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ORIGINAL ARTICLE

Usefulness of cutting balloon angioplasty for the treatment of congenital heart defects

Jacek Kusa[1, 2], Magdalena Mazurak[2], Agnieszka Skierska[1], Leslaw Szydlowski[1], Pawel Czesniewicz[2], Lukasz Manka[1]

[1]Pediatric Cardiology Department, Medical University of Silesia, Katowice, Poland
[2]Pediatric Cardiology Department, Regional Specialized Hospital — Research and Development Centre, Wroclaw, Poland

Abstract

Background: *Patients with complex congenital heart defects may have different hemodynamic problems which require a variety of interventional procedures including angioplasty which involves using high-pressure balloons. After failure of conventional balloon angioplasty, cutting balloon angioplasty is the next treatment option available. The purpose of this study was to evaluate the safety and efficacy of cutting balloon angioplasty in children with different types of congenital heart defects.*

Methods: *Cutting balloon angioplasty was performed in 28 children with different congenital heart defects. The indication for cutting balloon angioplasty was: pulmonary artery stenosis in 17 patients, creating or dilatation of interatrial communication in 10 patients, and stenosis of left subclavian artery in 1 patient.*

Results: *In the pulmonary arteries group there was a significant decrease in systolic blood pressure (SBP) in the proximal part of the artery from the average 74.33 ± 20.4 mm Hg to 55 ± 16.7 mm Hg ($p < 0.001$). Distal to the stenosis there was an increase in SBP from 19.8 ± 3.82 mm Hg to 30.3 ± ± 13.3 mm Hg ($p = 0.04$). This result remained constant in the follow-up. In atrial septal defect/fenestration group, cutting balloon angioplasty was performed after an unsuccessful classic Rashkind procedure. After cutting balloon angioplasty there was a significant widening of the interatrial communication.*

Conclusions: *Cutting balloon angioplasty is a feasible and effective treatment option in different congenital heart defects.* (Cardiol J 2018; 25, 2: 165–170)

Key words: cutting balloon, angioplasty, children, congenital heart defect

Introduction

The use of cutting balloons (CB) in coronary stenoses is a common procedure in catheterization laboratories [1]. However, cutting balloon angioplasty (CBA) in congenital heart defects is not as frequent. Patients with complex congenital heart defects may have various hemodynamic problems, which require a variety of interventional procedures including angioplasty by using high-pressure balloons. The conventional balloon dilation technique traditionally performed to treat vessel stenoses can be unsuccessful in some cases [2]. Lack of Dacron tunnel compliance in individuals with Fontan circulation poses serious problems during the creation of percutaneous fenestration in patients with failing Fontan circulation. Thick, muscular interatrial septum in hypoplastic left heart syndrome (HLHS) children can be unsusceptible to angioplasty in some cases. After failure of conventional balloon angioplasty CBA is an important additional available treatment option.

Address for correspondence: Jacek Kusa, MD, PhD, Regional Specialized Hospital, Pediatric Cardiology Department, ul. Kamieńskiego 73a, 51–124 Wrocław, Poland, tel: +48 71 3270141, fax: +48 71 3270578, e-mail: jkusa@poczta.onet.pl

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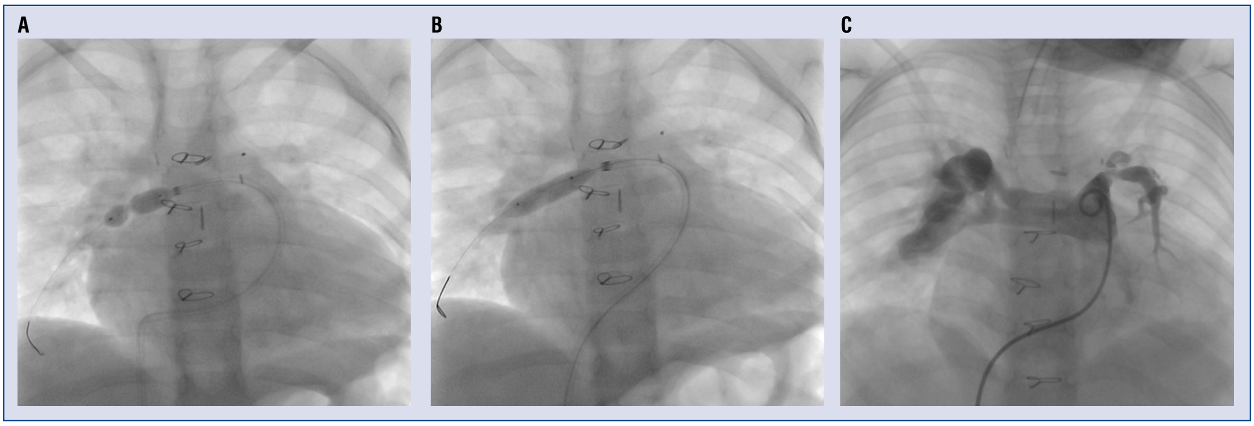

