cambridge.org/cty

Original Article

Cite this article: Castaldi B, Di Candia A, Cuppini E, Sirico D, Reffo E, Padalino M, Vida V, and Di Salvo G (2024) Percutaneous approach to residual pulmonary bifurcation stenosis in conotruncal diseases. *Cardiology in the Young* **34**: 24–31. doi: 10.1017/S1047951123000999

Received: 10 August 2022 Revised: 6 February 2023 Accepted: 11 April 2023 First published online: 4 May 2023

Keywords:

Tetralogy of Fallot; pulmonary artery stenosis; pulmonary branches stenosis; stent; kissing balloon

Corresponding author: Biagio Castaldi, Department of Women's and Children's Health, University of Padua, Via Giustiniani 3, 35128 Padova, Italy. Email: biagio.castaldi@unipd.it

© University of Padua, 2023. Published by Cambridge University Press. This is an Open Access article, distributed under the terms of the Creative Commons Attribution licence (http://creativecommons.org/licenses/by/4.0/), which permits unrestricted re-use, distribution and reproduction, provided the original article is properly cited.



Percutaneous approach to residual pulmonary bifurcation stenosis in conotruncal diseases

Biagio Castaldi¹, Angela Di Candia¹, Elena Cuppini¹, Domenico Sirico¹, Elena Reffo¹, Massimo Padalino², Vladimiro Vida² and Giovanni Di Salvo¹

¹Department of Women's and Children's Health, University of Padua, Padua, Italy and ²Department of CardioThoracic Sciences, University of Padua, Padua, Italy

Abstract

Residual stenosis after right ventricle outflow tract surgery represents a major issue to manage in the children and adult patient with conotruncal defects. Despite a detailed multimodality imaging, the anatomy of distal pulmonary trunk and pulmonary artery bifurcation may be challenging in these patients.

The aim of this study was to analyse retrospectively the outcome of the percutaneous transcatheter treatment in children with post-surgical stenosis of pulmonary artery bifurcation.

We enrolled 39 patients with a median age of 6.0 years. Standard high-pressure balloon dilation was attempted in 33 patients, effective in 5 of them. Pulmonary branch stenting was performed in 10 patients, effective in 6. A kissing balloon approach was chosen in 17 patients (6 after angioplasty or stenting failure), and this technique was effective in 16 cases. Finally, a bifurcation stenting was performed in 10 patients (second step in 9 cases), effective in all the cases. None of the patients approached by kissing balloon needed a bifurcation stenting.

In conclusion, standard balloon angioplasty and standard stenting might be ineffective in post-surgical stenosis involving pulmonary artery bifurcation. In this population, kissing balloon or bifurcation stenting, followed by side branch de-jailing, may be more effective in relieving the gradient.

Residual stenosis after right ventricle outflow tract surgery represents a difficult problem to manage in the children and adult patient with conotruncal defects. Moreover, the anatomy of pulmonary artery bifurcation can be heterogeneous due to the underlying anatomical features and the surgical approach.^{2,3} Percutaneous pulmonary artery balloon angioplasty and/or stenting are considered the standard treatments in case of right ventricle outflow tract obstruction and pulmonary artery branches stenosis. 4,5 However, the re-intervention rate in this cohort of patients is relevant.⁵ In fact, percutaneous treatment of the distal main pulmonary artery presents several pitfalls regarding the anatomical setting (e.g. lumen diameter discrepancy between main pulmonary artery and pulmonary artery branches, acute angle of the bifurcation, ab-extrinsic distortions), the presence of different surgical materials (e.g., patches, conduits, etc.) and post-surgical scars. In addition, the risk of balloon instability (i.e., milking) during the inflation and stent dislodgment can lead to an unsuccessful procedure. In order to overcome these problems, some techniques were described to approach the distal pulmonary artery by one or more stents implantation. 6-11 On the other hand, this type of procedure needs to be tailored on the patient's characteristics, thanks to non-invasive assessment of the anatomy (CMR or CT scan) and with a careful pre-operative planning, taking into account possible issues due to the vascular access availability. Finally, in small children, percutaneous stenting with devices not expandable to adult size may create problems for future treatments of the same lesion, and they should be limited to rescue procedure and critical settings. In these patients, a kissing balloon approach may achieve a good result by avoiding stent implantation.

The aim of this study was to retrospectively analyse the outcome of the percutaneous transcatheter treatment in children with conotruncal disease involving the pulmonary artery bifurcation. In particular, we sought to evaluate the mid-term outcome of kissing balloon angioplasty in terms of safety and efficacy and compare the outcome of this technique with standard balloon dilatation and standard stenting (SS) approach.

Methods

We reviewed retrospectively all patients with conotruncal disease and post-surgical lesions involving the pulmonary artery bifurcation and the origin of one or both the pulmonary arteries undergoing percutaneous treatment between January 2014 and December 2021 in the Pediatric Cardiology Unit of University Hospital of Padua.

