First-in-man pulmonary artery stenting in children using the Bentley® BeGrow™ stent system for newborns and infants

Quandt, Daniel; Knirsch, Walter; Michel-Behnke, Ina; Kitzmüller, Erwin; Obradovic, Miko; Uhlemann, Frank; Kretschmar, Oliver

Abstract: BACKGROUND: Stent implantation into growing vessels is a common treatment option in infants and children with congenital heart disease (CHD) and corresponding vessel lesions. After stent implantation in small children, repetitive stent redilations are frequently necessary to accommodate for somatic growth. Until now, all available stents have limited final expansion diameters. MATERIAL AND RESULTS: The new Bentley BeGrow™ stent system for newborns and infants is a L605 cobalt-chromium, pre-mounted, balloon expandable stent, which is compatible with a 4 French sheath and 0.014 inch guide wire thus allowing implantation in small vessels (4-6 mm). It offers a new, unique stent design that allows post-dilation steps up to Ø11.5 mm. While re-dilating up to Ø11.5 mm this new stent maintains radial force and shows uniform expansion with only minimal foreshortening. Predetermined breaking points allow the stent struts to break in a controlled manner when exceeding a diameter of 11.5 mm. Residual radial force maintains even after stent opening due to spiral arrangement of the predetermined breaking points. The 2 first-in-man pulmonary artery stent implantations in a newborn with univentricular circulation and a toddler with biventricular circulation are reported as part of the currently performed licencing trial (ClinicalTrials.govNCT03287024). CONCLUSION: The low-profile BeGrow™ stent system offers new treatment options for transcatheter stent implantations in newborns and infants. In our first experience, it can be effectively implanted. Longer follow-up will evaluate multiple, stepwise redilations and controlled stent strut breakage, which have the potential to accommodate for somatic vessel growth and/or subsequent implantation of larger stents.

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Short communication

First-in-man pulmonary artery stenting in children using the Bentley® BeGrow™ stent system for newborns and infants

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ABSTRACT

Background: Stent implantation into growing vessels is a common treatment option in infants and children with congenital heart disease (CHD) and corresponding vessel lesions. After stent implantation in small children, repetitive stent redilations are frequently necessary to accommodate for somatic growth. Until now, all available stents have limited final expansion diameters.

Material and results: The new Bentley BeGrow™ stent system for newborns and infants is a L605 cobalt-chromium, pre-mounted, balloon expandable stent, which is compatible with a 4 French sheath and 0.014 inch guide wire thus allowing implantation in small vessels (4–6 mm). It offers a new, unique stent design that allows post-dilation steps up to Ø11.5 mm. While re-dilating up to Ø11.5 mm this new stent maintains radial force and shows uniform expansion with only minimal foreshortening. Predetermined breaking points allow the stent struts to break in a controlled manner when exceeding a diameter of 11.5 mm. Residual radial force maintains even after stent opening due to spiral arrangement of the predetermined breaking points. The 2 first-in-man pulmonary artery stent implantations in a newborn with univentricular circulation and a toddler with biventricular circulation are reported as part of the currently performed licencing trial (ClinicalTrials.gov NCT03287024).

Conclusion: The low-profile BeGrow™ stent system offers new treatment options for transcatheter stent implantations in newborns and infants. In our first experience, it can be effectively implanted. Longer follow-up will evaluate multiple, stepwise redilations and controlled stent strut breakage, which have the potential to accommodate for somatic vessel growth and/or subsequent implantation of larger stents.

1. Introduction

Vascular stenosis in a growing vessel and a growing child (e.g. pulmonary artery stenosis, aortic coarctation) is a frequent problem faced in the treatment of children with congenital heart disease (CHD) [1]. Transcatheter stenting of these vessel stenosis principally is an attractive, minimal invasive treatment option [2]. Especially in small children stents often have to be re-dilated and all have final maximal expansion diameters, which makes surgical explantation necessary during further vessel growth [3,4]. This is especially true for stent implantations using currently available, small, flexible, low-profile coronary stent systems in newborns and infants, as these stents cannot be expanded beyond approximately 6–7 mm diameter [5].

The new Bentley BeGrow™ stent system for newborns and infants offers a new, unique stent design that allows post-dilation steps up to Ø11.5 mm to follow the growth of the vessel (see Fig. 1). While redilating this stent, it maintains radial force and shows uniform expansion with only minimal foreshortening before exceeding a diameter of Ø11.5 mm. Furthermore, predetermined breaking points allow the stent struts to break in a controlled and reliable manner when exceeding a diameter of 11.5 mm. Residual radial force maintains even after stent opening due to spiral arrangement of the predetermined breaking points (see Fig. 1). First-in-man usage in children is reported here, while results of ex-vivo bench testing and preclinical animal studies were reported at recent conferences [6].

