Journal of Cardiology 66 (2015) 120–124

Contents lists available at ScienceDirect

Journal of Cardiology

journal homepage: www.elsevier.com/locate/jjcc

Original article

Stenting for curved lesions using a novel curved balloon: Preliminary experimental study

Hideshi Tomita (MD, FJCC)[a,*], Takashi Higaki (MD)[b], Toshiki Kobayashi (MD)[c], Takanari Fujii (MD)[a], Kazuto Fujimoto (MD)[a]

[a] Cardiovascular Center, Showa University Northern Yokohama Hospital, Yokohama, Japan
[b] Department of Pediatric Cardiology, Children's Medical Center, Ehime University Hospital, Toon, Japan
[c] Department of Pediatric Cardiology, Saitama Medical University International Medical Center, Hidaka, Japan

ARTICLE INFO

Article history:
Received 28 July 2014
Received in revised form 25 September 2014
Accepted 20 October 2014
Available online 6 November 2014

Keywords:
Congenital heart disease
Curved balloon
Stenting
Curved lesion
Systemic-pulmonary shunt

ABSTRACT

Background: Stenting may be a compelling approach to dilating curved lesions in congenital heart diseases. However, balloon-expandable stents, which are commonly used for congenital heart diseases, are usually deployed in a straight orientation. In this study, we evaluated the effect of stenting with a novel curved balloon considered to provide better conformability to the curved-angled lesion.

Materials and methods: In vitro experiments: A Palmaz Genesis® stent (Johnson & Johnson, Cordis Co, Bridgewater, NJ, USA) mounted on the Goku® curve (Tokai Medical Co. Nagoya, Japan) was dilated in vitro to observe directly the behavior of the stent and balloon assembly during expansion. Animal experiment: A short Express® Vascular SD (Boston Scientific Co, Marlborough, MA, USA) stent and a long Express® Vascular LD stent (Boston Scientific) mounted on the curved balloon were deployed in the curved vessel of a pig to observe the effect of stenting in vivo.

Results: In vitro experiments: Although the stent was dilated in a curved fashion, stent and balloon assembly also rotated conjointly during expansion of its curved portion.

Animal experiment: In the primary stenting of the short stent, the stent was dilated with rotation of the curved portion. The excised stent conformed to the curved vessel. As the long stent could not be negotiated across the mid-portion with the balloon in expansion when it started curving, the mid-portion of the stent failed to expand fully. Furthermore, the balloon, which became entangled with the stent strut, could not be retrieved even after complete deflation.

Conclusion: This novel curved balloon catheter might be used for implantation of the short stent in a curved lesion; however, it should not be used for primary stenting of the long stent. Post-dilation to conform the stent to the angled vessel would be safer than primary stenting irrespective of stent length.

Introduction

Obstruction occasionally develops at the angled portion of the vascular pathway in congenital heart diseases, such as systemic-pulmonary shunts, the pulmonary artery bifurcation, and right ventricle to pulmonary artery connections. Stenting may be an attractive option for treating such a lesion, however, balloon-expandable stents, which are commonly used for congenital heart diseases, are usually deployed in a straight orientation. Consequently, they conform less well to the vessel wall when implanted in a curved lesion. In vitro and in an animal experiment, we evaluated the feasibility of stenting with a novel curved balloon for better conformability to angled lesions.

Materials and methods

The Goku® curve (Tokai Medical Co., Nagoya, Japan) is manufactured from a relatively compliant polyamide elastomer. The balloon diameter range is 3, 4, 5, and 6 mm, while each has a length of 2 cm and 4 cm. The nominal/rated burst pressure is 13/18 atmosphere for all sizes. This balloon catheter is low profile, and can go through a 4F sheath and its wire lumen accepts a 0.018 in. guide-wire. A special property of the balloon is that it develops curvature with some rotation when it is inflated (Fig. 1). The curved

* Corresponding author at: Cardiovascular Center, Showa University Northern Yokohama Hospital, 35-1 Chigasakichuo, Tsuzuki-ku, Yokohama City, Kanagawa 224-8503, Japan. Tel.: +81 45 949 7000; fax: +81 45 949 7117.
E-mail address: tomitah@med.showa-u.ac.jp (H. Tomita).