The inclusion criteria were conotruncal CHD and post-surgical stenosis involving distal main pulmonary artery and/or the origin of pulmonary artery branches. We excluded patients with univentricular physiology, undergoing Glenn or Fontan palliation, patients with tetralogy of Fallot and pulmonary atresia or other complex heart disease palliated with Goretex conduit, patients with right ventricle outflow tract obstruction localised below the sinotubular junction, patients with peripheral pulmonary branches stenosis, and patients with single pulmonary branch stenosis.

Among the 290 patients treated in our centre for right ventricle outflow tract and pulmonary artery angioplasty and/or stenting, 39 patients resulted eligible for this study.

The following patients' characteristics were described: demographics, cardiac diagnosis, surgical history, time to catheterisation, indications for catheterisation, haemodynamic data, angiographic measurements, type of percutaneous treatment, adverse events, patients' outcome, and follow-up including subsequent cardiac catheterisations or surgical procedures.

All cardiac catheterisations were performed under general anaesthesia. Pulmonary artery diameters were measured through selective angiograms. Balloon size was chosen based on the type of procedure, the size of the stenosis to be treated as well as the diameters of main pulmonary artery and pulmonary artery branches:

- standard high-pressure balloon (single balloon) (SB): balloon size was chosen between 1.5 and 2.5 times the stenosis diameter, provided that it did not exceed the nominal diameter of the vessel distal to the stenosis;
- kissing balloon (KB): the balloons maximum diameter were chosen in such a manner that the sum of the diameter of the two balloons multiplied by 0.8 was less than 1.5 times the diameter of the pulmonary artery trunk (the highest ratio suggested for balloon dilatation of pulmonary valve), and that the maximum diameter of the single balloon was equal to the nominal diameter of the corresponding pulmonary branch (to minimise the risk of pulmonary branch injury).
- Stent implantation: the stent diameter was selected based on the post-stenotic distal vessel size, and the length of the stent was based on the length of the stenosis and on the necessity to cover a tract of main pulmonary artery and/or pulmonary branch to straighten the bifurcation or to create an anchoring for a second stent. Procedures isolated to main pulmonary artery or pulmonary artery branches were defined as SS approach. When the pulmonary bifurcation was intentionally covered (jailing stent technique, JS), patients underwent de-jailing of the opposite pulmonary branch in order to preserve bilateral blood flow. Postdilatation of the stent, de-jailing or second/further stent(s) implantation were performed to shape the stent(s) on the anatomy of right ventricle outflow tract. Details on stent implantation can be found in previous works.⁶⁻¹¹ After stent implantation, we administrated Aspirin 2-5 mg/kg (max 100 mg) for 1 month in case of stents > 7 mm of diameter, or for 6 months in case of small stents (≤7 mm) or concomitant percutaneous pulmonary valve implantation.

Based on the technique chosen, procedures were divided in four groups: SB group, KB group, SS group, and JS group.

Procedural outcome

The procedure was considered effective if the residual invasive pressure gradient on the pulmonary bifurcation was <20

mmHg.¹² It was considered partially effective if the whole post-procedural invasive gradient remained between 20 and 40 mmHg, and it was at least halved, and the systolic pressure in the right ventricle was inferior to 2/3 of the systemic pressure.¹³

Follow-up

After the discharge, the patients were followed up in outpatient clinic every 6 months by clinical examination, electrocardiogram, and transthoracic echocardiogram in order to assess clinical status, to exclude the presence of arrythmia and evaluate biventricular function, and estimate right ventricle pressure and right ventricle outflow tract mean and peak gradients. In case of suspected significant residual lesions, a CT scan or a CMR was scheduled. Further management (clinical, surgical, or percutaneous interventions) was planned according to current recommendations or guidelines. 12–14

Statistical analysis

The statistical analysis was performed using SPSS Software (v. 27.0). Continuous variables were expressed as means and standard deviations and/or median and in interquartile ranges (Q25/Q50/Q75), depending on their distribution. The normal distribution was verified by Shapiro–Wilk test. Qualitative data were compared using Mantel–Haenszel's test. Continuous variables were compared using unpaired t-test or the Mann–Whitney U-test. The correlations were studied by linear regression analysis. The null hypothesis was rejected for a p value <0.05. The comparison of dichotomic variables were performed by using Chi-square text and applying the Yates' correction or Fisher's exact test, when appropriate.

Results

Thirty-nine patients fulfilled the inclusion criteria for this study. Twenty-two patients presented a surgically corrected tetralogy of Fallot, eight patients presented a surgically corrected truncus arteriosus, and nine patients presented a d-transposition of great arteries s/p arterial switch. Indication to treatment was right ventricle outflow tract obstruction in 23 patients, hypoperfusion of one lung in 5, right ventricle outflow tract obstruction and single lung hypoperfusion in 7, and associated right ventricle outflow tract obstruction and pulmonary regurgitation in 4. Haemodynamic measurement showed a mean gradient of $46.9 \pm 11.8 \text{ mmHg}$.

The treatment algorithm was synthetised in Figure 1. The mean age was 8.7 ± 7.8 years (median 6.0 years), and weight and body surface area were $31.0 \pm 26.3(19.0)$ kg and 1.00 ± 0.53 (1.00) m², respectively (Table 1).