Figure 1. A. Predilation of the right pulmonary artery in a patient post total correction (with unifocalization) of pulmonary atresia, ventricular septal defect without pulmonary arteries; **B.** The subsequent angioplasty with cutting balloon; **C.** The final result — the optimal widening of the vessel.

The purpose of this study was to evaluate the efficacy and safety of CBA in children with different types of congenital heart defects.

Methods

Between October 2008 and July 2016 30 CBA were performed in 28 children (16 of them boys). Two individuals had a repeated procedure. Children were in the age range from 1 month to 15 years (mean 62 ± 67 months, median 36 months) and body weight ranged from 2.4 to 61 kg (mean 20.6 ± ± 18.65 kg).

Clinical presentation covered an expanded spectrum of congenital heart defects: pulmonary atresia with ventricular septal defect (PA+VSD) — 10 (35.7%) patients, HLHS — 6 (21.4%) patients, transposition of the great arteries (TGA) — 4 (14,3%), common arterial trunk (TAC) — 2 (7.1%), tetralogy of Fallot (ToF) — 2 (7.1%), coarctation of the aorta (CoA) — 1 (3.6%) patient, double outlet right ventricle (DORV) — 1 (3.6%), tricuspid atresia (TA) — 1 (3.6%) and congenital severe mitral regurgitation — 1 (3.6%) patient.

Indications for CBA were the following: iatrogenic pulmonary arteries stenosis after Glenn/ /Fontan operation — 3 (9.7%) patients, iatrogenic pulmonary arteries stenosis after arterial switch operation, ToF or TAC correction — 6 (19.4%) patients, iatrogenic pulmonary arteries stenosis after unifocalization or homograft implantation — 11 (35.5%) patients, restriction at atrial level — 7 (22.6%) patients, failing Fontan — 3 (9.7%) patients and left subclavian artery stenosis in CoA — 1 (3.2%) patient.

Overall, 31 lesions were treated: atrial septal defect (ASD) — 7 (22.6%) patients, right pulmonary artery (RPA) — 16 (51.6%), left pulmonary artery (LPA) — 4 (12.9%), fenestration — 3 (9.7%), left subclavian artery (LSA) — 1 (3.2%) patient.

More than one structure was treated by angioplasty during 15 (48.4%) procedures, CBA of two vessels was performed in 3 of them (9.7%).

In 3 (9.7%) patients CBA was performed as an emergency procedure, being a planned procedure in the rest of the cases.

In the majority of patients the peripheral CB was used (Boston Scientific, Marlborough, MA). In 1 case AngioSculpt PTA Scoring Balloon Catheter (Spectranetics, Colorado Springs, CO) was used.

The diameters of cutting balloons were: 4 mm in 5 (16.1%) patients, 6 mm in 12 (38.7%) patients, 7 mm in 1 patient and 8 mm in 13 (41.9%) patients.

Predilation by low pressure balloon was performed in 28 (90.3%) cases for calibration and the adjustment of the narrowing (Fig. 1). The diameter of selected CB was equal or slightly larger (not more than 20%) compared to the diameter of the vessel proximal to the narrowing. After CBA the vessel pressures and diameters were measured again. If the result was suboptimal an additional conventional balloon angioplasty was performed (17 cases; 54.8%) (Fig. 2).

In 1 case of a 15-year-old boy, ASD was successfully dilated by using two balloons simultaneously: 8 mm cutting balloon and 15 mm conventional balloon (ASD was wider than the largest available cutting balloon). In another patient, CBA was performed having a very good result after the failure of high-pressure balloon angioplasty of an in-stent restenosis.