http://dx.doi.org/10.1016/j.jjcc.2014.10.009
0914-5087/

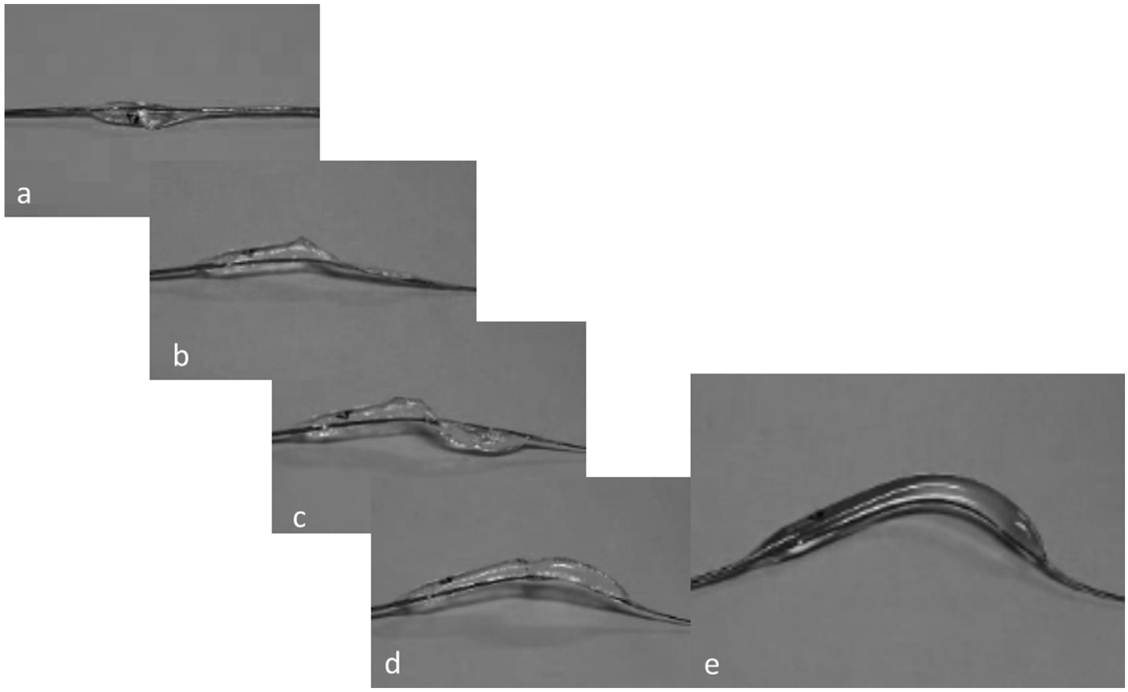

Fig. 1. Serial picture during expansion of the curved balloon. The balloon rotates during curving (a to e).

angle is 90°, 88°, and 80° at 10, 13, and 18 atmospheres, respectively. With this property, the curved balloons generate a uniform stress on the entire length of the vessel wall [1]. In this preliminary experiment, we performed the following in vitro and in animal studies. Our aim was to evaluate if primary stenting of curved lesions would be possible using this balloon.

In vitro experiment

A Palmaz Genesis® stent (Johnson & Johnson, Cordis Co, Bridgewater, NJ, USA), which is commonly used for congenital heart diseases, length 18 mm and dilatable diameter 6 mm was mounted on this balloon for direct observation of the behavior of the stent and balloon assembly when it was dilated in vitro.

Animal experiment

The experiment was performed at the Intervention Technical Center (IVTeC) Kobe laboratory of Medical Device Development Center (MEDDEC), and the protocol was approved by the local ethical committee of the MEDDEC. A pig weighing 35 kg was anesthetized with thiamylal sodium and midazolam and maintained with sevoflurane. We exposed the femoral arteries bilaterally and a 10 F sheath was introduced into each artery.

After selective angiography of the anterior mesenteric artery, an Express® Vascular SD stent (Boston Scientific Co, Marlborough, MA, USA) with a length of 18 mm and a dilatable diameter of 6 mm (short stent) mounted on the Goku® curve with a diameter of 6 mm and a length of 40 mm was introduced into the curved lesion over the guide-wire and dilated. Secondly, an Express® Vascular LD stent with a length of 37 mm (long stent) and a dilatable diameter 7 mm mounted on a balloon of the same specification was similarly deployed in the other curved lesion. Finally, an Express® Vascular LD stent length 37 mm and dilatable diameter 7 mm, which was deployed in advance, in the curved lesion using the straight balloon (TMP Sphere® 6 mm/40 mm, Tokai Medical, Co) was post-dilated by the Goku® curve (6 mm/40 mm).

The animals were killed with intravenous pentobarbital sodium and potassium chloride and the stented vessels were surgically removed. We examined the stented vessel macroscopically, although microscopic examination was not performed.

