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/

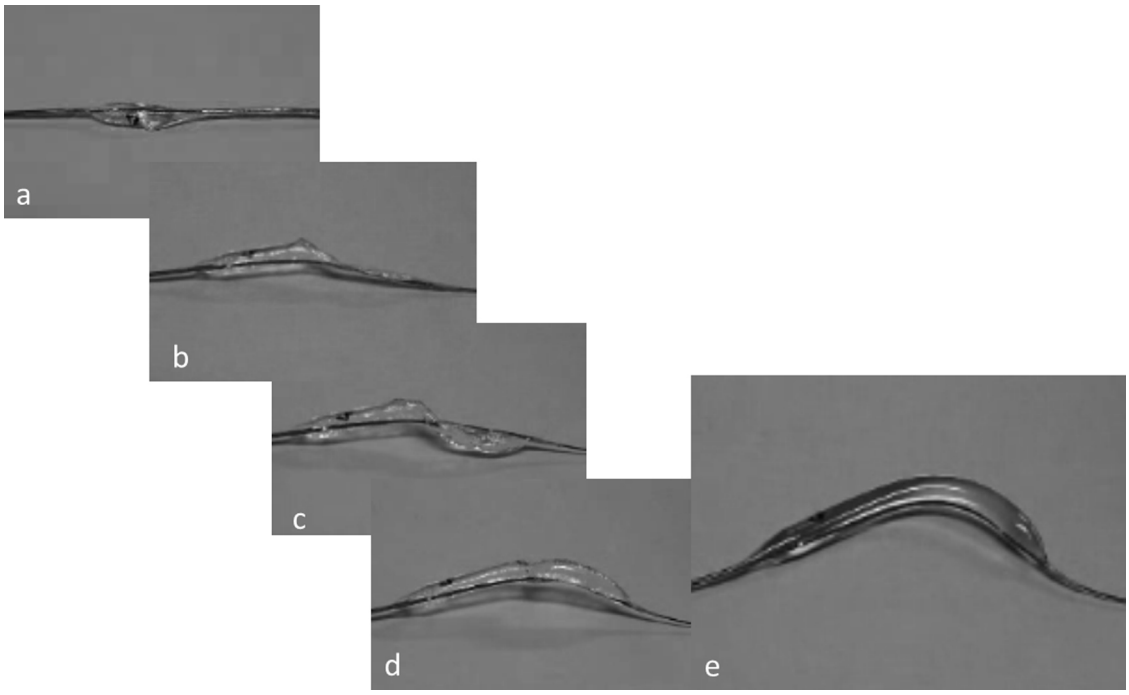

Fig. 1. Serial picture during expansion of the curved balloon. The balloon rotates during curving (a to e).

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