Hybrid balloon valvuloplasty through the ascending aorta via median sternotomy in infants with severe congenital valvular aortic stenosis: feasibility of a new method†

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Abstract

OBJECTIVES: To evaluate a novel hybrid balloon valvuloplasty procedure for severe congenital valvular aortic stenosis in low-weight infants, performed through the ascending aorta via median sternotomy.

METHODS: Eighteen infants (<90 days of age) with severe congenital aortic stenosis were included in this study. Hybrid balloon valvuloplasty procedures were performed in a hybrid operating room. Patients were followed up at 3 months, 6 months, 1 year and then annually following the procedure.

RESULTS: The hybrid balloon valvuloplasty procedure was successful in all patients. Eight patients were successfully rescued from left ventricular systolic dysfunction by cardiac compression under direct vision. The aortic valve pressure gradient decreased from 80.3 ± 20.8 mmHg preoperatively to 16.0 ± 3.6 mmHg immediately postoperatively (P < 0.001). None of the patients developed significant aortic insufficiency. The fluoroscopy time was 6.2 ± 2.9 min. Intraoperative blood transfusions and pacing were not required. The patients were all alive and healthy at the end of the follow-up period (mean 21.3 months; range 3–41 months), and the aortic valve pressure gradient remained low (21.7 ± 5.3 mmHg). Reintervention was not required in any of the patients.

CONCLUSIONS: Hybrid balloon valvuloplasty through the ascending aorta via median sternotomy is an effective and safe procedure for infants with severe congenital aortic stenosis.

Keywords: Aortic valve stenosis • Balloon valvuloplasty • Hybrid • Infant

INTRODUCTION

Patients with severe congenital aortic stenosis (AS) are at risk of sudden cardiac death and left heart failure [1]. Percutaneous balloon valvuloplasty has become an important alternative treatment to open surgery for congenital AS, but still carries a high risk because balloon dilatation may completely block the blood flow in the aorta and induce fatal left ventricular systolic dysfunction [2–4]. In approximately 5% of patients with severe AS, the aortic valve orifice is so small that it is not possible to pass a guide wire through it, and conversion to surgical treatment is required [5]. A temporary pacemaker is required to help stabilize the balloon, which increases the cost and complications. Percutaneous valvuloplasty may also cause severe aortic valve insufficiency or rupture, or cardiac tamponade [6]. Together, these factors lead to a perioperative mortality of 4–22% [7–9].

Percutaneous balloon aortic valvuloplasty is particularly challenging in low-weight infants with severe AS because of their fragile femoral arteries and aortic valve and poor heart function. We developed a novel hybrid balloon valvuloplasty procedure for emergency treatment of these patients that is performed through the ascending aorta via median sternotomy.

MATERIALS AND METHODS

Patients

Between October 2010 and November 2013, hybrid balloon valvuloplasty was performed in 18 infants (12 males and 6 females)
with severe congenital AS. The patients were 25–83 days of age (mean 50.4 ± 17.5 days) with a body weight of 3.1–5.8 kg (mean 4.6 ± 0.8 kg) at the time of the procedure. The indications for the procedure were congenital AS, age <90 days, and an aortic valve pressure gradient of >80 mmHg (1 mmHg = 0.133 kPa) or a left ventricular ejection fraction (LVEF) of <35%. Patients with moderate or severe aortic insufficiency were excluded. Written informed consent was obtained from each patient’s guardian before enrolment in the study. The study protocol was approved by the Ethical Committee of Fuwai Hospital, Beijing, China.

Surgical procedure

Hybrid balloon valvuloplasty procedures were performed in a hybrid operating room. Patients were placed supine and the trachea was intubated. Median sternotomy was performed and a purse-string suture was placed in the wall of the ascending aorta. Heparin (100 U/kg) was administered and a 7-Fr arterial sheath was inserted into the aorta. A 0.035-inch guide wire was advanced into the left ventricle under echocardiographic guidance. Left ventricle and ascending aortic angiography was performed to determine the severity of AS and the diameter of the aortic valve (Fig. 1). The valvuloplasty balloon (NuMED Canada Inc., Cornwall, ON, Canada) was selected according to the diameter of the aortic valve, starting with a balloon/annulus diameter ratio of 0.8, but not exceeding 1.0. The balloon catheter was stabilized by hand at the site of the aortic insertion, to prevent movement of the balloon during dilatation. The duration of each dilatation was ≤5 s. The aortic valve pressure gradient was measured before and after dilatation. Left ventricle and ascending aortic angiography was performed after balloon valvuloplasty to evaluate the anatomy and function of the valve.