Results

In vitro experiment

The balloon rotated when its curved portion of Goku® curve was expanded. Although the stent was dilated in a curved fashion, stent and balloon assembly also rotated in unison during expansion of its curved portion (Fig. 2). Stent integrity was preserved after dilation with the curved balloon.

Animal experiment

In primary stenting of the short stent, the stent was dilated with rotation at the curved portion. The excised stent conformed to the curved vessel (Fig. 3). Meanwhile, as the long stent could not be negotiated across the mid-portion of the expanded balloon when it started curving, the mid-portion of the stent failed to expand fully. Furthermore, the balloon could not be retrieved even after complete deflation. The excised balloon entangled with the strut at the mid-portion of the stent (Fig. 4). Post-dilation by the curved balloon bent the stent pre-implanted by the straight balloon in the curved lesion conforming to the curved vessel (Fig. 5).

Discussion

Systemic-pulmonary shunts and cavopulmonary connections are common palliative operations for patients with complicated congenital heart diseases featuring decreased pulmonary blood flow. Obstruction at the anastomosis can sometimes develop post-operatively, which requires urgent surgical or catheter intervention to maintain adequate pulmonary blood flow [2,3]. Successful

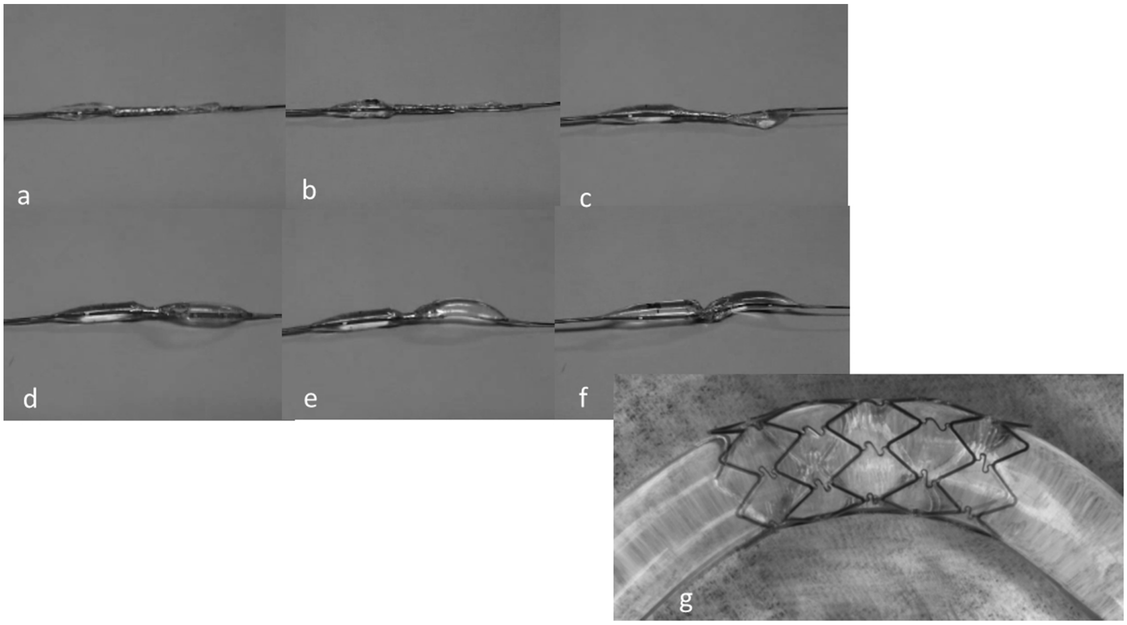

Fig. 2. In vitro dilatation of the stent with the curved balloon. The balloon and the stent assembly rotate during expansion of the stent (a to g).

percutaneous interventions for such lesions have been previously reported [4–10]. However, acute angulation at the proximal and/or distal anastomosis may cause slipping of a straight balloon or excessive stress on the vessel wall adjacent to the stenosis during the procedure. Previously, we reported efficacy of this novel curved balloon in transcatheter dilation of the angled lesions associated with congenital heart diseases [1]. Stenting for curved lesions is occasionally necessary for an early post-operative, kinked, compressed, or long-segmented lesion, where simple balloon dilation has limited efficacy. As we have reported previously, there may be a risk of damage to the angled vessel by excessive stress at the mid-portion and at both ends of the greater curvature when it is dilated by a straight balloon [1]. Consequently, we examined the possibility of stenting with a curved balloon for the angled lesions in vitro and in an animal model.

