ± 2,5 mm
The bigger balloon application	5
Standart dimensions balloon	3
Periinterventional pacing	6

All eight cases of endovascular correction of aortic coarctation were resolved by implanting the BeGraft Bentley aortic stent. The average length of the device was 29.3 mm. In 3 patients the stent adjustment was performed with a standard-sized balloon, in another 5 cases the larger balloon was selected. Atrial pacing was performed in 6 patients.

Table 3. Post-procedural complications of Bentley aortic stent implantation. Of all 8 patients enrolled in the study, 6 had no complications. In 2 cases - nonsignificant restenosis at control after 6 months post-stenting

Complications	N
Restenosis	2
Important	0
Non significant	2
None	6
Parietal lesions	0
Aneurism	0
Dissection	0

ranges from 7 bar for 12-14 mm diameter and 5 bar for postdilation diameter 24-30 mm. The length of the stent varies between 19 and 59 mm. It is compatible with sheath diameter of 9, 11 and 14 F.

Stent-graft involves a modern concept of intra-arterial biomechanics - there are three design variants of the Co-Cr metal casing to precisely adjusting aortic arterial angioaritectonics. This approach to stent assembling allows the elastic recoil phenomenon to be avoided after implantation, and the ratio of the radial forces applied to the vessel walls was also calculated. All these "anatomical" device features, provide excellent flexibility after implantation and ensure optimal expansion.

Indications for the use of BeGraft aortic stent assume the conditions of primary or secondary aortic coarctation in children and adults, but also the conditions necessary for the restoration and improvement of iliac artery permeability.

NOVAMED CLINIC EXPERIENCE

During the period 01.2017 - 01.2018, 8 cases of aortic coarctation were solved by stenting. Patients age was from 6 to 32 years. All cases were approached endovascular with the implantation of a "BeGraft Bentley" dedicated graft stent.

Figure 5. Three-dimensional virtual projection of aortic stent- graft Bentley.

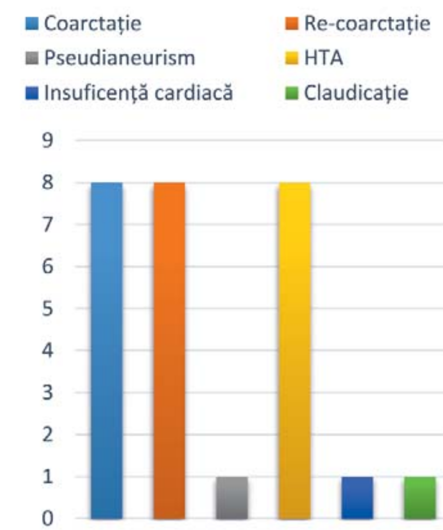

Figure 6. Periprocedural characteristics of patients undergoing endovascular treatment.
The main cause for patients undergoing endovascular intervention - Aortic Coarctation (in all 8 cases), was associated with heart failure in 3 patients. Arterial hypertension, which de develops in all patients, and claudication - an indirect symptom associated with coarctation, has been observed in 7 patients. The post-stenting complications, the most common being the recoarctation was absent in all, and pseudoaneurism-diagnosed in one case.

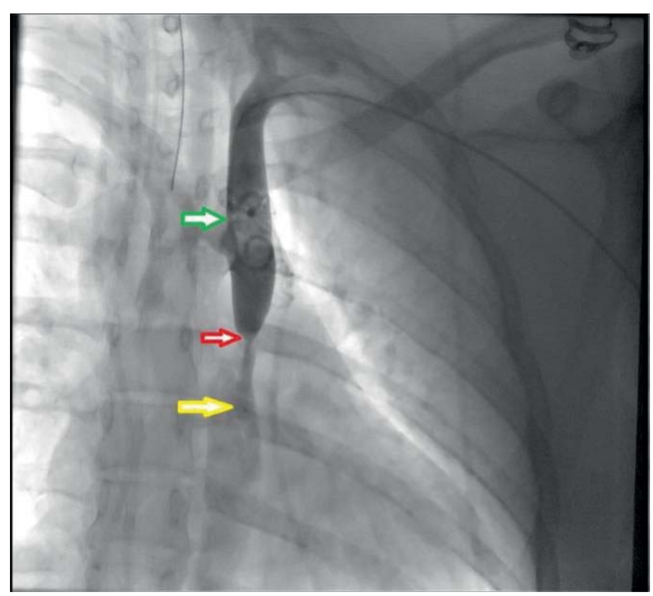

Figure 7. Pre-procedural angiography of patient A.
Green arrow - adequate arterial flow in the aorta arch and descending Ao; Red arrow - severe stenosis 90-95% in the thoracic Ao, distal to the emergence of the left a. subclavia. Yellow arrow - post stenotic dilatation, severe contrastation deficit.