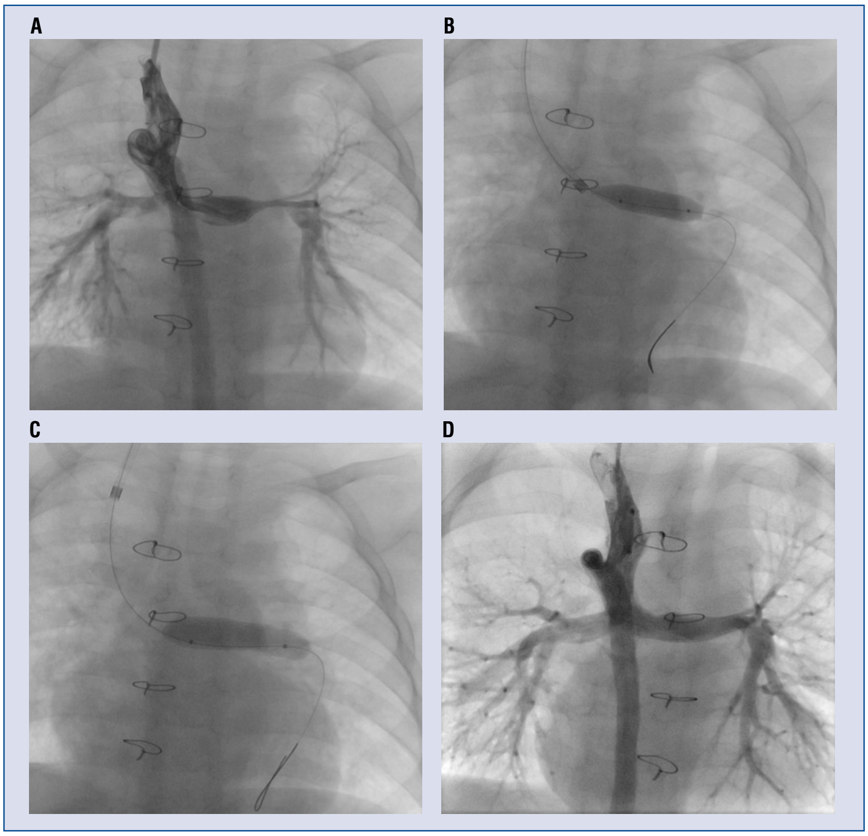

Figure 2. A. The critical stenosis of the left pulmonary artery in a patient with hypoplastic left heart syndrome after banding of both pulmonary arteries; **B.** The angioplasty with a cutting balloon; **C.** The subsequent angioplasty with a high-pressure balloon; **D.** The final result with normalization of the diameter of the vessel.

Results

Lesions were divided into three groups: ASD/ /fenestrations — 10 (32.3%) patients, pulmonary arteries — 17 (54.8%) and others — 1 (3.2%) patient.

Pulmonary arteries

Cutting balloon angioplasty (17 patients, 20 procedures) was performed in children with HLHS — 3, TAC — 2, PA+VSD — 11, TGA — 2, ToF — 2 (Table 1). In 16 (80%) of these cases primary angioplasty was performed by conventional balloon dilation, followed by CBA. CBA was performed in 4 LPA and in 16 RPA. Post-CBA, secondary angioplasty by conventional or high-pressure balloons was performed in 11 (55%) cases.

A successful procedure was defined as achieving ≥ 50% increase in the vessel diameter and a significant reduction of peak systolic gradient at catheterization. In the present study the mean value of minimum lumen diameter (MLD) increased from 2.16 ± 0.72 mm to 5.6 ± 1.26 mm ($p < 0.001$; Wilcoxon test). There was a significant decrease in systolic blood pressure (SBP) in the proximal part of the vessel from the average 74.33 ± 20.4 mm Hg to 55 ± 16.7 mm Hg ($p < 0.001$). Distal to the stenosis there was an increase in SBP from 19.8 ± ± 3.82 mm Hg to 30.3 ± 13.3 mm Hg ($p = 0.04$).

The RV/Ao SBP ratio decreased significantly from 0.9 ± 0.24 to 0.59 ± 0.03 ($p < 0.01$). The Fontan patients were excluded from this analysis due to a different patophysiology.

In this group a high correlation ($r = 0.8$; $p = 0.001$; Pearson correlation) was observed between CB/MLD diameter ratio and the percentage increase in dimension of the dilated arteries.

There was no significant difference in the percentage increase of vessel size between the group in which secondary angioplasty by conventional balloon post-CBA was performed and the group without it (164.6 ± 79.6% vs. 188.35 ± 82.1%, $p = 0.57$).

The results of echocardiographic assessment of the tricuspid regurgitation maximum instantaneous gradient measured prior to and post-catheterization were also compared. They revealed a significant decrease in tricuspid regurgitation

Table 1. Cutting balloon angioplasty (except Glenn patients) — procedural characteristics.