In the in vitro study, an 18-mm length Genesis® stent could be dilated in a curved fashion, although it rotated during expansion. As we believe that such rotation may injure the vascular wall by the edge of the stent, we conducted an animal experiment. Because of non-availability of the Genesis® stent, we used short and long Express® Vascular stents in the animal experiment. Despite the different strut patterns in the Genesis® and Express® Vascular stent, the short Express® Vascular SD stent was successfully deployed in the curved lesion with similar rotation to that which

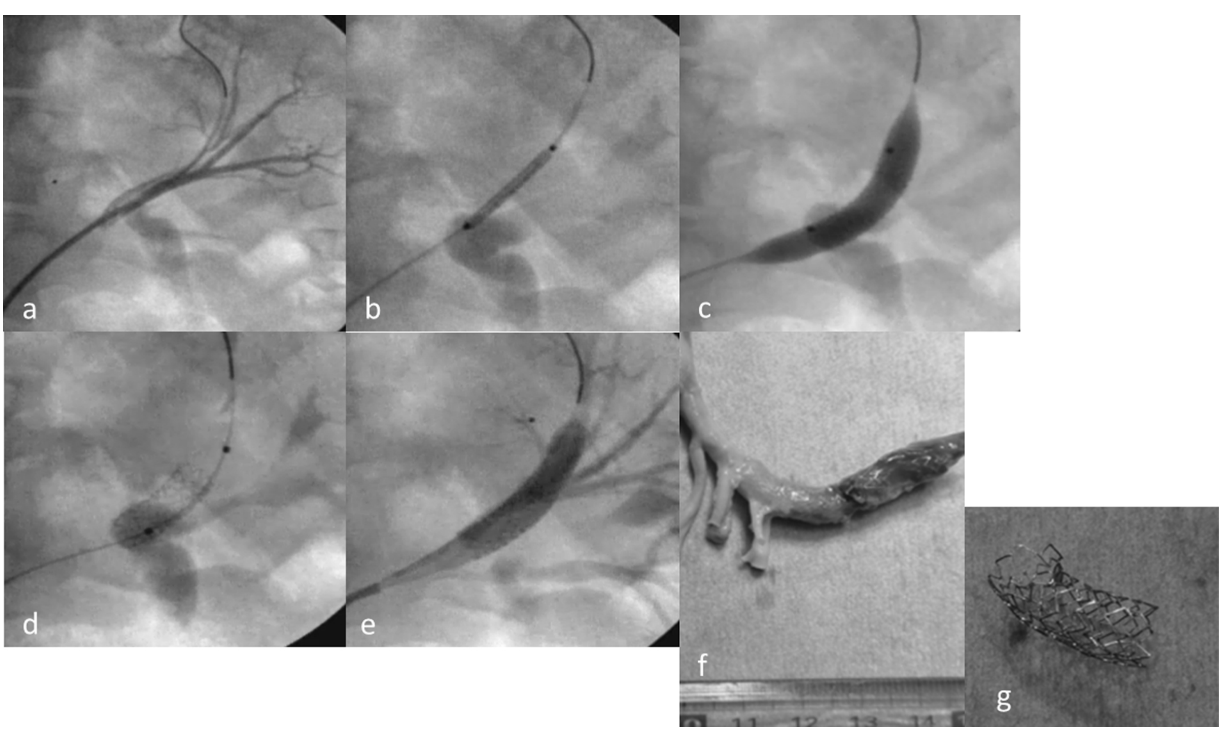

Fig. 3. Implantation of the short stent with the curved balloon (a to e), and the excised vessel and the stent (f, g).

