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Original article

Stenting for pulmonary artery stenosis complicated by univentricular physiology: Subanalysis of JPIC stent survey



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ABSTRACT

Background and purpose: Stent implantation is an important treatment option for pulmonary artery stenosis (PS), even if complicated by univentricular physiology (UVP). However, there is paucity of evidence concerning not only its hemodynamic and morphologic indications but also on markers for its optimal target attainment in UVP. The purpose of this study was to evaluate the acute outcome and factors associated with efficacy of stenting for PS complicating UVP.

Methods and subjects: A subanalysis was performed using the data of the Japanese Society of Pediatric Interventional Cardiology (JPIC) stent survey. We analyzed the morphologic and hemodynamic data of 11 patients with UVP who underwent stenting for PS. We defined "a 50% increase in the minimum lumen diameter (MLD)" as "morphologically effective," and "an achievement of 0 mmHg pressure gradient" as "hemodynamically effective." We analyzed the success rate for each criterion and determined factors which may have contributed to hemodynamic effectiveness.

Results: Stenting was morphologically effective in all patients, while it was hemodynamically effective in 6/11 (55%). The percent diameter stenosis after stenting was significantly lower in the "hemodynamically effective" group ($2.5 \pm 5.5\%$ vs $19.6 \pm 13.1\%$, p = 0.017). The cutoff value of percent diameter stenosis after stenting to "hemodynamically effective" was 14.6%; the sensitivity was 80% and the specificity was 100% (area under the curve 0.825, p = 0.021).

Conclusions: The percent diameter stenosis after stenting significantly contributed to achieving a "0 mmHg" pressure gradient, while in order to achieve a "0 mmHg" pressure gradient, the residual percent diameter stenosis should be less than around 15%.

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Introduction

The Fontan operation has contributed to improved survival of patients with univentricular physiology (UVP); concurrently, after its first description in 1989 [1,2], the use of metallic stents for pulmonary arterial stenosis (PS) in congenital heart disease has become an important option for treating PS even in patients with

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UVP. PS in such patients may be attributed to anatomical and surgical risk associated with growth failure of a segment of the native vessel, external compression by anatomic structures, and an inadequate patching at a previous operation. Consequently, catheter intervention is a reasonable approach to relieve stenosis affecting such low pressure systems. The increasing number of Fontan patients under follow-up means an increased number of potential cardiac catheterization and interventional procedure candidates. These procedures may be an important component of staged surgical palliation for univentricular heart, especially in the management of PS requiring prompt intervention. Intervention may allow high-risk surgical repair to be deferred or may even replace it. However, little has been written about stent implantation

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in patients with univentricular heart, and factors associated with successful stent implantation for PS in these patients, while outcomes of this situation have not been published. Thus, accurately identifying the optimal stent diameter implanted for PS may be crucially important for patients with UVP. The purpose of this study was to evaluate the acute outcome and factors associated with efficacy of stenting for PS complicating UVP.

Methods

A subanalysis was performed from the data of the Japanese Society of Pediatric Interventional Cardiology (JPIC) stent survey, which is a retrospective questionnaire-based survey of stenting for congenital heart diseases from May 1995 to February 2009 at 14 leading hospitals in Japan [3]. We retrospectively analyzed the impact of stent implantation for treatment of PS in patients with UVP undertaken to optimize the circulation, with special attention to morphologic and hemodynamic effectiveness, and factors that may have contributed to its effectiveness. We analyzed morphologic and hemodynamic data of patients with UVP, who underwent stenting for PS associated with a mean pressure gradient of at least 1 mmHg. Patients who had morphologic stenosis but no measurable pressure gradient across the stenosis were excluded. For analysis, 11 patients who received at least one stent implantation for PS after a bidirectional Glenn or Fontan operation were enrolled. We defined "a 50% increase in the minimum lumen diameter (MLD)" as "morphologically effective" [4], and "an achievement of 0 mmHg pressure gradient" as "hemodynamically effective." Each criterion was examined. Furthermore, we analyzed factors that may have contributed to hemodynamic effectiveness, including MLD, reference vessel diameter (RVD), mean pressure gradient through the target lesion before and after stenting, and balloon diameter used for deployment. Percent increase in MLD and percent diameter stenosis (%DS) were defined as [(MLD after - MLD before)/MLD before] and [(RVD – MLD)/RVD], respectively. If the MLD after stent is larger than RVD, %DS becomes a negative value; we treated the negative value as "0%" for the analysis, because the negative value of %DS does not have a practical meaning. Each data point was expressed as a mean value \pm SD. The values between the "effective" and "non-effective" groups were also compared. The Student's *t*-test was used to compare means between each group. The cutoff value was evaluated using receiver operating characteristic (ROC) curve of factors which contributed to effective stenting. Statistical analyses were performed with the statistical software package JMP[®] 10 (SAS Institute Inc., Cary, NC, USA).