Standard approach by starting with a SB dilation was adopted in 33 patients. In one patient, due to a kinking of the origin of the left pulmonary branch, a direct SS was chosen. JS was the first treatment in one patient. Finally, KB approach was the first choice in four patients. The largest balloon used was a Sterling balloon in 5 cases and a Dorado/Atlas Gold balloon in 21 patients. In three cases, a cutting balloon was needed to resolve a tight stenosis.

The results are summarised in Table 2.

SB was effective in five patients. In these patients, the global right ventricle outflow tract gradient dropped from 38.6 ± 3.0 to 12.7 ± 9.5 mmHg (p = 0.013) and the right ventricle/left ventricle pressure ratio from 0.70 ± 0.17 to 0.40 ± 0.12 (p = 0.014). In the remaining 28 cases, the pressure gradient reduction was below 10 mmHg, so a second step was planned: SS in 9, KB in 12, and JS in 7 patients (Table 2).

26 B. Castaldi et al.

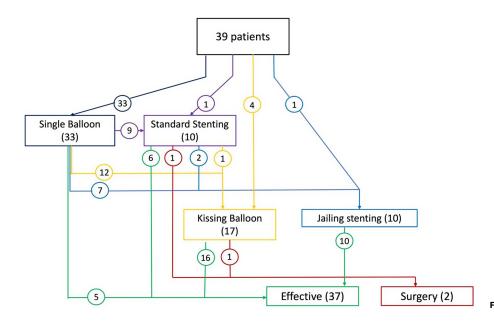


Figure 1. Algorithm of treatment and outcome.

Ten patients underwent a SS. This procedure was effective in 6/10 patients. Globally, the right ventricle outflow tract gradient dropped from 46.0 ± 12.3 mmHg to 23.2 ± 14.8 mmHg (p = 0.002) and right ventricle/left ventricle pressure ratio from 0.81 ± 0.25 to 0.52 ± 0.16 (p = 0.004). Between the six patients showing an effective result, the right ventricle outflow tract gradient dropped from 41.2 ± 13.2 mmHg to 13.1 ± 4.6 mmHg (p = 0.012) and right ventricle/left ventricle ratio from 0.76 ± 0.19 to 0.44 ± 0.11 (p = 0.007). Palmaz Blue stent was used in two patients (pulmonary branch), coronary stent in one patient (pulmonary branch), Andra XXL stent in one patient (main pulmonary artery), Palmaz Genesis stent in three and (pulmonary branch), and CP stent in two patients (main pulmonary artery).

In the four failing procedures, a JS was effectively performed in two cases, in one case a KB of pulmonary artery bifurcation was attempted, while in one patient the next step was surgery.

Seventeen patients were treated by KB approach (Figs 2 and 3), 4 as primary approach, 1 after left pulmonary artery SS, and 12 after ineffective SB. In these patients, the right ventricle outflow tract gradient dropped from 49.1 ± 11.9 mmHg to 21.8 ± 11.0 mmHg (p < 0.001) and right ventricle/left ventricle pressure ratio from 0.80 ± 0.33 to 0.45 ± 0.09 (p = 0.005). Between the 14 patients showing an effective procedure, the right ventricle outflow tract gradient dropped from 44.8 ± 8.0 mmHg to 17.0 ± 3.3 mmHg (p < 0.001) and right ventricle/left ventricle ratio from 0.69 ± 0.07 to 0.40 ± 0.09 (p = 0.01). The procedure was performed by using Dorado, Atlas Gold balloons, or a combination of both in 12 cases (2 veins approach in 13 and single vein approach in one); in five patients, two Sterling balloons were used (single vein approach). Among the cases with partially effective result after kissing balloon, two presented a post-arterial switch anatomy, and the third patient a truncus arteriosus already treated with left pulmonary artery stenting. The latter patient described underwent surgery at 8 years of life (4 years after kissing balloon procedure) for surgical replacement of pulmonary conduit and pulmonary branch angioplasty.

Finally, 10 patients were treated with JS (Figs 4 and 5), as first procedure in 1 patient, after failing SB approach in 7, and after single-branch stenting in 1 patient. Eight of them were scheduled for

further percutaneous pulmonary valve implantation. The procedure was effective in all the patients, and the right ventricle outflow tract gradient dropped from 58.1 ± 9.5 mmHg to 12.0 ± 8.2 mmHg (p < 0.001) and right ventricle/left ventricle pressure ratio from 0.93 ± 0.19 to 0.41 ± 0.10 (p < 0.001). The technique of stent(s) deployment consisted of a stent implantation in the smallest pulmonary artery branch and subsequent de-jailing in four patients, "culotte" technique in three, and "T" stenting in three patients. He fifurcation was covered with Andra XL stent in seven cases and XXL in two cases, and a Palmaz Genesis XD stent was used in one case. A single stent (excluding percutaneous pulmonary valve stent) was used in four cases, two stents in four cases, and three stents in two cases.