2. Material and results

We report the first-in-man 2 cases of stent implantation into the pulmonary arteries using the new Bentley BeGrow™ stent system for newborns and infants. Both reported procedures were performed within the clinical licencing trial currently performed as

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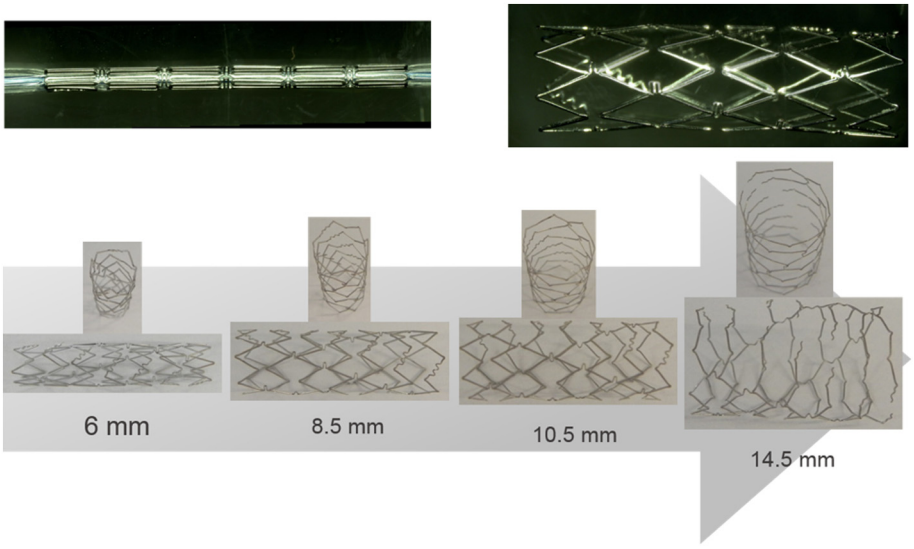

Fig. 1. The low-profile, 4 French compatible Bentley BeGrow™ stent system for newborns and infants with its unique stent design and predetermined stent strut breakage points (top row). Multiple stepwise redilations of the stent showing stent expansion and stent strut breakage with maintenance of radial force even after stent opening, due to spiral arrangement of predetermined stent strut breaking points (lower row).

prospective, multicentre study in central Europe (ClinicalTrials.gov NCT03287024). The Bentley BeGrow™ stent system is a L605 cobalt-chromium, pre-mounted, balloon expandable stent. It is a low-profile stent, which is compatible with a 4 French sheath and 0.014 inch guide wire. Currently available balloon diameter is 6 mm and stent lengths are 10, 13, 17, 20, and 24 mm. The stent is delivered on a low-profile balloon with a balloon catheter length of 100 cm. The nominal balloon pressure is 8 atm (800 kPa) and the rated burst pressure of the balloon is 14 atm (1400 kPa). Predetermined breaking points of the stent allow the stent struts to break in a controlled and reliable manner when exceeding a stent diameter of 11.5 mm.

2.1. Case 1

This newborn baby underwent surgical Norwood I procedure for hypoplastic left heart disease (mitral- and aortic atresia) with Damus-Kaye-Stansel anastomosis, aortic arch reconstruction, ligation of the PDA and right sided modified Blalock-Taussig-Shunt (mBTS, 3.5 mm) to palliate univentricular circulation on day 3 of life. Postoperatively the baby remained ventilator dependent and echocardiography showed a stenosis at the origin of the left pulmonary artery (LPA). Cardiac catheterization and angiography 2 days after surgery (patient weight at procedure 3.2 kg) confirmed LPA origin stenosis,