Patient A, 27 years old, normal BMI, with a normostennial constitution, was admitted to the clinic based on persistent high blood pressure level over several years. Coronary artery angiography and aortography were performed, where coarctation of the thoracic segment of the aorta was detected. Presumptive diagnosis - Congenital heart malformation. Aortic coarctation. For multiple-sided visualization of the stenosis, the patient underwent evaluation by MDCT.

For the purpose of correcting the detected primary congenital malformations, the decision is made to perform the angioplasty of the deseased aortic segment. The procedure is performed under general anesthesia and cardiac pacing with a good result. A reduction in

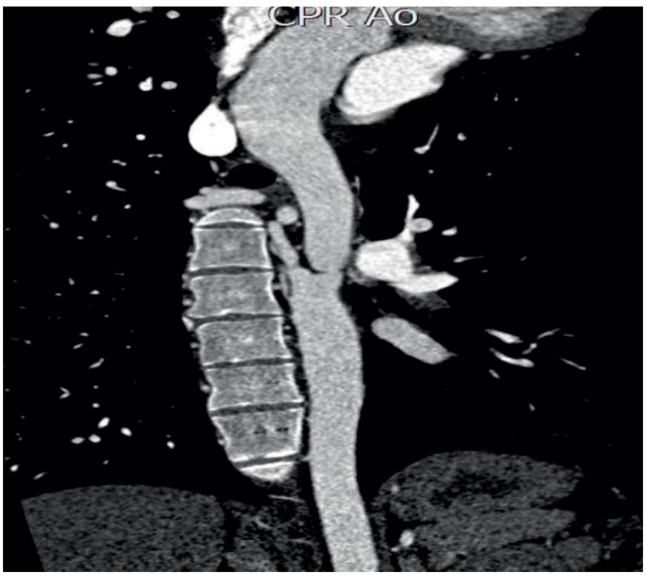

Figure 8. MDCT of the descending aorta, the thoracic segment. Severe stenosis distal to the aortic arch.

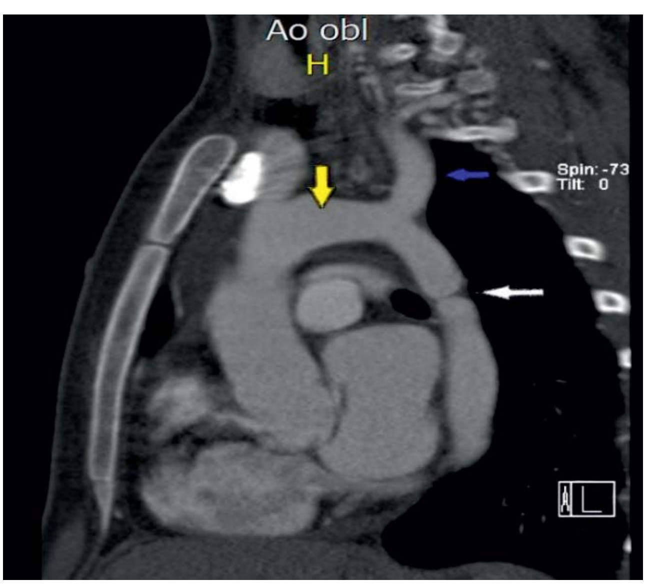

Figure 9. Pre-stenting MDCT of pacient A.
Sagittal projection of the aortic arch and descending Ao. The white arrow – descending thoracic Ao stenosis. The yellow arrow - the aorta arch. The blue arrow - Left subclavian artery.

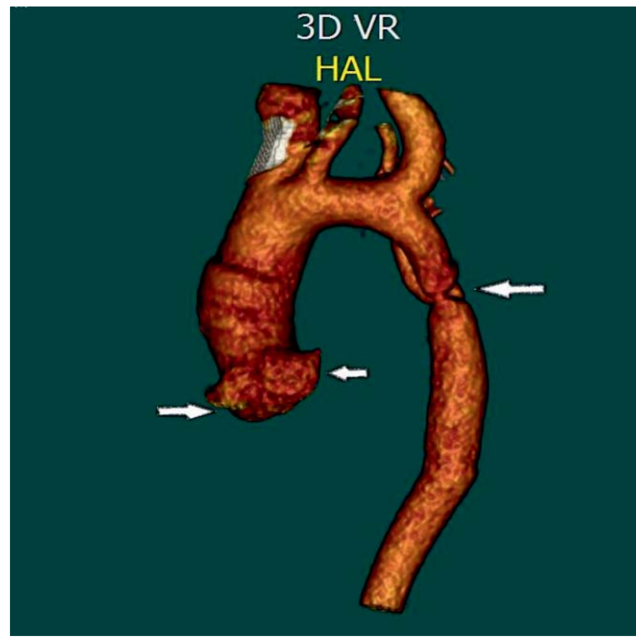

Figure 10. Pre-stenting MDCT of Pacient A. 3D VR (Volume Rendering) Mode. The level of aortic coarctation is determined; coronary sinus and aortic arch.