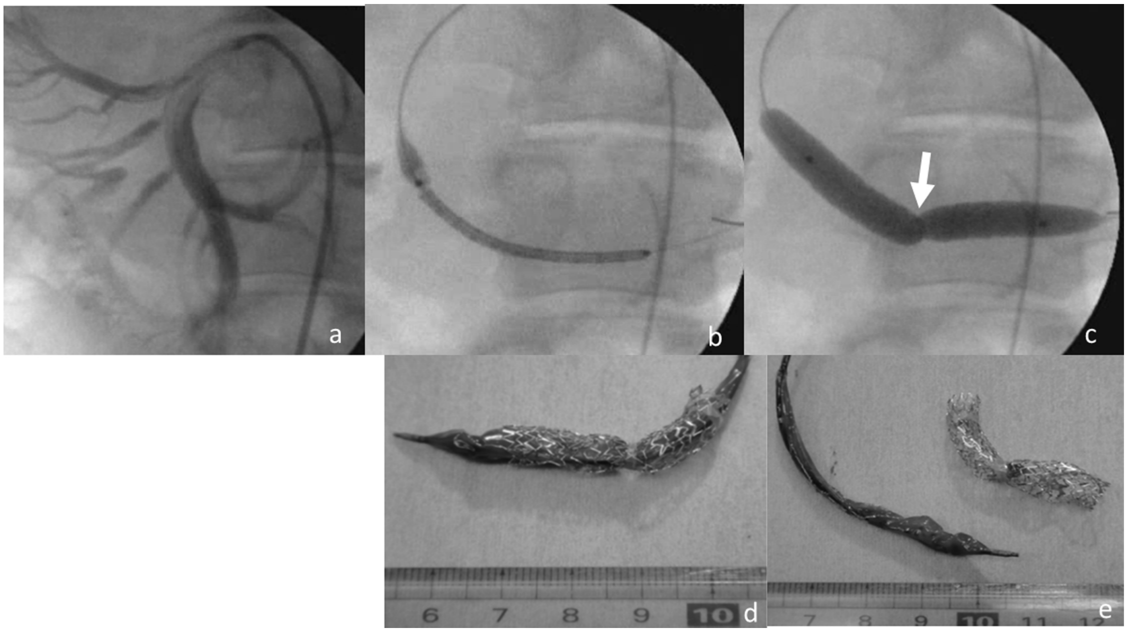

Fig. 4. Implantation of the long stent with the curved balloon (a to c), and the excised vessel and the stent (d, e).

occurred in the in vitro dilation. Macroscopically, we did not find any serious injury to the vascular wall such as dissection or rupture. However, the long stent could not be fully expanded as the balloon became entangled at the mid-portion of the stent. Furthermore, the balloon could not be retrieved in this animal. Because of the folding technique to make the curve, this balloon spontaneously rotates during inflation. We suppose the balloon with stent on could not be fully dilated without rotation, and subsequently entangled with the stent at the mid-portion. In post-dilation of the pre-implanted straight stent, this curved balloon re-shaped the stent to conform to the curved lesion. We believe, even though the short stent may be primarily implanted with this balloon, there is potentially some risk of injury to the vessel wall with the rotation of the balloon and the stent assembly during expansion.

How the long stent can be primarily implanted with this curved balloon is another concern. We believe that not only stent length but also some factors such as the balloon diameter, the reference vessel, and the minimal lumen diameter may determine possibility of primary stenting with this curved balloon. Considering injury to the vascular wall with rotation, and that post-dilation with this balloon could re-shape the pre-implanted straight stent to conform to the curve, for now, this balloon should be used for post-dilation problems to conform to the angled lesion rather than for primary stenting irrespective of the stent length.

Limitations

How much the stent can be curved depends not only on the property of the curved balloon but also on the mechanical property