Compared to JS, patients treated with a KB approach were younger (6.0 ± 5.2 years, median 2.0 years versus 13.6 ± 5.4 years, median 11.5 years). In addition, 9/10 of JS group were tetralogy of Fallot and only 1 had d-transposition of great arteries, while in KB group 6 patients had d-transposition of great arteries, 8 tetralogy of Fallot, and 3 truncus arteriosus. Interestingly, patients with a KB approach did not need further JS. Regarding the three unsuccessful KB procedure, one patient was referred for surgery due to an undilatable intra-stent stenosis and conduit degeneration in truncus arteriosus history, while two patients presented residual stenosis due to the effect of ascending aorta on the Lecompte manoeuvre. In all of them, stenting implantation was contraindicated.

Complications

In SS group, a contralateral branch jailing was documented in two cases. In one patient, no further manoeuvre was planned, while in the second patient a balloon dejailing by stent strut enlargement was performed. The third patient showed a second-grade fracture, and the patient was addressed to surgery for concomitant conduit replacement and pulmonary branches angioplasty.

In JS group, one patient suffered from hemothorax due to peripheral guidewire injury requiring emergent percutaneous drainage and blood transfusion. The culprit vessel was embolised successfully with an Amplatzer Vascular Plug IV 6 mm. The patient was discharged 2 days after the procedure. His follow-up was uneventful.

Table 1. Patients' characteristics.

	Mean ± SD	Quartiles [25 th ;50 th ;75 th]
Age (years)	8.7 ± 7.8	2.4 ;6.0; 14.7
Weight (kg)	31.0 ± 26.3	11.5; 19; 51.5
Height (cm)	119.1 ± 36.6	92; 113; 156
BSA (m²)	1.00 ± 0.53	0.54; 0.75; 1.55
LV pressure (mmHg)	90.0 ± 15.8	80; 90;100
RV pressure (mmHg)	67.3 ± 14.6	55; 65; 75
RV/Ao ratio	0.75 ± 0.24	0.62; 0.73; 0.85
Total RVOT gradient (mmHg)	46.9 ± 11.8	38.0; 47.0; 67.0

Ao = aorta; LV = left ventricle; PA = pulmonary artery; RV = right ventricle; RVOT = right ventricular outflow tract; SD = standard deviation.

Follow-up

The mean follow-up was 20 ± 15 months (interquartile range 8/20/35 months). The five patients with effective SB approach showed a right ventricle pressure of 45.8 ± 20.2 mmHg, and an right ventricle outflow tract peak gradient was 33.2 ± 14.7 mmHg. Among the six patients with effective SS, one patient with right pulmonary artery stenting underwent surgical replacement of right ventricle conduit due to degeneration of the 12-mm Contegra conduit. The remaining five patients presented a peak right ventricle outflow tract gradient of 30.0 ± 7.8 mmHg. Among the eight patients treated with successful or partially effective KB, right ventricle pressure was 44.0 ± 8.1 mmHg and right ventricle outflow tract peak pressure gradient was 25.0 ± 11.2 mmHg. Finally, the 11 patients undergone JS showed a right ventricle pressure of 31.3 ± 8.8 mmHg and a right ventricle outflow tract peak pressure gradient of 25.4 ± 13.1 mmHg.

Subgroup analysis

The analysis of d-transposition of great arteries patients group showed: seven patients underwent SB angioplasty, ineffective in all the cases, and six of them treated by KB approach. A JS was the first choice in one patient. After SB, the gradient dropped from 40.2 \pm 8.6 mmHg to 35.6 \pm 20.1 mmHg (p = 0.51), while after KB and bifurcation stenting the gradient dropped from 50.0 \pm 8.0 to 21.5 \pm 2.6 mmHg (p = 0.02), with effective procedure in one patient, partially effective in two patients, and ineffective in one patient (Table 3). In the latter, patient persisted a valvular stenosis not eligible of stenting due to coronary compression documented during the angioplasty.

The analysis of the baseline pressure gradient among our cohort revealed that only six patients started the first procedure with a peak gradient between right ventricle and distal pulmonary artery ≤40 mmHg. The SB was effective in four of them, while in two patients a stent was implanted due to a persisting stenosis secondary to vessel kinking. The gradient was >40 mmHg in 26 patients. In this subgroup, SB dilatation was effective in only 1 patient, while a second step by a KB was effective in 13 patients. However, 16 patients were treated with 1 or more stents implantation, while in 2 patients no further treatment was attempted due to the small age of the children.

Discussion

Right ventricle outflow tract and pulmonary artery branches stenoses mainly affect conotruncal defects and represent a frequent scenario in the post-surgical history of these patients.¹ Guidelines summarise the indications for percutaneous/surgical treatment of this population; ^{13,15} however, the operative modalities need to be customised on the patient's anatomy. Percutaneous approach is preferred because less invasive and better tolerated and often is sufficient to improve the lesion avoiding a second or further surgery. Nevertheless, the efficacy of interventional procedure relies on several factors, such as the location of the stenosis, the underlying pathology, previous surgical operation(s), the relationship with surrounding structures/organs (i.e. aorta, coronary arteries, and bronchi), and the age of the patient.

