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Balloon-expandable stents for recoarctation of the aorta in small children. Two centre experience

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ABSTRACT

Background: In young patients with native aortic coarctation (CoA), the management of choice is surgery. However, in re-coarctation (re-CoA) surgery is associated with increased morbidity and even mortality. Some children with native CoA present relative contraindications for surgery.
Methods: From 2006 to 2017, thirty-four patients (male $n = 20$; 59%) from two centres with re-CoA (31) and native CoA (3) were managed by stent implantation with premounted balloon expandable stents. Inclusion criteria were age < 3 years and >1 month, weight < 16 kg. Median age was 6,5 months (min. 1; max. 34 months), median weight 6,2 kg (min. 3,7; max. 16 kg). Thirteen patients (38%) had *Re*-CoA and hypoplastic left heart syndrome (HLHS). In three patients (9%) the native CoA was stented due to contraindications for surgical treatment.
Results: All procedures were successful. The median peak invasive systolic pressure gradient declined from 31 mm Hg (max. 118; min. 4) to 0 mm Hg (max. 32; min.-7) ($p < 0.001$). The median minimal diameter of the narrowed segment of aorta increased from 3 mm (max. 6,9; min. 1,0) to 7 mm (max. 11,5; min. 3,5) ($p < 0.001$). There were no serious complications. The median follow-up time was 12,5 months (max. 88; min. 0 month). During this time ten patients (29%) required re-dilatation and two of them re-stenting.
Conclusion: Percutaneous stent implantation for Re-CoA and in selected patients for native CoA can be performed successfully in very young patients with a good immediate hemodynamical result. However, repeated stent angioplasties and further on interventional 'opening' of the stent is necessary to augment the aorta to adult size.

1. Introduction

Since 1944, when the first surgical repair of coarctation of the aorta was successfully performed by Crafoord [1], up to now surgery remains the management of choice for young children with aortic coarctation (CoA) [2]. If surgery is performed at young age or if complex aortic arch abnormalities are present as in hypoplastic left heart syndrome (HLHS), re-coarctation of the aorta (re-CoA) may occur at a rate of 9–30% [3–6]. Surgery for re-CoA is associated with an increased risk of morbidity and even mortality [7,8]. Balloon angioplasty has been shown to be safe and effective in this patient group, but due to the elastic properties of the aortic wall may only widen the aorta permanently in 2/3 of the patients [6,9]. Stent implantation has been shown to be safe and effective in patients with native coarctation and re-CoA [10,11]. Today patients with native – or re-CoA are managed by stent implantation in many centers, if a stent dilatable to adult size can be used [11,12]. Furthermore, stent implantation may be a successful alternative for small patients with re-CoA or native CoA with evident contraindications for surgery. We report on our series of young patients with native and re-CoA who were managed by stent implantation with balloon expandable stents. Each patient had been discussed within the Heart Team for the best treatment option and it was decided to choose the catheter interventional treatment pathway.

2. Aim

In this retrospective two-centre study we present acute outcome and short- mid-term results of stent implantation in young children (<three years of age) with re-CoA or in young patients with native CoA who have contraindications for surgery.

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3. Material and methods

3.1. Bench testing

The ex vivo bench tests were performed for Cook Formula stents. The maximal diameters and shortening characteristics were verified to assess the redilatation capability. Firstly, the stents were inflated to the recommended nominal diameter of the stent and next sequential overdilatation with larger balloons (increments of 2 mm) was done. Additionally, the bench test results in the literature were reviewed [13,14].

3.2. Patients

The study group consisted of 34 patients (male $n = 20$; 59%) from two centres (German Heart Centre Munich and Polish Mother's Memorial Hospital Research Institute) who underwent aortic isthmus stenting between 2006 and 2017. Median age at stent implantation was 6,5 (min. 1; max. 34) months, median weight 6,2 (min. 3,7; max. 16) kg. In the same time period some newborns with HLHS and re-CoA early after a Norwood operation were stented in the early post-operative period as a life-saving intervention. Due to the critical perioperative state of the patients it was decided to exclude these from this evaluation. All available data were collected and analyzed retrospectively. An informed consent was obtained from all guardians of the patients.

3.3. Indication for treatment

The diagnosis of CoA/re-CoA of the aorta was established by clinical means (absence of femoral pulses, blood pressure gradient >20 mm Hg between right arm and legs, elevated blood pressure at the right arm). Standard echocardiography provided images of the aortic arch. Flow acceleration was detected using Doppler flow calculations and typically the presence of a diastolic "run-off" signal.

