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Stent implantation and balloon angioplasty for treatment of branch pulmonary artery stenosis in children

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■ **Abstract** *Objectives* Comparison of the results of branch pulmonary artery stenosis treated with balloon angioplasty (BA) or stent implantation (SI) in children. *Background* Branch pulmonary artery stenosis may be treated with BA or SI. *Methods* We compared the results of 147 interventions of branch pulmonary artery stenosis in 87 children (median age 3.6 years). Patients were treated during 1989–2000 with BA and during 2001–2004 with SI. Primary endpoints were acute complications and reintervention during follow up. Secondary variables were age, vessel diameter increase, acute success rate, balloon/vessel diameter ratio, pulmonary artery hypoplasia indices, and procedure related factors. *Results* The acute vessel diameter increase with BA (4.31 ± 1.98 vs. 7.15 ± 2.31 mm) and SI (3.71 ± 1.58 vs. 6.97 ± 2.68 mm) was significant within both groups ($P < 0.001$), but not between both groups. The reintervention rate was comparable between both groups, but median time to reintervention was shorter after SI in infants compared to BA. The balloon/vessel diameter ratio was on average higher in BA than the stent/vessel diameter ratio in SI (3.49 ± 2.16 vs. 2.42 ± 0.56; $P < 0.05$) and was a significant risk factor ($P < 0.01$) for the higher complication rate after BA (BA: 14.1% vs. SI: 4.8%). No mortality occurred in both groups. *Conclusion* BA and SI are safe interventional catheter therapies of branch pulmonary artery stenosis. The immediate results of BA and SI are comparable. The higher complication rate after BA, especially in infants, was associated with a higher balloon/vessel diameter ratio. SI seems to be a safe permanent alternative with foreign material, but requires more reinterventions in infants due to its therapeutic strategy.

■ **Key words** paediatric cardiac interventions – pulmonary angioplasty – stent – restenosis – right ventricle

Introduction

Branch pulmonary artery stenosis may be primary due to hypoplasia of the central or peripheral pulmonary arteries or may develop secondary after cardiac surgery of congenital heart disease. The results of surgical treatment are not satisfying, especially in growing children [23]. Therefore, catheter interventional treatment has been established as an alternative option [12, 16]. Two methods of cardiac interventions are available: balloon angioplasty (BA) and endovascular stenting have been compared recently [2, 5, 9, 12, 14, 16]. The success rate of both methods and possible risk factors may influence the outcome.

The aim of our study was to compare the efficacy of the two methods in the past 15 years in our institution with regard to further pulmonary artery growth

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after BA or stent implantation (SI) of branch pulmonary arteries.

Materials and methods

◼ Study patients

From November 1989 to October 2004 a total of 87 patients (46 male and 41 female) underwent 147 interventional catheter procedures for the treatment of branch pulmonary artery stenosis. The diagnosis of the patients are listed in Table 1. A surgical repair for congenital heart disease was performed in 79 patients and eight patients had a primary hypoplasia of the pulmonary arteries. Medical records, hemodynamic data, angiographies, and lung perfusion scans were reviewed. Indications for a catheter interventional procedure were one or more of the following: (a) elevated right ventricular systolic pressure (more than 75% of the left ventricular systolic pressure), (b) relevant stenosis (stenotic vessel diameter <50% of the surrounding vessels) of the left or right pulmonary artery leading to decreased flow of the affected lung (assessed by radionuclid scan or cardiac magnetic resonance imaging), (c) hypertension of other unobstructed pulmonary artery segments, or (d) clinical symptoms (exercise intolerance or increasing cyanosis).

Cardiac interventions were performed for the central right (60/147) or left (87/147) pulmonary artery stenosis. We compared the two techniques (BA vs. SI): during the years 1989–2000 patients were treated by a primary BA (n = 92), while during the years 2001–2004 patients (n = 21) were treated by a primary SI. Repeated (up to four) cardiac catheterizations with necessary interventional procedures are shown in Fig. 1.