Thus, a stenosis close to the pulmonary bifurcation often represents a complex lesion, challenging to define and to treat.^{7,16} Although single-balloon angioplasty of post-surgical stenotic right ventricle outflow tract often yields pressure gradient reduction and effective vessel diameter increase, the results obtained are often temporary, necessitating re-intervention in the mean to long term. 17,18 Since the introduction of high-pressure balloons, results of balloon pulmonary angioplasty have improved significantly, and stent implantation has further increased the short-term success rate up to 90% and more. 13,15-17 Various stenting techniques have been implemented for complex anatomies, achieving good results in terms of procedure effectiveness. 5,6,8,19-22 Nonetheless, stent implantation in children is burdened by a relatively high rate of complications (e.g. coronary compression, aneurysm-dissection or rupture of pulmonary arteries, aorto-pulmonary fistula formation, and stent malposition). 16,23,24 In addition, the need of large delivery systems in small children may cause problems on the vascular access and haemodynamic instability due to catheterinduced pulmonary and tricuspid valve regurgitation. Finally, as suggested by guidelines, stent implantation should be considered only if the device can be dilated up to adult size, when the risk to compromise the pulmonary valve function is low and when the pulmonary bifurcation is not impinged.¹³ Despite the recent availability of low-profile stents dilatable to large diameters, balloon pulmonary angioplasty continues to be the first option in pulmonary bifurcation stenosis in small children or infants. 13,25 Procedural technical failure can be summarised in: balloon undersizing or balloon instability due to change in calliper between pulmonary artery and pulmonary branches, transient change in geometry of right ventricle outflow tract during balloon inflation with consequent loss in radial force during the manoeuvre, undilatable stenoses despite high pressure or cutting balloons, and presence of arterial kinking.

KB technique was described for the first time in the 1980 by Kurt Amplatz, by using two 9-mm balloons from a bilateral femoral artery approach to treat a Leriche syndrome. ²⁶ In the next decades, this approach became a valuable technique for aortic lesions involving iliac bifurcations. ²⁷ The same technique was used for the first time in 1989 to treat a coronary lesion by using a single guiding catheter. ²⁸ Since that first experience, KB became the standard of care for coronary bifurcation stenoses, before or after stenting. ²⁹

Based on our data, a severe distal right ventricle outflow tract stenosis with a right ventricle–pulmonary artery branches peak-to-peak gradient >40 mmHg is unlikely to be due to a single-branch stenosis; therefore, a standard approach (SB or SS) has high probability to fail.

28 B. Castaldi et al.

Table 2. Procedural outco	omes. The gradients are expre	essed in mmHg. EP: effective or	partially effective procedures.
---------------------------	-------------------------------	---------------------------------	---------------------------------

	n. pts treated	RVOT press	RVOT pressure gradient		RV/LV pressure ratio			
Group	(EP)	pre	pre post		pre	post	p-Value	
SB	33	44.4 ± 15	29 ± 14.7	0.002	0.77 ± 0.26	0.53 ± 0.18	0.001	
	(5)	38.6 ± 3.0	12.7 ± 9.5	0.013*	0.7 ± 0.17	0.4 ± 0.12	0.014	
SS	10	46.0 ± 12.3	23.2 ± 14.8	0.002	0.81 ± 0.25	0.52 ± 0.16	0.004	
	(6)	41.2 ± 13.2	13.1 ± 4.6	0.012*	0.76 ± 0.19	0.44 ± 0.11	0.007	
KB	17	49.1 ± 11.9	21.8 ± 11.0	<0.001	0.80 ± 0.33	0.45 ± 0.09	0.005	
	(16)	44.8 ± 8. 0	17.0 ± 3.3	>0.001*	0.69 ± 0.07	0.40 ± 0.09	0.01	
JS	10 (10)	58.1 ± 9.5 -	12.0 ± 8.2 -	<0.001*	0.93 ± 0.19 -	0.41 ± 0.10 -	<0.001 -	

LV = left ventricle; RV = right ventricle; RVOT = right ventricular outflow tract.

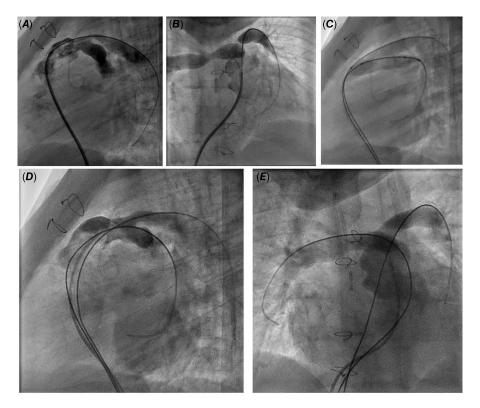


Figure 2. Three-year baby, residual multiple stenosis after surgical correction of truncus arteriosus. (*A*) Severe stenosis of the origin of left pulmonary artery and distal main pulmonary artery; (*B*) stenosis of distal right pulmonary artery. After selective balloon dilatation of right, left, and main pulmonary artery stenosis (see supplementary video 1), whole gradient dropped from 75 mmHg to 45 mmHg. Finally, a kissing balloon approach was used (*C*), with a good result (*D*, *E*). Final RVOT gradient was 20 mmHg, and RV/Ao dropped to 75% after standard balloon approach to fall to 50% after kissing balloon.

According to our institutional protocol, an approach with SB angioplasty was applied as first-line option, followed by KB. On the other hand, SS was considered in case of vessel kinking (first choice) or in case of angioplasty failure or complications.