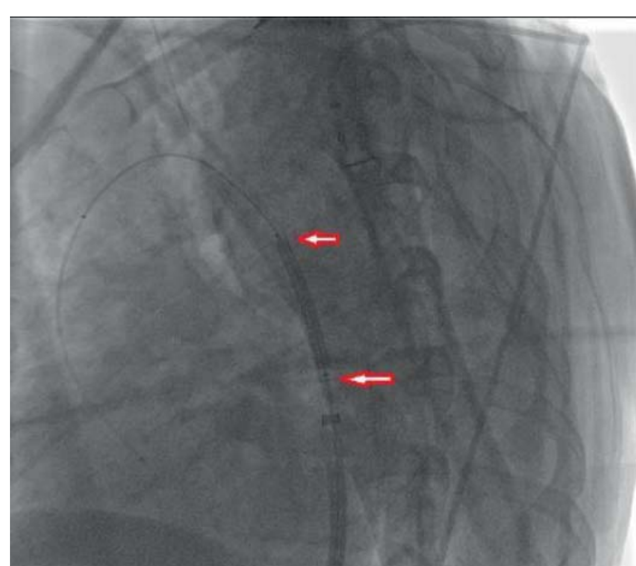

Figure 11. Patient A endovascular correction of Aortic Coarctation.
On a "AMPLATZ-SUPER-STIFF" guide, the stent-graft "BENTLEY" is 16-38 mm.

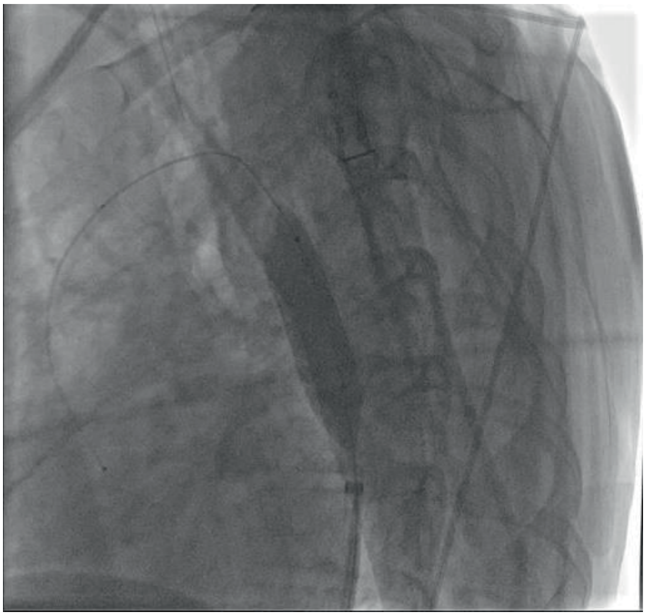

Figure 12. Adjustment of the Bentley aortic stent graft after implantation. Balloon inflated to 10 atm - brought to 18 mm.

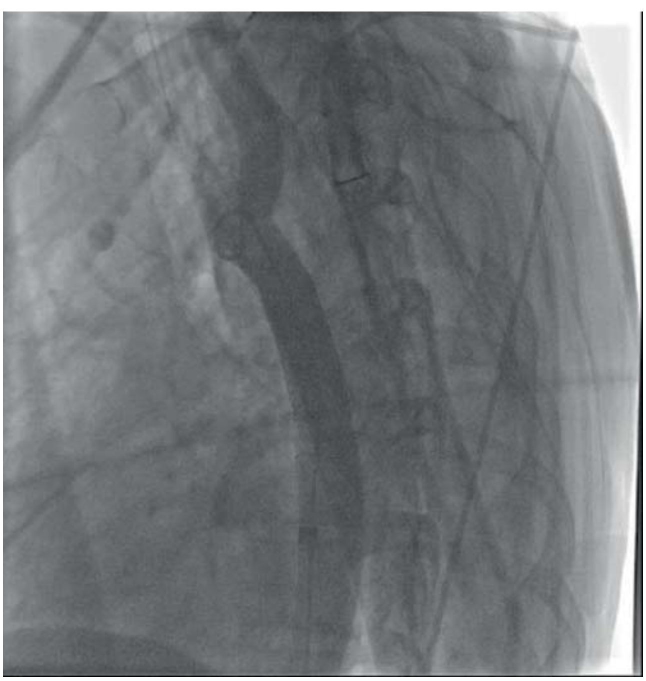

Figure 13. Patient A. Post stenting with good final result. Achieved reduction of Ao stenosis from 95 to 0%.