	Sex/age [months]	Baseline diameter [mm]	Post-treatment diameter [mm]	Percent increase in diameter (% change of diameter, initial to final)	Initial RV/Ao	Final RV/Ao
1	M/4	1.7	5	194	n/d	n/d
2	M/4	2.3	5.1	121	n/d	n/d
3	M/52	4	5	25	0.73	0.57
4	F/18	2	6.2	210	1.11	0.64
5	F/30	2.3	6.8	195	1.17	0.69
6	M/7.5	1.3	3.5	169	1.08	0.7
7	M/7.5	2	3.65	82.5	n/d	n/d
8	F/44	2.4	5.6	133	1.41	0.8
9	F/44	1.8	6.9	283	1.45	0.75
10	F/35	1.6	6.2	287	1.1	0.65
11	F/36	1.8	6.8	277	0.49	0.35
12	F/28	1.7	5.6	229	0.73	0.41
13	M/72	2	3.5	75	1.06	0.65
14	M/165	2.1	5.8	176	n/d	n/d
15	M/94	3.7	7.5	103	0.89	0.49
16	F/43	1.9	5.5	189	1.07	0.61

Ao — aorta; F — female; M — male; RV — right ventricle; n/d — no data

peak gradient (TRPG) from 76.1 ± 19.3 mm Hg to 52.7 ± 17.7 mm Hg ($p < 0.01$; Wilcoxon test).

The first follow-up was conducted 1 month post-angioplasty. There was a significant decrease in the TRPG compared to TRPG values evaluated immediately post-catheterization (from 52.7 ± 17.7 mm Hg to 42.4 ± 9.8 mm Hg, $p < 0.01$). A control echocardiographic examination was performed approximately at 6 months post-catheterization (in 13/17 patients; 76,5%). The difference in the average value of TRGP in comparison to the previous examination did not reach statistical significance threshold (39 ± 11.5 mm Hg vs. 44 ± 18.1 mm Hg, $p = 0.35$). The results remained the same in the next 6-month follow-up. The diagnostic cardiac catheterization was performed in 6 patients 1-year post-angioplasty. They confirmed constant satisfying result: sufficiently dilated vessels, reduced pressure in the right ventricle and reduced pressure gradient.

Fenestration/interartial septum

Cutting balloon angioplasty (7 patients, 7 procedures) was performed in 3 (50%) patients with HLHS, 2 (33.3%) patients with TGA-2, 1 patient with PA+IVS+hypoplastic TV (16.7%) and as an emergency procedure in 1 neonate with severe congenital mitral stenosis and regurgitation. In this group, the indication for CBA was a severe restriction at the interatrial septal defect level, i.e. unsuccessful classic Rashkind procedure in neonates — 4 (57%) and the restriction of interatrial communication in others defects — 3 (43%). A significant post-procedural increase in the mean diameter of the interatrial communication was observed: from 2.97 ± 2.03 mm to 6.94 ± 3.32 mm ($p = 0.43$). The mean transatrial gradient pressure significantly decreased from 9.2 ± 3.97 mm Hg to 2.8 ± 3.18 mm Hg ($p = 0.02$). Also, the results of echocardiographic assessment of transatrial gradient pressure measured prior to and post-CBA were compared. There was a significant fall in the transatrial gradient from 14.8 ± 4.2 mm Hg to 5.2 ± 4.3 mm Hg ($p < 0.001$).

In 3 patients with failing Fontan physiology the procedures were performed successfully. In 2 of them mechanical perforation of Fontan tunnel followed by dilation of the communication between the Fontan circuit and the left atrium was performed using CB. In the third patient a small fenestration was enlarged using an 8 mm CB. Immediately after the procedure, all patients improved and desaturated (by 6%). However, one of them died 2 months post-procedure due to the worsening of severe heart and renal failure.

There were no CBA complications except a single case of transient hemoptysis (3.5%) in a patient post-right-pulmonary-artery-angioplasty (previous Jatene operation).

Discussion

Cutting balloon angioplasty has been described in pediatric patients in case reports and clinical studies in small groups of children. Although the evidence for CBA in various congenital heart defects is limited and indications for CBA are not well-established, CBA is used to treat a variety of lesions resistant to conventional balloon dilation, such as: resistant peripheral pulmonary artery stenosis, pulmonary vein stenosis, renal artery stenosis, systemic and pulmonary collateral artery stenosis. Based on the limited experience it has been suggested that the use of CBA is relatively safe and effective [3–8].