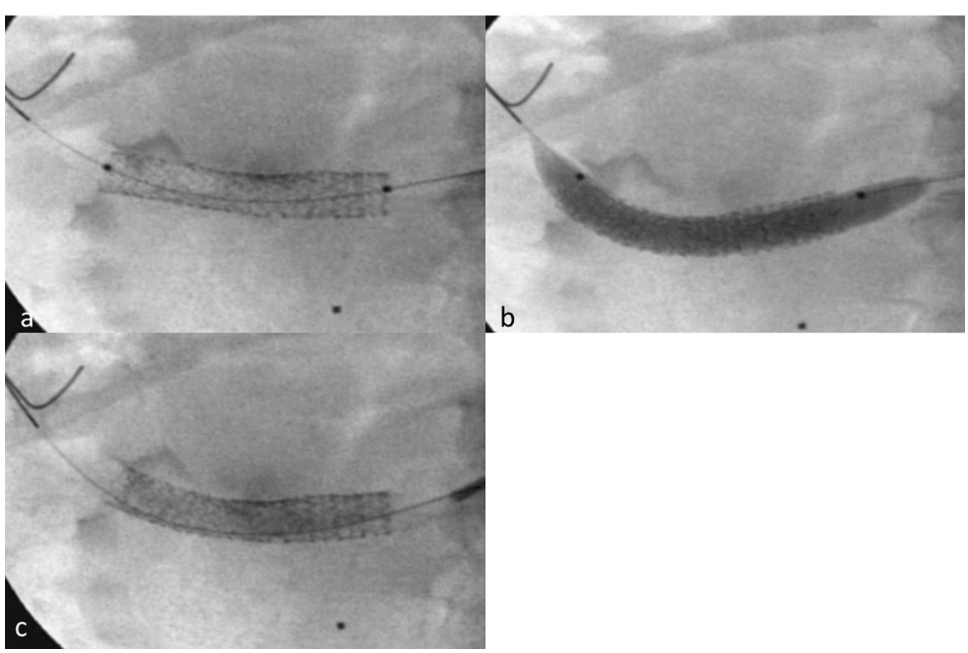

Fig. 5. The previously implanted straight stent (a) was curved by post-dilation by the curved balloon (b, c).

of the stent itself. As the normal stent is commonly not designed to be deployed in the curved fashion, there are no data on its radial strength and durability when bent. In this preliminary experiment, we did not examine such mechanical properties. We examined the stented vessel only macroscopically, while there are no data on microscopic changes that may determine long-term prognosis.

Conclusion

This novel curved balloon catheter is a reasonable choice for better conformability in acutely curved lesions. It might be used for implantation of the short stent in the curved lesion; however it should not be used for primary stenting with the long stent. Post-dilation to conform to the angle would be safer than primary stenting irrespective of stent length. Further investigation of the mechanical properties and long-term prognosis of the bent stent are mandatory.

Funding

This research received no grant from any funding agency in the public, commercial, or not-for-profit sectors.

Disclosures

The authors declare that there are no conflicts of interest.

Acknowledgement

We thank Dr Peter M. Olley, Professor Emeritus of Pediatrics, University of Alberta, and Dr Setsuko Olley for their kind acceptance to provide language consultation.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.jjcc.2014.10.009.

References

[1] Kise H, Miyata A, Tomita H, Fujii T, Fujimoto K, Kiguchi H, Oyama N, Soga T, Hata Y, Hirata M, Itoh A, Ishino K, Hasebe Y, Hoshiai M. Novel curved balloon catheter for dilating postoperative angled lesions associated with congenital heart disease. J Interv Cardiol 2014;27:408–13.

[2] O'Connor MJ, Ravishankar C, Ballweg JA, Gillespie MJ, Gaynor JW, Tabbutt S, Dominguez TE. Early systemic-to-pulmonary artery shunt intervention in neonates with congenital heart disease. J Thorac Cardiovasc Surg 2011; 142:106–12.

[3] Guzzetta NA, Foster GS, Mruthinti N, Kilgore PD, Miller BE, Kanter KR. In-hospital shunt occlusion in infants undergoing a modified Blalock-Taussig shunt. Ann Thorac Surg 2013;96:176–82.

[4] Marks LA, Mehta AV, Marangi D. Percutaneous transluminal balloon angioplasty of stenotic standard Blalock-Taussig shunts: effect on choice of initial palliation in cyanotic congenital heart disease. J Am Coll Cardiol 1991;18: 546–51.

[5] Rao PS, Levy JM, Chopra PS. Balloon angioplasty of stenosed Blalock-Taussig anastomosis: role of balloon-on-wire in dilating occluded shunts. Am Heart J 1990;120:1173–8.

[6] Wang JK, Wu MH, Chang CI, Chiu IS, Lue HC. Balloon angioplasty for obstructed modified systemic-pulmonary artery shunts and pulmonary artery stenosis. J Am Coll Cardiol 2001;37:940–7.

[7] Kogon B, Villari C, Shah N, Kirshbom P, Kanter K, Kim D, Raviele A, Vincent R. Occlusion of the modified Blalock-Taussig shunt: unique methods of treatment and review of catheter-based intervention. Congenit Heart Dis 2007;2:185–90.

[8] Sreeram N, Emmel M, Ben-Mime L, Brockmeier K, Bennink G. Transcatheter recanalization of acutely occluded modified systemic to pulmonary artery shunts in infancy. Clin Res Cardiol 2008;97:181–6.

[9] Gillespie MJ, Rome JJ. Transcatheter treatment for systemic-to-pulmonary artery shunt obstruction in infants and children. Catheter Cardiovasc Interv 2008;71:928–35.

[10] Moszura T, Zubrzycka M, Michalak KW, Rewers B, Dryzek P, Moll JJ, Sysa A, Burczynski P. Acute and late obstruction of a modified Blalock-Taussig shunt: a two-center experience in different catheter-based methods of treatment. Interact Cardiovasc Thorac Surg 2010;10:727–31.