Follow-up

Patients were followed up at 3 months, 6 months, 1 year and then annually following the procedure. Clinical interviews, clinical examinations, echocardiography and electrocardiography were performed at each visit.

Statistical analysis

All measurement data are presented as the mean ± standard deviation, except for LVEF, which is presented as the median. Pre- and postoperative data were compared by paired-samples t-test using SPSS 20 software. A two-tailed P value of <0.05 was considered statistically significant.

RESULTS

Immediate outcomes

Hybrid balloon valvuloplasty was successfully performed in all patients. The fluoroscopy time was 6.2 ± 2.9 min (range 3–15 min), the diameter of the aortic annulus was 8.3 ± 1.3 mm and the diameter of the balloon was 8.2 ± 1.2 mm. The aortic valve pressure gradient decreased significantly from 80.3 ± 20.8 mmHg before balloon dilatation to 16.0 ± 3.6 mmHg after dilatation (P < 0.001; Table 1). The LVEF increased significantly from 58.5% before dilatation to 62.7% after dilatation (P < 0.001; Table 1). The left ventricular end-diastolic dimension (LVEDD) decreased significantly from 27.1 ± 5.1 mm before dilatation to 23.5 ± 3.9 mm after dilatation (P < 0.001; Table 1).

Eight patients had a persistent decrease in heart rate from 160–170 to 20–30 bpm after deflation and withdrawal of the balloon, due to left ventricular systolic dysfunction. These patients were all successfully resuscitated by cardiac compression under direct vision, with the heart rate gradually returned to 140–170 bpm and recovery of cardiac contractility. In 2 patients, the initial dilation was insufficient and a second balloon dilation was performed 5 min after normalization of the heart rate. Intraoperative blood transfusions and pacing were not required. Two patients developed mild aortic insufficiency. All the patients were discharged with no adverse events or complications.

Mid-term outcomes

The patients were all alive and healthy at the end of the follow-up period (mean 21.3 months; range 3–41 months). The aortic valve pressure gradient on postoperative echocardiography was...
21.7 ± 5.3 mmHg, which was significantly lower than the preoperative gradient value (P < 0.001; Table 1). The postoperative LVEF was 67.4%, which was significantly higher than the preoperative value (P < 0.001; Table 1). And the postoperative LVEDD was 24.1 ± 2.5 mm, which was significantly lower than the preoperative value (P = 0.001; Table 1). No developed aortic insufficiency was observed. Repeat intervention was not required in any of the patients.

**DISCUSSION**

This clinical study included infants <90 days of age with a high aortic pressure gradient of 80.3 ± 20.8 mmHg. LVEF was <35% in 6 patients, indicating that they were at high risk of adverse events such as sudden cardiac death, and that they were unlikely to thrive while awaiting conventional treatment. We performed balloon valvuloplasty through the ascending aorta, which effectively decreased the aortic valve pressure gradient without significant adverse events.

The hybrid balloon valvuloplasty procedure has clear advantages compared with percutaneous balloon valvuloplasty. Firstly, the ascending aortic approach provides good control of the guidewire because of the short distance to the aortic valve, and it is therefore much easier to pass the guidewire through the stenotic aortic valve than in percutaneous balloon valvuloplasty. The orientation of the aortic valve orifice is easily adjusted to facilitate insertion of the guidewire, by pulling on the aortic adventitia. Use of ultrasound guidance while passing the guidewire through the aortic valve significantly decreases the radiation dose to patients. Ewert et al. [10] reported a median fluoroscopy time for balloon valvuloplasty of 18 min. In the present study, the fluoroscopy time was only 6.2 min. Secondly, the balloon is stabilized by hand instead of with a temporary pacemaker to reduce balloon swing, thereby reducing injury to the aortic valve, which may result in aortic insufficiency, as well as reducing costs. Finally, the hybrid procedure enables cardiac compression under direct vision, which was required in 8 patients in the present study. Balloon dilatation-induced arrhythmia and left ventricular systolic dysfunction are usually serious and fatal [11–13]. Extracorporeal circulation can also be established quickly if required because of severe complications.

In conclusion, balloon valvuloplasty through the ascending aorta via median sternotomy effectively decreased the aortic valve pressure gradient in our patients. Extracorporeal circulation was not required, and some of the limitations of percutaneous balloon valvuloplasty were overcome. Hybrid balloon valvuloplasty is a novel procedure that is effective and safe for the treatment of infants with severe congenital AS.

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**REFERENCES**