After reviewing clinical, procedural, hemodynamic and echocardiographic data of patients who underwent an interventional catheterization with CBA, it is noteworthy to underline the heterogeneity of this group of children with a wide spectrum of congenital heart defects, both with uni- and bi-ventricular circulation. Experience reveals that CBA is a useful procedure in different clinical situations during cardiac catheterization in children. CB were successfully used in various types of peripheral pulmonary artery stenoses (post-Fontan procedure, unifocalization of collaterals, stenosis of "true" pulmonary arteries) and restrictive interatrial communication, which were resistant to conventional balloon angioplasty. In patients with TGA, the intervention was guided by transesophageal echocardiography, which revealed a significant enlargement of the interatrial communication with no signs of flow restriction. In addition, transatrial pressure gradient had decreased and peripheral blood saturation had increased.

In more than half of the cases the indication for CBA was pulmonary arteries stenosis. This study revealed that CBA was a safe and effective option for treatment in tight stenoses, especially those resistant to conventional balloon angioplasty. These results are consistent with the Bergersen et al. [5] randomized study. According to their study only 29% of pulmonary arterial stenoses were treated successfully with low-pressure balloons, 52.4% with high-pressure balloons and 85.1% required CBA. In addition, in 55% of the vessels treated with high-pressure balloons the operators switched to CBA [5]. There was a significant relationship between the ratio of the diameter of the balloons used in the diameter of the stenotic part of the vessel and the percentage increase in the size of the vessel diameter. In the echocardiographic examination the reduction of TRPG was observed in the 1-month follow-up. The right ventricular pressure decreased and the clinical performance of the patients improved. Later further improvement is probably the effect of healing and the regression of edema, which was secondary to the iatrogenic damage done by the CBA. The follow-up was not long enough but the effect of the procedure remained constant during this period (control catheterization in 6 of the patients in a 1-year follow-up confirmed a stable result). Procedural success in patients after unifocalization and in others after biventricular circulation was expressed as an enlargement of the vessel diameter and a decrease in the RV/Ao ratio. In patients with Glenn shunt CBA success was observed as an improvement in vessel diameter (in the majority of cases the measurement of pressure gradient is inadequate due to the development of collateral circulation and completely changed patophysiology).

The use of CBA both in pulmonary stenoses and the dilation of interatrial septal defects caused a significant increase in the dimensions of the dilated structures and an improvement in the hemodynamic parameters analyzed in subsequent cardiac catheterizations and echocardiographic studies.

According to our experience CBA proved especially useful in patients with the failing Fontan circulation. In this group the creation of a fenestration is especially challenging because of the low elasticity of the material used (Gore-Tex) for the interatrial baffle. Consequently, the conventional angioplasty was ineffective in most of them. Furthermore, the use of stents (both in the atrial cavity and Fontan tunnel) can provoke thromboembolic complications due to slow flow and hepatic failure. Therefore, the use of CBA can be a very attractive alternative in this population of patients (at the cost of a reduced saturation).

Cutting balloons were mainly designed for coronary and some peripheral vessel lesions, hence their use in congenital heart defects is limited (the largest CB is 8 mm in diameter). This limitation was overcome in 1 patient (TA, PA) with the restrictive interatrial communication (diameter of 5.5 mm) using the combination of an 8 mm balloon with a simultaneous introduction of a high-pressure balloon (15 mm) into the defect. The result of this procedure was an effective interatrial communication dilation with unrestrictive blood flow. There were no procedural complications. According to available research this was the first procedure of this kind.

The next interesting application of CBA is in cases of in-stent restenoses. There are many available treatment options for patients with coronary arteries in-stent restenoses however, in the population of patients with congenital heart defects surgery it is commonly the only one. The percutaneous dilation of in-stent restenoses can be very difficult especially for larger stents, since available high-pressure balloons are often inefficient and the procedure is far more dangerous when compared with the coronary arteries. In selected cases CBA can be used to avoid surgery.

Conclusions

Based on the results of this study it was concluded that CBA is safe and efficient in the treatment of different congenital heart defects. It is believed that CBA can be used as a definite approach in selected cases in avoiding surgery, in certain cases it is the only method of treatment and in very rare cases as a palliative option only. The persistence of CBA results in mid- and long term follow-up needs to be confirmed in larger trials.

Conflict of interest: None declared

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