◼ Technique

Informed parental consent was obtained for all interventional procedures. The study complies with the

Table 1 Cardiac diagnosis and number of interventions for catheter interventional treatment of branch pulmonary artery stenosis

| Diagnosis	Patients (n = 87)	Interventions (n = 147)
Postoperative branch pulmonary artery stenoses		
Tetralogy of Fallot	22	35
Pulmonary atresia with VSD	11	24
Double outlet right ventricle (Fallot type)	3	4
D-transposition of the great arteries after arterial switch operation	25	50
Truncus arteriosus communis after repair	7	10
Single ventricle after bidirectional cavopulmonary anastomosis	7	10
Single ventricle after Fontan procedure	1	1
Other diagnosis[a]	3	3
Native branch pulmonary artery stenoses		
Isolated peripheral pulmonary artery stenosis without and	5	6
with Williams Beuren syndrome	3	4

[a]Other diagnosis are interrupted aortic arch, ventricular septal defect after pulmonary artery banding, pulmonary atresia without VSD

Fig. 1 Eighty-seven patients with branch pulmonary artery stenosis treated with 147 different catheter interventional procedures. Fifteen patients after primary balloon angioplasty were successfully treated with a secondary stent implantation
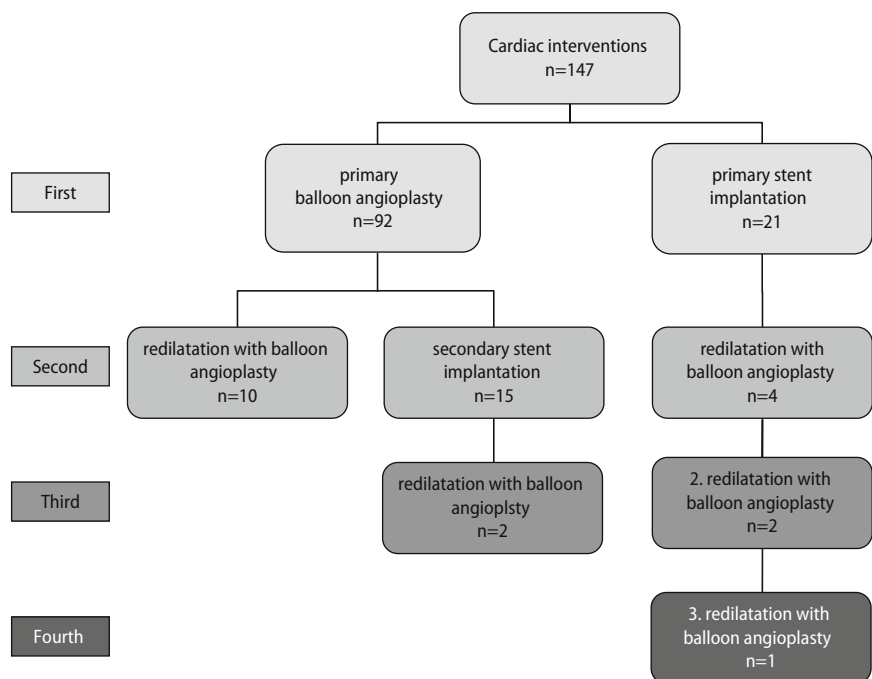
declaration of Helsinki. All procedures were performed under general anesthesia. Standard hemodynamic parameters were measured and selective angiographies were undertaken. The BA technique was performed as described by others [12]. Balloon inflation time was 10–60 s depending on the response of the waist and the degree of interference with cardiac output. Balloons were inflated for two or three times. The balloon size was chosen two to six times greater than the diameter of the treated stenotic vessel segment or 1.5 times greater than the diameter of the surrounding pre- or postenotic vessel segments. Different types of BA catheters were used, high pressure balloons were used in the latter part of the study. SIs were performed as described by others [16]. In brief, for the stent intervention procedures the standard venous sheaths were replaced with a larger diameter, long sheath over a stiff, exchange wire previously anchored across the stenosis. The stents were mounted on low pressure angioplasty balloons with diameters not exceeding the diameter of the vessel adjacent to the stenosis. The sheaths were advanced through the stenosis and the balloon-stent assembly were advanced within the sheath to the level of the stenosis. Then the sheath was withdrawn, exposing the balloon-stent assembly. The correct position of the balloon-stent assembly was confirmed by repetitive angiographies. After stent deployment, subsequent dilatations with low and high pressure balloons optimized the result. The Palmaz Genesis peripheral stents (Johnson and Johnson, Warren, NJ, USA) and Jostents (Jomed, Amsterdam, The Netherlands) were used most frequently. Postdilatation angiographies and hemodynamic measurements were performed after the intervention (Fig. 2).