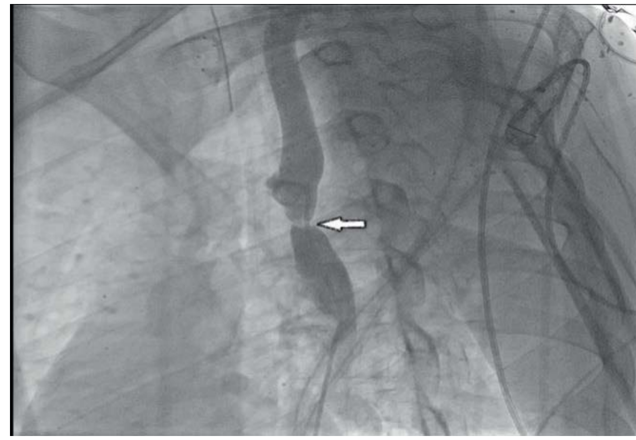

Figure 14. Aortic angiography in patient B. Aortic coarctation next to bifurcation with left subclavicular artery.

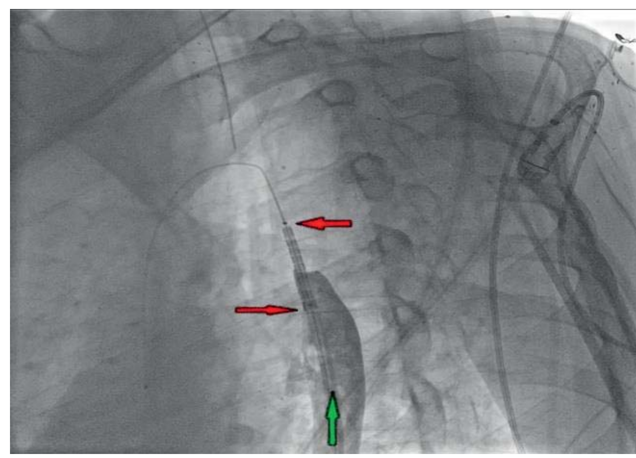

Figure 15. Patient B. Affected aortic segment angioplasty with 12-29 mm "BENTLEY" stent-graft.

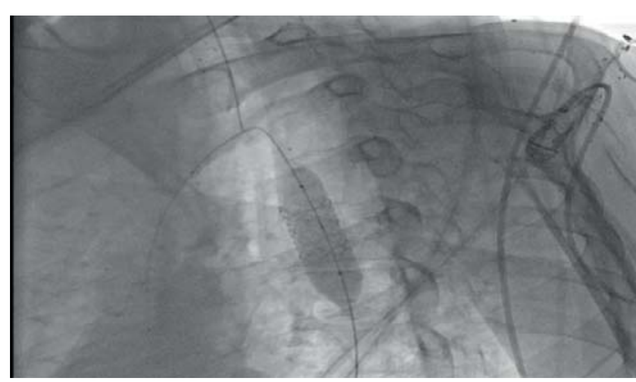

Figure 16. Bentley stent-graft alignment. Inflation at 14 atm - brought to 16-17 mm.

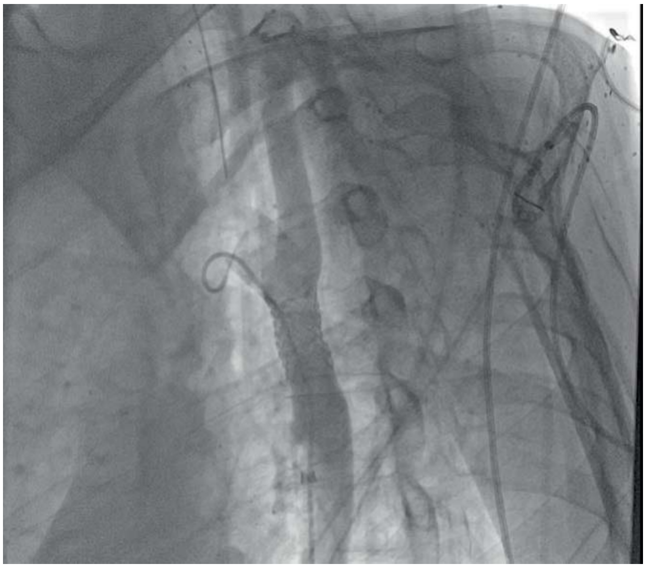

Figure 17. Post-stenting result in patient B. Reduction of Ao stenosis from 90% to 0%.