In our experience, KB enables to accommodate safely the balloons in the pulmonary branches, allowing larger effective diameters and higher stability of the system during balloon inflation. Moreover, in young children, a KB approach might be also performed with smaller (4–5 Fr) short sheaths using double-vein approach, minimising the risk of vascular access injuries. Since 2018, KB technique was considered in selected cases as the first choice or as alternative approach, when SB was ineffective.

To the best of our knowledge, this is the first study to evaluate systematically the short- and mid-term efficacy of KB on pulmonary artery bifurcation lesions in the paediatric age. Specifically, we demonstrated that this technique is particularly effective in patients with post-arterial switch anatomies and in presence of significant

distortion of the pulmonary bifurcation, since standard balloon dilatation often fails in relieving the gradient, avoiding or delaying further and challenging manoeuvres (stenting or surgery).

In older patients with concomitant pulmonary valve degeneration, JS can be considered as the first approach to resolve the pulmonary branch stenosis and create a landing zone for pulmonary valve implantation in the same procedure or in the short- or midterm follow-up. In fact, a radical relief of the gradient can improve the outcome of the procedure, by reducing the risk of both pulmonary valve degeneration and endocarditis and by increasing the stress tolerance. ^{30–31} In addition, in pyramidal right ventricle outflow tract shape, the JS technique may offer a unique landing zone and increase the stability of the implanted pulmonary valve. In our centre, a two-stage approach was offered when the stents implantation was expected to be long or when the stent implanted required further shape optimisation, to limit the procedural time, the X-ray exposure, and contrast media administration.

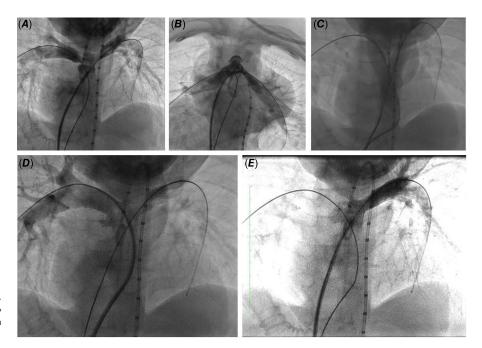


Figure 3. TGA s/p arterial switch, 5-year bilateral pulmonary branch stenosis involving distal pulmonary artery (A,B), approached with direct kissing balloon (C), with good final result (D,E).

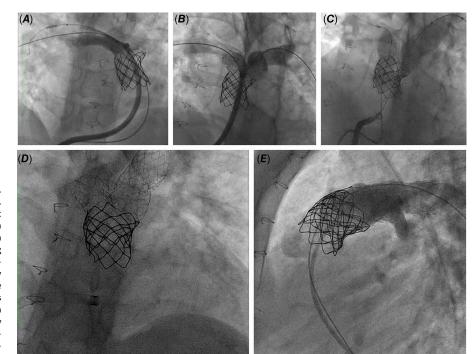


Figure 4. Multiple stenosis in ToF patient (age 16 years). A CP stent was implanted in a previous procedure (A). Baseline gradient was 40 mmHg. The stenosis of right pulmonary artery was treated first with a 48-mm Andra XL stent (B), and the stent was post-dilated in order to shape the distal part of the stent following the bifurcation. The left pulmonary artery was progressively de-jailed up 14 mm and the pulmonary artery bifurcation was dilated by kissing balloon technique up (C), then a second Andra XL stent 57 mm was implanted on the left pulmonary artery to straighten a kinking (TAP technique) (D). Finally, a 22-mm Melody valve was implanted in anatomic position (E). Final gradient is 15 mmHg. For more details, please see supplementary video 2.

Limitations

This study has some limitations. First is the retrospective nature of the study. Therefore, no randomisation or the application of pre-fixed algorithm of treatment was possible. Second, the number of patients enrolled is relatively low, despite this is the large case series published in this field. Third, age and weight and anatomical features of the patients were heterogeneous. All these factors may impact the therapeutical choice and the options available.

Conclusion

Despite a detailed multimodality imaging to study the right ventricle outflow tract anatomy, the treatment of distal pulmonary trunk and pulmonary artery bifurcation in patients surgically treated for conotruncal CHDs may be difficult.

In patients with right ventricle outflow tract obstruction involving this anatomical site, standard balloon angioplasty and selective pulmonary branch stenting may be ineffective. In this setting, a kissing balloon approach may be more appropriate and more effective. 30 B. Castaldi et al.

Table 3. Subgroup analysis based on the underlying pathology and the baseline gradient.

		E or	E or PE procedure/n°pts treated		$\begin{array}{c} \text{p-Value} \\ \text{(SB} + \text{SS versus KB)} \end{array}$	$ \begin{array}{c} {\sf p\text{-}Value} \\ {\sf (SB+SS\ versus\ KB+JS)} \end{array} $	
Subgroup according to disease	N. of pts			SB	SS	КВ	JS
d-TGA	9	0/8	0/0	5/6	1/1	0.003	0.001
ToF	23	3/17	5/8	7/7	9/9	0.002	<0.001
TA	8	2/8	1/2	3/4	_	0.24	0.24
Subgroup according to RV–PA gradient							
RV-PA ≤ 40 mmHg	6	4/4	1/1	_	0/0	_	
RV-PA > 40 mmHg	34	1/29	5/9	15/17	10/10	<0.001*	<0.001

E = effective; KB = kissing balloon; PE = partially effective; RV-PA = right ventricle-pulmonary artery; SB = single balloon; SS = standard stenting; ToF = tetralogy of Fallot.