The vessel diameter was measured after calibration with a grid or the catheter diameter. Digitalised angiographies were re-evaluated with a vessel diameter software (Inturis Cardio Image Viewing Package, Release 1.2, Philips Medical systems, Eindhoven, The Netherlands). Cross sectional area of the left and right pulmonary arteries (Nakata index), lower lobe pulmonary artery index (LL-Nakata), McGoon ratio, and lower lobe ratio McGoon ratio (LL-McGoon) were calculated from pulmonary angiograms [1, 15, 18, 19].

For follow up patients underwent clinical evaluation, two-dimensional echocardiography with Doppler studies or radionuclide scan.

■ Criteria for success

The success rate for the interventions were the following: (a) increase of more than 50% of the predilatation diameter, and (b) decrease of more than 20% of the ratio of right ventricular systolic pressure to aortic systolic pressure.
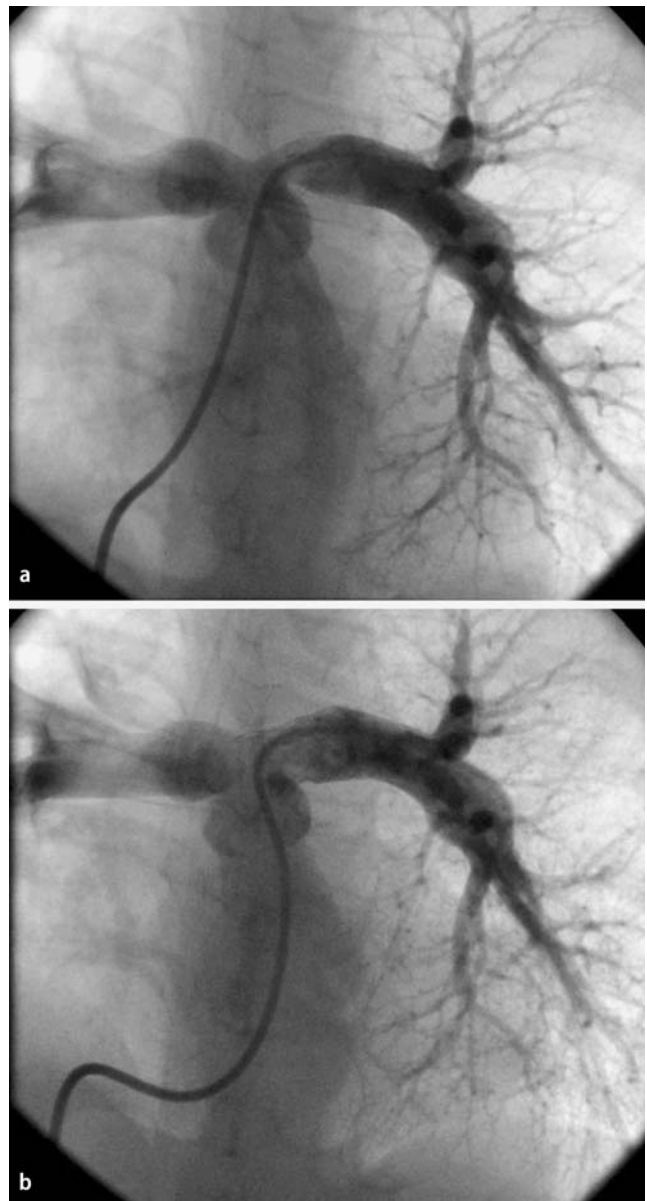

Fig. 2 Left branch pulmonary artery stenosis in a 2½-year-old child after operative repair of truncus arteriosus communis (**a**) treated with implantation of a Palmaz Genesis stent (**b**)

■ Criteria for complications

As acute complications we included aneurysm formation (defined as a postinterventional increase of the vessel diameter of more than 150% of the diameter of the surrounding vessels), vessel dissection, vessel rupture, stent dislocation, stent fracture, or overstented vessels. Death either related acutely to the intervention or during follow up were defined as a major complication.

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Criteria for redo

A significant restenosis leading to a repeat catheterization was defined by a stenotic vessel diameter <50% of the surrounding vessels measured either if possible by echocardiography or otherwise by cardiac magnetic resonance imaging. Signs of right ventricular pressure overload an increase of right ventricular pressure measured by an elevated Doppler flow signal of the tricuspid regurgitation and signs of hypertrophy of the right ventricle in echocardiography served as additional criteria.