Results

From May 1995 to February 2009, 31 patients with UVP underwent stent implantation. In 11 of them (3 after Fontan operation

Table 2

Morphologic and hemodynamic parameters, before and after stenting

Table 1

Patients' profile (basic diagnosis and type of operation).

No.	Age	Sex	Basic diagnosis	Type of operation	
1	0.8	Female	Ebstein, PA	BDG	
2	1.0	Male	HLHS	BDG	
3	1.0	Male	HLHS	BDG	
4	1.0	Male	SRV	BDG	
5	2.0	Male	HLHS	Fontan	
6	2.0	Male	PA/IVS	Fontan	
7	4.0	Male	HLHS	BDG	
8	8.0	Female	TA	BDG	
9	8.0	Female	DORV, PA	Fontan	
10	17.0	Female	TA	BDG	
11	20.0	Female	AVSD	BDG	

PA, pulmonary atresia; HLHS, hypoplastic left heart syndrome; SRV, single right ventricle; PA/IVS, pulmonary atresia with intact atrial septum; TA, tricuspid atresia; DORV, double outlet right ventricle; AVSD, atrioventricular septal defect; BDG, bidirectional Glenn.

and 8 after bidirectional Glenn operation), a stent was implanted to treat PS with a measurable pressure gradient. The patient profiles are summarized in Table 1. The median age of the patients at catheterization was 2.0 (0.8-20.0) years. The original Palmaz stent was used in 10 patients (extra-large, 1; large, 4; medium, 5) and a Palmaz Genesis stent in one patient. Stents were deployed using standard techniques. Morphologic and hemodynamic parameters, before and after stenting, are presented in Table 2. As mentioned above, we treated the negative value of %DS as "0%". Stent implantation resulted in a significant reduction of the pressure gradient and %DS in the majority of our patients. Stenting was morphologically effective in all patients, while it was hemodynamically effective in 6/11 (55%) patients. The comparisons of parameters in the two groups (hemodynamically "effective" and "non-effective") are summarized in Table 3. The %DS after stenting was significantly lower in the "hemodynamically effective" group than in the "noneffective" group $(2.5 \pm 5.5\% \text{ vs } 19.6 \pm 13.1\%, p = 0.017)$ (Fig. 1). The cutoff value of %DS after stenting to "hemodynamically effective" was 14.6%; the sensitivity was 80% and the specificity was 100% (area under the curve 0.825, p = 0.021) (Fig. 2).

Discussion

PS complicating UVP may lead to various morbidities, including changes in the pulmonary vascular bed, increased central venous pressure, ascites, pleural effusion, and protein losing enteropathy. The long-term outcome after bidirectional Glenn and Fontan procedures depends on pulmonary artery growth [5]. In these patients, the pulmonary circulation lacks a pumping chamber and pulmonary blood flow is driven by systemic venous pressure. Unobstructed pulmonary blood flow in a univentricular circulation is a major determinant of a good long-term outcome, and in relieving PS

No.	Type of stent	Before ste	Before stent		After stent		RVD	% change in MLD	
		MLD	%DS	Mean PG	MLD	%DS	Mean PG		
1	P1506	2.1	73.8	4.0	5.3	33.8	3.0	8.0	152.4
2	P2006	2.2	60.0	1.0	5.4	1.8	0.0	5.5	145.5
3	P2007	3.8	32.1	1.0	6.3	0	0.0	5.6	65.8
4	PG2980	3.9	58.1	1.0	7.4	20.4	1.0	9.3	89.7
5	P2007	3.8	34.5	3.0	6.6	0	0.0	5.8	73.7
6	P2007	4.1	43.8	2.0	6.3	13.7	0.0	7.3	53.7
7	P3008	4.0	40.3	4.0	7.3	0	1.0	6.7	82.5
8	P3008	2.0	79.2	3.0	10.0	0	0.0	9.6	400.0
9	P4010	5.3	33.8	2.0	8.2	0	0.0	8.0	54.7
10	P3008	4.4	47.6	9.0	7.1	15.5	6.0	8.4	61.4
11	P3008	4.7	63.8	2.0	9.3	28.5	1.0	13.0	97.9

MLD, minimum lumen diameter; %DS, percent diameter stenosis; PG, pressure gradient; RVD, reference vessel diameter.

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