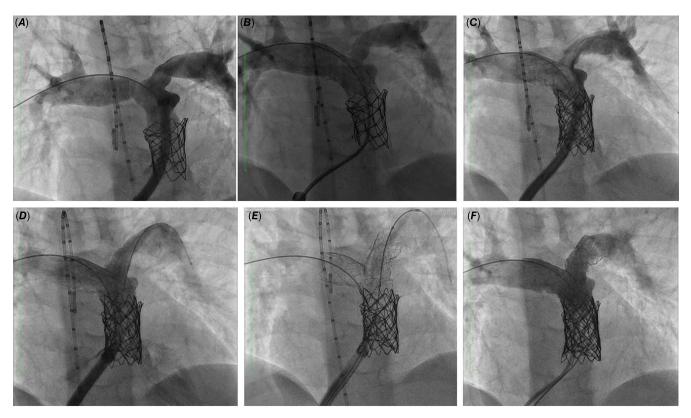


Figure 5. Tetralogy of Fallot with multiple stenosis. A CP stent was previously implanted in the conduit; however, it showed several fractures. First, a 57-mm XL Andra stent was implanted in right pulmonary artery (**A**), and the overlap between CP and Andra stent was weak (**B**), so a CP stent was implanted to stabilise the system (**C**). The left pulmonary artery was approached by opening the Andra stent struts up to 14 mm by using an Atlas Gold balloon (**D**). The residual stenosis was approached by implanting a 30-mm Andra stent (TAP technique) (**E**). Finally, a 22-mm Melody valve was implanted. Whole gradient dropped from 50 mmHg to 0 mmHg. See supplementary video 3 for more details.

When the percutaneous pulmonary valve implantation is indicated, stenting of the bifurcation starting from the left or the right pulmonary branch may be chosen to break down the right ventricle outflow tract gradient and create an effective anchoring before the valve placement.

Supplementary material. To view supplementary material for this article, please visit https://doi.org/10.1017/S1047951123000999

Financial support. This research received no specific grant from any funding agency, commercial, or not-for-profit sectors.

Competing interest. None.

References

- Michalak KW, Moll JA, Sobczak-Budlewska K, et al. Reoperations and catheter interventions in patients with transposition of the great arteries after the arterial switch operation. Eur J Cardiothorac Surg 2017; 51: 34–42.
- Boumpouli M, Danton MHD, Gourlay T, Kazakidi A. Blood flow simulations in the pulmonary bifurcation in relation to adult patients with repaired tetralogy of Fallot. Med Eng Phys 2020; 85: 123–138.
- Tang T, Chiu I-S, Chen H-C, Cheng K-Y, Chen S-J. Comparison of pulmonary arterial flow phenomena in spiral and Lecompte models by computational fluid dynamics. J Thorac Cardiovasc Surg 2001; 122: 529–534.
- Budts W, Pieles GE, Roos-Hesselink JW, et al. Recommendations for participation in competitive sport in adolescent and adult athletes with Congenital Heart Disease (CHD): position statement of the Sports

Cardiology & Exercise Section of the European Association of Preventive Cardiology (EAPC), the European Society of Cardiology (ESC) Working Group on Adult Congenital Heart Disease and the Sports Cardiology, Physical Activity and Prevention Working Group of the Association for European Paediatric and Congenital Cardiology (AEPC). Eur Heart J 2020: 41: 4191–4199.