Criteria for choice of stent or balloon

Primary BA was performed as the method of choice between the years 1989 and 2000. Although SI was performed before the year 2000, we ruled out this small number of patients due to a learning curve. After the year of 2000 primary stenting was used as the method of choice for stenosis, which seemed to be untreatable by BA alone due to elastic recoil after intervention, nondilatable fibrotic lesions or external compression. Secondary stenting was performed in case of unsuccessful primary BA after the year 2000 (Fig. 1).

Statistical analysis

Data are presented in percentages or relative frequencies for discrete data and as means and standard deviations or median and range for continuous variables as appropriate.

Group comparisons were performed by using the Mann–Whitney U test for continuous variables. Differences in proportions were tested by the Chi square test. Survival analysis (anaylsis of time to reintervention) was performed with the Kaplan–Meier method and the Log-rank test for differences between groups. Logistic regressions were performed with time to a first complication as primary endpoint and balloon/vessel diameter ratio, pulmonary artery hypoplasia indices and age at intervention as risk factors, both in an univariable (one risk factor at a time) and multivariable analysis (several risk factors combined).

$P < 0.05$ was considered as significant.

Statistical analysis was performed with SPSS11 for MacIntosh.

Results

The median age of all 87 patients included for the study at the time of the first intervention was 3.6 years (range 0.1–19.5 years). Demographic data of

Table 2 Comparison of different demographic and procedure related parameters between the two study groups

	Primary balloon angioplasty	Primary stent implantation	P value
Age (years)	2.1 (0.01–19.5)	4.1 (0.05–17.2)	0.10
Weight (kg)	11.7 (3.6–84.0)	13.0 (2.8–88.0)	0.19
Height (cm)	85 (52–175)	96 (48–178)	0.15
Surface area (m^2)	0.52 (0.23–1.99)	0.59 (0.19–2.10)	0.17
X-ray dose (cGy/m^2)	13.3 (4.7–46.9)	13.5 (2.2–62.5)	0.90
Procedure time (min)	98.5 (60–240)	120 (55–180)	0.72
Follow up (years)	8.5 (3–15)	1.8 (0.18–3)	<0.001

Median and range are given. Mann–Whitney U test was performed

the patients treated with primary BA and with primary SI are summarized (Table 2).

Determined by the first intervention the patients were divided into a group treated by primary BA and into a group treated by primary SI (Fig. 1). The patients of both groups were comparable concerning age, body weight, body height, body surface area, X-ray dose, and procedure time (Table 2). The follow up period was longer for the patients treated by primary BA (primary BA: median, 8.5 years; range, 3–15 years Vs. primary SI: median 1.8 years; range, 0.18–3 years; $P < 0.001$).

First intervention

With a primary BA 92 stenotic pulmonary vessels were treated (age: median 2.1 years; range 0.1–19.5 years): The mean diameter of the pulmonary artery increased from 4.31 ± 1.98 to 7.15 ± 2.31 mm ($P < 0.001$) with a relative increase rate of 88.6%. The mean decrease of the systolic right ventricular/aortic pressure ratio was from 80.8% to 50.6% (Table 3).

With a primary SI 21 pulmonary artery stenosis were treated (age: median 4.1 years; range 0.1–17.2 years): The mean diameter of the pulmonary artery increased from 3.71 ± 1.58 to 6.97 ± 2.68 mm ($P < 0.001$) with an increase rate of 102.3%. The mean decrease in the systolic right ventricular/aortic pressure ratio was from 85.8% to 34.6%.

There was no significant difference between the mean diameter increase between both groups ($P = 0.86$).

The mean balloon/stenosis diameter ratio in primary BA was higher compared to the mean stent size/stenosis diameter ratio in primary SI (primary BA: 3.49 ± 2.16 vs. primary SI: 2.42 ± 0.56, $P < 0.05$) (Table 2). The success rate (defined as an increase of more than 50% of vessel diameter) was comparable in both groups: primary BA 69.6% and primary SI 71.4%.