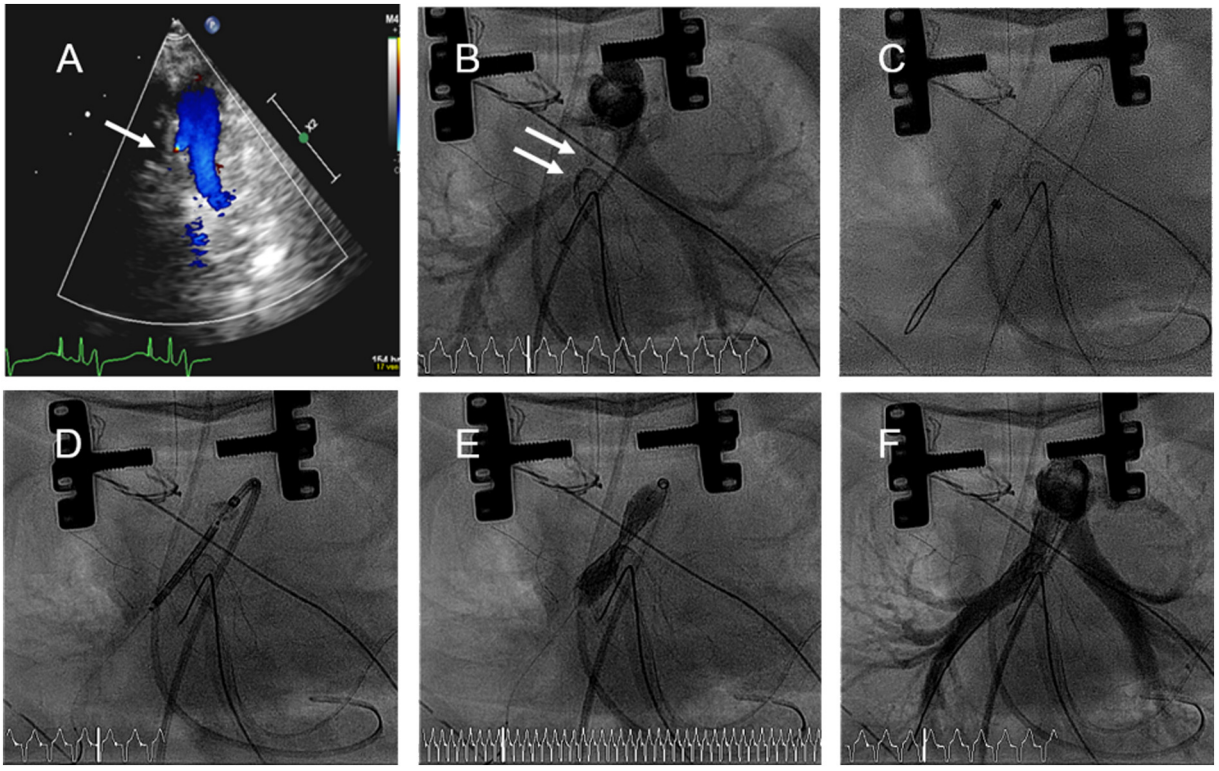

Fig. 2. A + B) Echocardiography and angiography showing severe right pulmonary artery (RPA) stenosis. C + D) Advancement of a 4 French Cook Flexor sheath to guide stent positioning. E) Stent implantation of the BeGrow™ stent system into the right pulmonary artery. F) Postinterventional angiography showing successful stent expansion of the RPA and regular contrast flow to both PAs on angiography.

with a minimal diameter at the site of stenosis of 1.9 mm. Distal LPA diameter was maximal 3.5 mm, with the right pulmonary artery (RPA) centrally measuring 4.4 mm. A retrograde arterial approach via the mBTS was used to place a 0.014 inch guidewire distally into the left lower lobe PA. The stent system was guided into its position using a Cook Flexor 4 Fr long sheath. Stent positioning and implantation were successful, opening the stent balloon using a maximum of 4 atm, generating a final stent diameter of 5.3 mm, which is the minimal stent diameter achievable with the currently available 6 mm stent diameter. Postinterventional angiography confirmed successful stent expansion of the LPA and equal distribution of contrast flow to both PAs on angiography.

2.2. Case 2

This patient was born small for gestation age with a birth weight of 1.8 kg and a large perimembranous malalignment ventricular septal defect (VSD) and coarctation of the aorta and hypoplasia of the transverse aortic arch. The baby underwent surgery with extended resection of the aortic coarctation, patch augmentation of the transverse aortic arch and pulmonary artery banding (PA-banding) in the newborn period. At the age of 3 months the baby underwent surgical PA-debanding and VSD closure. Postoperatively echocardiography showed severe RPA stenosis (Fig. 2 A). Angiography confirmed RPA stenosis with a minimal diameter of 1.5 mm (Fig. 2 B). RPA reference vessels diameter distally was maximal 4.7 mm. An antegrade venous approach was used to place a 0.0014 inch guidewire into the right lower lobe PA. A Cook flexor 4 Fr long sheath was used to guide the Bentley BeGrow™ stent system into its final position. Stent implantation was successful and uneventful. A remaining indentation at the site of stenosis (minimal diameter 4.4 mm postintervention) was left for later redilation, as the intervention was performed across fresh surgical suture lines. Postinterventional angiography showed successful stent expansion of the RPA (Fig. 2 F).

3. Discussion and conclusion

Usage and handling of this new, low-profile stent system was easy and resulted in successful stent expansion of the PAs in both reported cases. In comparison to currently available coronary stent systems, the BeGrow™ stent system offers new treatment options for transcatheter stent implantations, as it has the potential for further redilations and importantly controlled stent strut breakage. Currently available, small and flexible coronary stent systems used in newborns and infants so far, are limited by their final expansion diameter of approximately 6–7 mm diameter [5]. The potential for further stent redilations is an important feature in both illustrated cases of infants with procedural bodyweights of 3.2 kg and 3.5 kg, respectively.

In comparison to other commonly used stents in children with CHD, as for example the Cook Formula stent [6] Palmaz stents [7] or the Bard Valeo stent [8], the mentioned stents have limited expansion diameters after redilations, need larger introducing sheaths or guide wires, have limited radial strength after further redilations and lack the potential for controlled stent strut breakage [6,8]. While other groups have reported intentional uncontrolled stent breakage of common available stents [9,10], this stent offers a new unique stent design with predetermined stent strut breakage points, which makes its use in newborns and infants with CHD lesions extremely attractive.

Impact on daily practise

The low-profile BeGrow™ stent system offers new treatment options for transcatheter stent implantations in newborns and infants. In our first experience, it can be effectively implanted. Longer follow-up will evaluate multiple, stepwise redilations and controlled stent strut breakage, which have the potential to accommodate for somatic vessel growth and/or subsequent implantation of larger stents.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcard.2018.11.029.

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