Figure 19. Control MDCT. Volume Rendering mode.

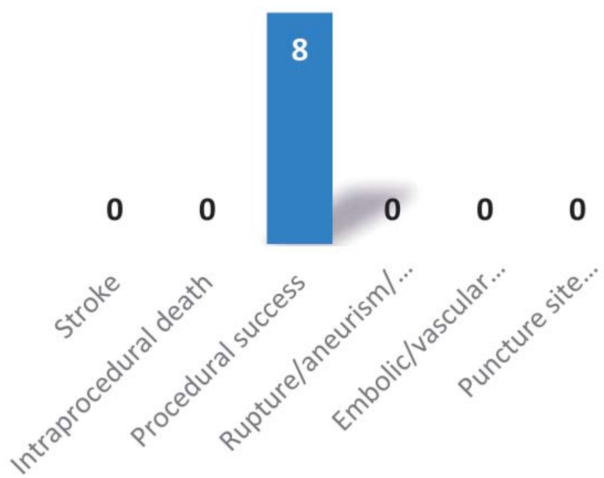

Figure 18. Immediate postprocedural success. All 8 patients undergoing endovascular correction of aortic coarctation had good final result. There were no cases of stroke, parietal rupture, embolic complications, and no intra-procedural deaths (0 cases).

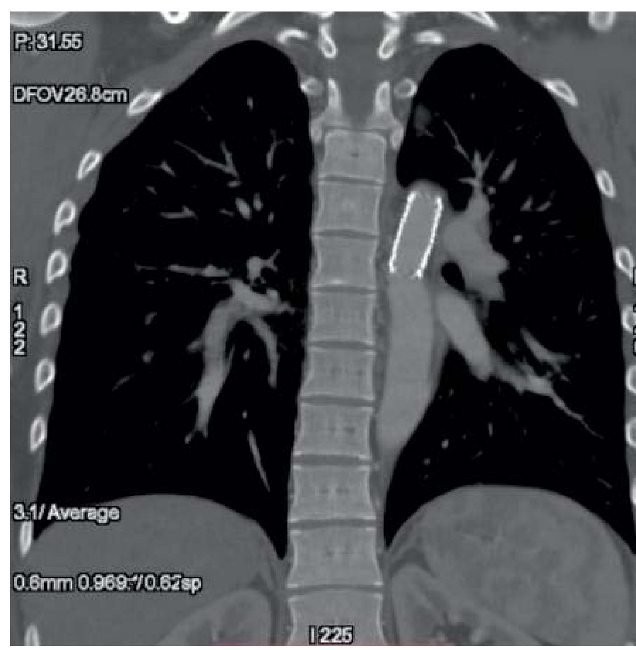

Figure 20. Patient A MDCT after 6 Months. Visualization of the Bentley stent-graft. Patent arterial lumen.

Ao stenosis is obtained from 95 to 0. The transcoarcatation gradient was reduced from 80 mmHg/Hg to 0 mmHg.

Patient B, male, 16 years old, normostenic. From anamnesis - known from 10 years with arterial hypertension, with AP values up to 160-180/100 mmHg. Initially detected by ultrasound in the «typical» aortic coarctation spot, subsequently assessed by contrast CT. Treated endovascular with implantation of the stent - graft Bentley.

Immediately after the intervention, 2 patients accused moderate chest pain with gradual improvement, most likely related to arterial extension syndrome.

All patients who has undergone endovascular intervention were monitorized and investigated at 1, 3, 6 months of post-stenting. Recent anamnestic details, clinical and paraclinical like ECG, transthoracic echocardiography data were analyzed. At 6th month, all investigations were repeated, including MDCT assessment of the posterior mediastinum.

CONCLUSIONS

1. The endovascular approach of aortic coarctation is currently the method of choice for treatment due to the low rate of complications, reduced hospitalization time, relative safety, and not of less importance for patient preference.
2. Bentley aortic stents appear to be very promising, being easily adjustable, with maximum safety and protection compared to older generations or the classic method - by balloon dilation.
3. The great advantage of the Bentley graft stents is the possibility of simultaneous treatment of the aortic coarctation and persistent arterial duct (if present).

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