Table 3 Results of the different catheter interventions for the treatment of branch pulmonary artery stenosis

	First intervention		Second intervention		
	Primary balloon angioplasty	Primary stent implantation	Redilatation after primary balloon angioplasty	Redilatation after primary stent implantation	Secondary stent implantation
Cardiac interventions	92	21	10	4	15
Median age at intervention	2.1	4.1	5.4	1.4	9.3
Vessel diameter pre-dilatation	$4.31 \pm 1.98^{\dagger}$	$3.71 \pm 1.58^{\dagger}$	5.63 ± 2.28	2.95 ± 1.18	4.50 ± 1.48
Vessel diameter post-dilatation	$7.15 \pm 2.31^{\dagger}$	$6.97 \pm 2.68^{\dagger}$	7.54 ± 2.59	4.43 ± 0.71	8.78 ± 2.24
RV/Ao pre-dilatation (%)	80.8	85.8	65.9	-	71.4
RV/Ao post-dilatation (%)	50.6	34.6	60.7	-	66.7
Success rate (%)	69.9	71.4	20.0	50.0	86.7
Complication rate (%)	14.1	4.8	10	0	13.3
Aneurysm formation ($n=$)	11	0	1	0	1
Vessel dissection ($n=$)	2	0	0	0	1
Vessel rupture ($n=$)	0	0	0	0	0
Stent dislocation ($n=$)	–	0	–	–	0
Stent fracture ($n=$)	–	0	–	–	0
Overstented vessels ($n=$)	–	1	–	–	0
Balloon/vessel diameter	$3.49 \pm 2.16^{*}$	$2.42 \pm 0.56^{*}$	2.84 ± 1.43	2.55 ± 0.83	2.85 ± 1.28

RV right ventricle systolic pressure, *Ao* aortic systolic pressure
* $P < 0.05$; † $P < 0.001$. Mann–Whitney U test was performed

The median time to reintervention was shorter after primary SI compared to the freedom of reintervention after primary BA, but did not reach statistical significance ($P = 0.051$) (Fig. 3). But in patients at an age less than 12 months the freedom of reintervention was significantly lower ($P = 0.04$) after primary SI compared to patients of an age older than 12 months. However, for primary BA no significant difference in median time to reintervention was observed between children below 12 months and older children ($P = 0.63$).

■ Second intervention

Thirty-four interventions became necessary due to our criteria for redo as mentioned above, 29 interventions in a second cardiac catheterization, four interventions in a third cardiac catheterization and in one patient in a fourth cardiac catheterization (Fig. 1).

The reintervention rate after primary BA was 27.2% during a total follow up of median 8.5 years (range 0.1–19.5 years). After primary BA redilatation with BA was performed in 10 cases (median age: 5.4 years; range 1.7–19.1 years) versus secondary stenting in 15 cases (median age: 9.3 years; range 1.2–9.3 years).

The reintervention rate after primary SI was 19.1% during a total follow up of median 1.8 years. After primary SI redilatation with BA (median age, 1.4 years; range 1.1–3.0 years) became necessary in

four patients. The results of the different reinterventions are summarized in Table 3.

■ Complications

The risk for acute complications (aneurysm formation, vessel dissection, vessel rupture, stent dislocation, stent fracture, or overstented vessels) was higher after primary BA than after primary SI (primary BA: 14.1% vs. primary SI: 4.8%) (Table 3). A multivariable logistic regression analysis with acute complications as primary endpoint was performed for the following variables balloon (respectively, stent)/vessel diameter ratio, age at intervention, and pulmonary artery hypoplasia indices. It revealed balloon (respectively, stent)/ vessel diameter ratio as a significant risk factor for complications (both in a multivariable regression with all explanatory variables $P = 0.048$, and in an univariable logistic regression $P = 0.007$).

There was no mortality in both groups.

The rate of minor complications varied in both groups with the age of the patients (Table 4).

■ Pulmonary artery size before the first and second catheter intervention

The pulmonary artery size before the first and second catheter intervention was analysed.

The patients treated with primary BA had higher Nakata indices, McGoon ratios, LL-McGoon, and LL-

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Table 4 Age distribution of the complication rate in the two groups treated by primary balloon angioplasty or primary stent implantation

Groups	0–1 year	1–5 years	6–12 years	>12 years
Primary balloon angioplasty				
Complications/interventions	6/21	5/45	2/20	0/6
Complication rate (%)	28.6	11.1	10.0	0
Primary stent implantation				
Complications/interventions	0/6	0/5	1/6	0/4
Complication rate (%)	0	0	16.6	0

The majority of complications occurred in children less than 1 year of age treated by primary balloon angioplasty

Nakata compared to those treated with primary SI (Table 5).