- Gonzalez I, Kenny D, Slyder S, Hijazi ZM. Medium and long-term outcomes after bilateral pulmonary artery stenting in children and adults with congenital heart disease. Pediatr Cardiol 2013; 34: 179–184.
- Stapleton GE, Hamzeh R, Mullins CE, et al. Simultaneous stent implantation to treat bifurcation stenoses in the pulmonary arteries: initial results and long-term follow up. Cathet Cardiovasc Intervent 2009; 73: 557–563.
- Stumper O, Bhole V, Anderson B, Reinhardt Z, Noonan P, Mehta C. A novel technique for stenting pulmonary artery and conduit bifurcation stenosis. Cathet Cardiovasc Intervent 2011; 78: 419–424.
- Narayan HK, Glatz AC, Rome JJ. Bifurcating stents in the pulmonary arteries: a novel technique to relieve bilateral branch pulmonary artery obstruction: bifurcating pulmonary artery stents. Cathet Cardiovasc Intervent 2015; 86: 714–718.
- Brown SC, Cools B, Boshoff DE, et al. Delivering stents in congenital heart disease using the double-wire technique: technical considerations: dualwire stenting: new applications. Cathet Cardiovasc Intervent 2013; 82: 1156–1163.
- Boudjemline Y, Legendre A, Ladouceur M, et al. Branch pulmonary artery jailing with a bare metal stent to anchor a transcatheter pulmonary valve in patients with patched large right ventricular outflow tract. Circ Cardiovasc Interv 2012; 5, 10.1161/CIRCINTERVENTIONS.112.968610 [cited 2021 Dec 6], https://www.ahajournals.org/doi/10.1161/CIRCINTERVENTIONS.112.968610,
- Violini R, Vairo U, Hijazi ZM. Stent strut breakage using high-pressure balloons for bifurcation stenting and subsequent percutaneous pulmonary valve replacement using the Edwards Sapien THV: Stent Strut Breakage & Edwards Sapien Pulmonary Valve. Cathet Cardiovasc Intervent 2013; 82: 834–837.
- Hiremath G, Qureshi AM, Meadows J, Aggarwal V. Treatment approach to unilateral branch pulmonary artery stenosis. Trends Cardiovasc Med 2021; 31: 179–184.
- Feltes TF, Bacha E, Beekman RH, et al. Indications for cardiac catheterization and intervention in pediatric cardiac disease: a scientific statement from the American Heart Association. Circulation 2011; 123: 2607–2652.
- Lassen JF, Holm NR, Stankovic G, et al. Percutaneous coronary intervention for coronary bifurcation disease: consensus from the first 10 years of the European Bifurcation Club meetings. EuroIntervention 2014; 10: 545–560. DOI 10.4244/EIJV10I5A97.
- Stout KK, Daniels CJ, Aboulhosn JA, et al. 2018 AHA/ACC guideline for the management of adults with congenital heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation 2018; 139: e698–e800.

- Patel ND, Sullivan PM, Takao CM, Badran S, Ing FF. Stent treatment of ostial branch pulmonary artery stenosis: initial and medium-term outcomes and technical considerations to avoid and minimise stent malposition. Cardiol Young 2020; 30: 256–262.
- Bush DM, Hoffman TM, Del Rosario J, Eiriksson H, Rome JJ. Frequency of restenosis after balloon pulmonary arterioplasty and its causes. Am J Cardiol 2000; 86: 1205–1209.
- Nellis JR, Turek JW, Aldoss OT, Atkins DL, Ng BY. Intervention for supravalvar pulmonary stenosis after the arterial switch operation. Ann Thorac Surg 2016; 102: 154–162.
- Zablah JE, Morgan GJ. Pulmonary artery stenting. Interv Cardiol Clin 2019;
 33-46.
- Lewis MJ, Kennedy KF, Ginns J, et al. Procedural success and adverse events in pulmonary artery stenting. J Am Coll Cardiol 2016; 67: 1327–1335.
- Conijn M, Breur H, Molenschot M, Voskuil M, Krings G. The Y-stenting technique for pulmonary artery bifurcation stenosis: initial results and midterm outcomes. Int J Cardiol 2018; 268: 202–207.
- Zampi JD, Loccoh E, Armstrong AK, et al. Twenty years of experience with intraoperative pulmonary artery stenting: Intraoperative Pulmonary Artery Stents. Catheter Cardiovasc Interv 2017; 90: 398–406.
- Holzer RJ, Gauvreau K, Kreutzer J, et al. Balloon angioplasty and stenting of branch pulmonary arteries: adverse events and procedural characteristics: results of a multi-institutional registry. Circul Cardiovasc Interv 2011; 4: 287–296.
- Lee J, Abdullah Shahbah D, El-Said H, Rios R, Ratnayaka K, Moore J. Pulmonary artery interventions after the arterial switch operation: unique and significant risks. Congenit Heart Dis 2019; 14: 288–296.
- Nakanishi T, Matsumoto Y, Seguchi M, Nakazawa M, Imai Y, Momma K. Balloon angioplasty for postoperative pulmonary artery stenosis in transposition of the great arteries. J Am Coll Cardiol 1993; 22: 859–866.
- Velasquez G, Castaneda-Zuniga W, Formanek A, et al. Nonsurgical aortoplasty in Leriche syndrome. Radiology [Internet] 1980, [cited 2021 Dec 6]; Available from:, https://pubs.rsna.org/doi/abs/10.1148/radiology.134.2. 7352213
- Tegtmeyer CJ, Kellum CD, Kron IL, Mentzer RM. Percutaneous transluminal angioplasty in the region of the aortic bifurcation. the two-balloon technique with results and long-term follow-up study. Radiology 1985; 157: 661–665.
- van Leeuwen K, Blans W, Pijls NHJ, van der Werf T. Kissing balloon angioplasty of a circumflex artery bifurcation lesion. Chest 1989; 95: 1144–1145.
- Sgueglia GA, Chevalier B. Kissing balloon inflation in percutaneous coronary interventions. JACC: Cardiovasc Interv 2012; 5: 803–811.
- Georgiev S, Ewert P, Tanase D, et al. A low residual pressure gradient yields excellent long-term outcome after percutaneous pulmonary valve implantation. JACC Cardiovasc Interv 2019; 12: 1594–1603.
- McElhinney DB, Zhang Y, Aboulhosn JA, et al. Multicenter study of endocarditis after transcatheter pulmonary valve replacement. J Am Coll Cardiol 2021; 78: 575–589.