Thirty-one patients (91%) had re-CoA, thirteen patients of these (38%) were diagnosed with HLHS and had undergone a Norwood procedure as a first step of univentricular palliation. Nine patients (26%) with CoA and hypoplastic aortic arch had undergone complex surgical aortic arch reconstruction, one patient with interrupted aortic arch was managed by anatomical correction, 8 patients (24%) had isolated CoA, 3 of them underwent surgical repair with the use of a patch, the other were initially managed with an end-to-end anastomosis and in one of these, 10 months later, an aortic arch augmentation with the use of a patch was necessary. Three patients (9%) had native CoA and contraindications for surgery. One of them was suffering from acute lymphoblastic leukemia and was receiving chemotherapy (Fig.1a, b). The other two patients were clinically in a critical state and, hence, poor candidates for thoracic surgery. Unsuccessful balloon angioplasty had been performed in 13 patients (38%) in two patients of them repeatedly. Before CoA-stenting all patients were discussed within the Heart Team. Detailed patients characteristics are presented in Table 1.

4. Procedure

All interventions were performed under general anesthesia. Heparin (100 U/kg) was administered in all children just after gaining vascular access. In 26 patients (76%) stent implantation was performed by arterial access (femoral artery) and in 8 patients (all HLHS) a venous access was used (femoral vein). Since these patients have small femoral vessels and vascular complications may occur the smallest possible introducer sheath was selected for stent implantation. The Cook Formula 414 (6 × 12) stent (Cook Medical, Bloomington, IN, USA) requires a 5F sheath. In the smallest patients, these stents were delivered through a 5F Glidesheath Slender (Terumo, Tokyo, Japan). This new sheath has a 1F reduced external diameter thus the stents are implanted through a 5F sheath with an internal diameter of a 5F but an external diameter of a 4F sheath [15]. The Cook Formula 535 (8 × 12) stents (Cook Medical, Bloomington, IN, USA) were delivered through a 6F sheath. The Palmaz Genesis stents (Johnson&Johnson, Cordis Corporation, Miami Lakes, FL, USA) were delivered through a 6F - and the Valeo Stents (Bard Peripheral Vascular, Tempe, AZ, USA) through a 7F sheath. The Osypka Baby Stent (Osypka, Rheinfelden, Germany) was delivered through a 4F sheath. Angiography was performed before and after stent implantation. Before choosing the optimal stent for each patient the minimal diameter of the aorta, the length of the narrowed segment, the diameter of the aortic arch and the diameter of the descending aorta distally to the stenosed segment were measured with the use of electronic calipers. Pullback gradients across the narrowed segment of the aortic isthmus were also measured before and after stent implantation. Stents were delivered over a 0.014′ wire (Formula 414 (6 × 12)), 0.018′ wire (Formula 418 (8 × 12), Osypka Baby Stent) and a 0.035′ wire (Formula Stent 535 (8 × 12), Valeo, Palmaz Genesis). Positioning and stent expansion were controlled with fluoroscopy. All patient received low-molecular-weight heparin 12 h after stent implantation, routine antibiotic prophylaxis and ASS (5 mg/kg/d) for at least 6 months from the stent implantation.

4.1. Follow up

During follow up the clinical state of the patients, the non-invasive arterial blood pressure (Dinamap-measurement (GE Medical Systems Information Technologies, Inc., Milwaukee, Wisconsin), the Doppler flow velocity across the aortic isthmus, the presence of diastolic runoff (both in echocardiography, suprasternal view) and the necessity for antihypertensive therapy, were examined. No invasive examinations were routinely performed among patients after stent implantation as a part of the follow up control.

5. Results

5.1. Bench testing

In our bench test we assessed the redilatation capability of the Cook Formula stents

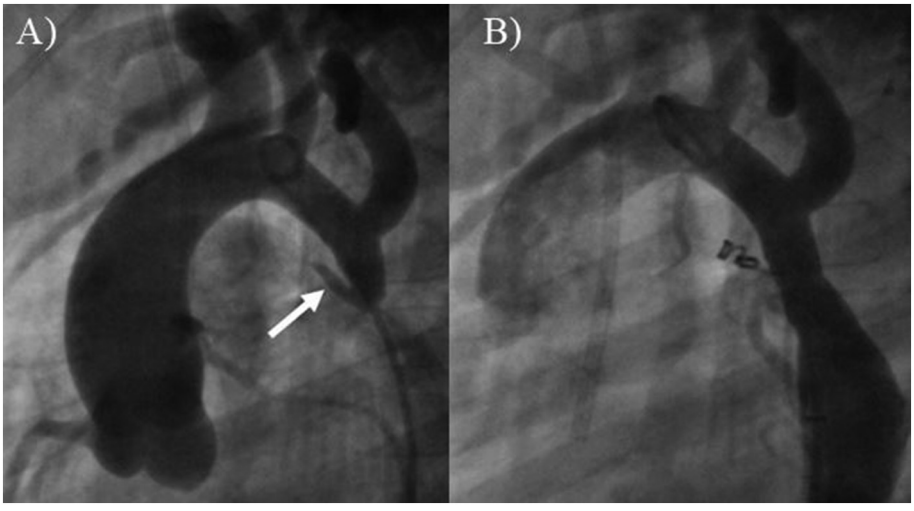

Fig. 1. A - Angiography presenting narrowed aortic isthmus in patient suffering from ALL before stent implantation. The patent ductus arteriosus is marked with the arrow. B - Angiography performed after stent implantation in the same patient. Additional, patient ductus arteriosus is closed with coil.