■ Further possible factors for restenosis leading to redo

The primary cardiac diagnosis of patients after primary BA with a restenosis leading to redo (redilatation after primary BA or secondary stent) were mainly patients with d-transposition of the great arteries ($n = 13$) and patients after repair of tetralogy of fallot ($n = 12$). In contrast, the primary cardiac diagnosis of the patients after primary SI suffering from significant restenosis were patients with pulmonary atresia with ventricular septal defect with severe hypoplastic pulmonary arteries ($n = 4$). An inflation pressure for primary BA of more than 6 atm resulted in rate of restenosis leading to redo in 32.3%. A balloon/vessel diameter ratio of less than 3.0 only resulted in a rate of restenosis leading to redo in 7.9%.

Discussion

Since more than two decades catheter interventional treatment of branch pulmonary artery stenosis with BA and SI is an established treatment [1, 2, 5, 7, 8, 10, 12, 13, 17, 20–22, 25]. The surgical therapy of branch pulmonary artery stenosis is limited to the central parts of the pulmonary arteries for technical reasons, and the results are not satisfying [23]. The aim of the study was to compare the results of the two methods for catheter interventional treatment of branch pulmonary artery stenosis with regard to pulmonary artery development, success, complications, and re-intervention.

Both catheter interventional therapies are effective, safe, and therefore most suitable for children with different cardiac diagnosis after operative repair of congenital heart disease or native branch pulmonary artery stenosis (Table 3). The results after BA in our population, especially with regard to the initial result (success rate 70%, complication rate 19%, reintervention rate 27%; follow up 8.5 years), were slightly better compared to the results described by Rothman et al. [21] (58%, 6%, 16%, respectively; 10 months), by Hosking et al. [8] (53%, 5%, 17%, respectively; 37 months) for the 1980s year period and by Zeevi et al. [27] (56%, 12%, respectively; no further data) for the early 1990s year period. The higher immediate success rate may be contributed to a moderately higher balloon/vessel diameter ratio compared to the recommendations of other studies [1, 12]. We did not find any differences between the use of low or high pressure balloon, even the pressure during dilatation did not correlate with the outcome [7]. Although we had no major complications leading to emergency surgery or death, the higher complication rate in our patients compared to other studies may partly be explained in case of dissection or aneurysm formation by this higher balloon/vessel diameter ratio (Table 3). In patients younger than 1 year of age we had the highest rate of complication (Table 4). Nevertheless, the radiographic assessment in only two planes without three-dimensional reconstruction concerning the degree of aneurysm formation, vessel dilatation or

Table 5 Pulmonary artery hypoplasia indices before first and second intervention in both groups

	Before first intervention				Before second intervention			
	McGoon (norm: 1.5–2.0)	Nakata (norm: 330 ± 30)	LL McG (norm: 0.7–1.7)	LL Nak (norm: 120 ± 30)	McGoon (norm: 1.5–2.0)	Nakata (norm: 330 ± 30)	LL McG (norm: 0.7–1.7)	LL Nak (norm: 120 ± 30)
Primary ballon angioplasty	$n = 74$				$n = 21$			
Range	0.91–3.40	45–607	0.67–2.80	17–338	1.42–2.06	26–468	1.43–1.78	22–297
Median	1.90	202	1.62	144	1.88	186	1.58	132
Primary stent implantation	$n = 21$				$n = 4$			
Range	1.33–2.09	39–483	1.11–2.09	49–347	0.89–1.78	48–304	0.95–1.44	43–190
Median	1.72	170	1.41	111	0.99	81	0.96	52
P value	0.188	0.039	0.299	0.119	0.05	0.034	0.03	0.115

McGoon McGoon ratio, *Nakata* Nakata index, *LL McG* lower lobe McGoon ratio, *LL Nak* lower lobe Nakata index. Mann–Whitney U test was performed

even vessel dissection might be quite difficult to compare in very small children. Even an uniform definition of those morphological entities remains controversial.

The reintervention rate after BA may be higher due to the longer follow up compared to the other studies and may be influenced by the induced vessel trauma with a higher pressure during dilatation and a high balloon/vessel diameter ratio. Stenosis mainly occurred postoperatively with scar tissue not showing the same growth dynamics as native vessels.

The results after SI in our population (success rate 71%, complication rate 5%, reintervention rate 19%; follow up 1.8 years) were comparable with the results of other groups: Chau and Leung [2] reported of 12 children undergoing 14 SI with success rate 93%, complication rate 17%, reintervention rate 17%, and follow up 26.3 months. McMahon et al. [13] has the most extensive series, in which he described 338 patients with 664 pulmonary artery stents implanted over a follow up of 5.6 years and very low complication rate 3.8%. Shaffer et al. [22] reported of 200 children undergoing 347 SI within pulmonary vessels (including 49 children with pulmonary venous stenoses stenting) with good immediate results and low complication rate 8.5%, over a follow up of 14 months.

The therapeutic approach for branch pulmonary artery stenosis with SI was used in our patients with more hypoplastic pulmonary arteries (Table 5). To reduce the complication rate we performed the SI within the recommended stent/vessel diameter ratios. Our treatment strategy was cautious for those patients, if the SI was performed early (<6 months) during postoperative follow-up. Of course, in paediatric patients this strategy implies the need of further redilatation during further growth (Fig. 3). We could demonstrate that redilatation of previously implanted stents could be performed with a high success rate and low complication rate (Table 3) [9]. This circumstance explains the relative high rate of reintervention in patients treated with primary SI, which is part of the therapeutic approach of a stepwise dilatation parallel to the growth of the child. But of course it has to be considered that those patients with SI will need a greater number of catheterisation procedures with a decreasing ease of venous access. Nevertheless, our success rate was 71% and in those patients, where we failed an vessel increase of more than 50%, we were confronted with severly hypoplastic pulmonary vessels.

The best results of BA have been shown for postsurgical branch pulmonary artery stenosis, while the indication for SI for pulmonary artery stenosis is given in patients after arterial switch operation [5, 21, 27]. D-transposition of great arteries after arterial
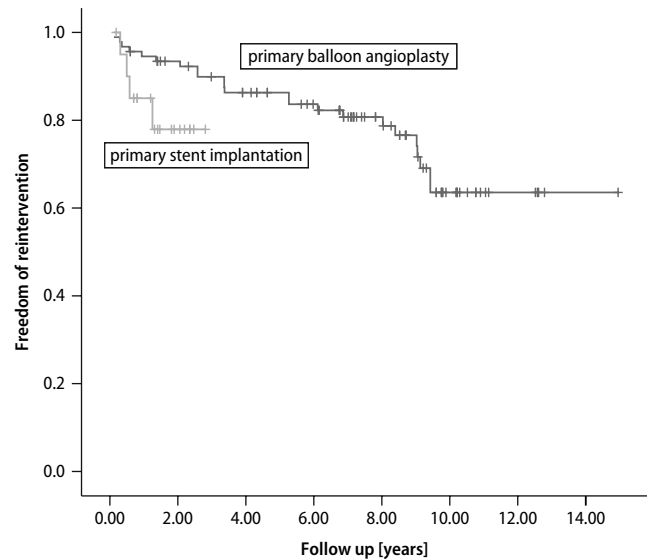

Fig. 3 Kaplan–Meier survival analysis comparing the interventional treatment of branch pulmonary artery stenosis in children with either primary stent implantation or primary balloon angioplasty. There was no statistical significant difference between the two methods ($P = 0.051$). Note, that the reintervention after primary stent implantation is part of the therapeutic approach which implies redilatation of the stents during further growth

switch operation was the most frequent primary cardiac diagnosis in patients treated with primary BA leading to redo with further interventions. SI in branch pulmonary artery stenosis after LeCompte maneuver during arterial switch operation seems to be a more suitable approach due to the morphology of these stenoses, which is characterized by tension or traction of the vessel more than scar formation [11]. Tetralogy of Fallot/pulmonary atresia with ventricular septal defect were the second frequent diagnosis leading to redo as well after BA as after SI because of the hypoplastic pulmonary arteries in these types of congenital heart defects.

These patients could be successfully treated by a secondary stent implantion after failure of primary BA (Fig. 1).

Interestingly, all patients with native hypoplastic pulmonary arteries have been treated with BA with excellent results [6].

Study limitations were the different length of follow up of the two groups and the circumstance that not all patients have been recatheterized routinely.

In conclusion, BA and SI are safe interventional catheter methods for treatment of branch pulmonary artery stenosis. The immediate results of primary BA and primary SI are comparable. The higher complication rate after primary BA, especially in very young children, may be explained by the used higher balloon/vessel diameter ratio. SI seems to be a safe alternative, but implies the potential need for further surgical reoperations in the future.

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Nevertheless, the use of stents in patients with congenital heart disease is increasing for different indications [3, 4, 24, 26]. New intravascular stents continue to be developed and improved. Biodegrad-able stents seem to be a hopeful alternative for severe stenosis in very small infants to "buy time" during further growth [24].

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