Stenting in infants with CHD

Seong-Ho Kim, MD
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Cardiac Catheterization Report

No : **201221656** | Name : 박서이 | Age/Sex : 8m16d/여 | Birth : 20121003

Date : 20130619 | Cath No : 2013004198 | Angio No : 62248

Physician : 김성호/김성호/이상윤 | Fluoro : 22.8 min | Dye :

Pt alertness: sedated with midazolam

Clinical :

Comment :

Complication :

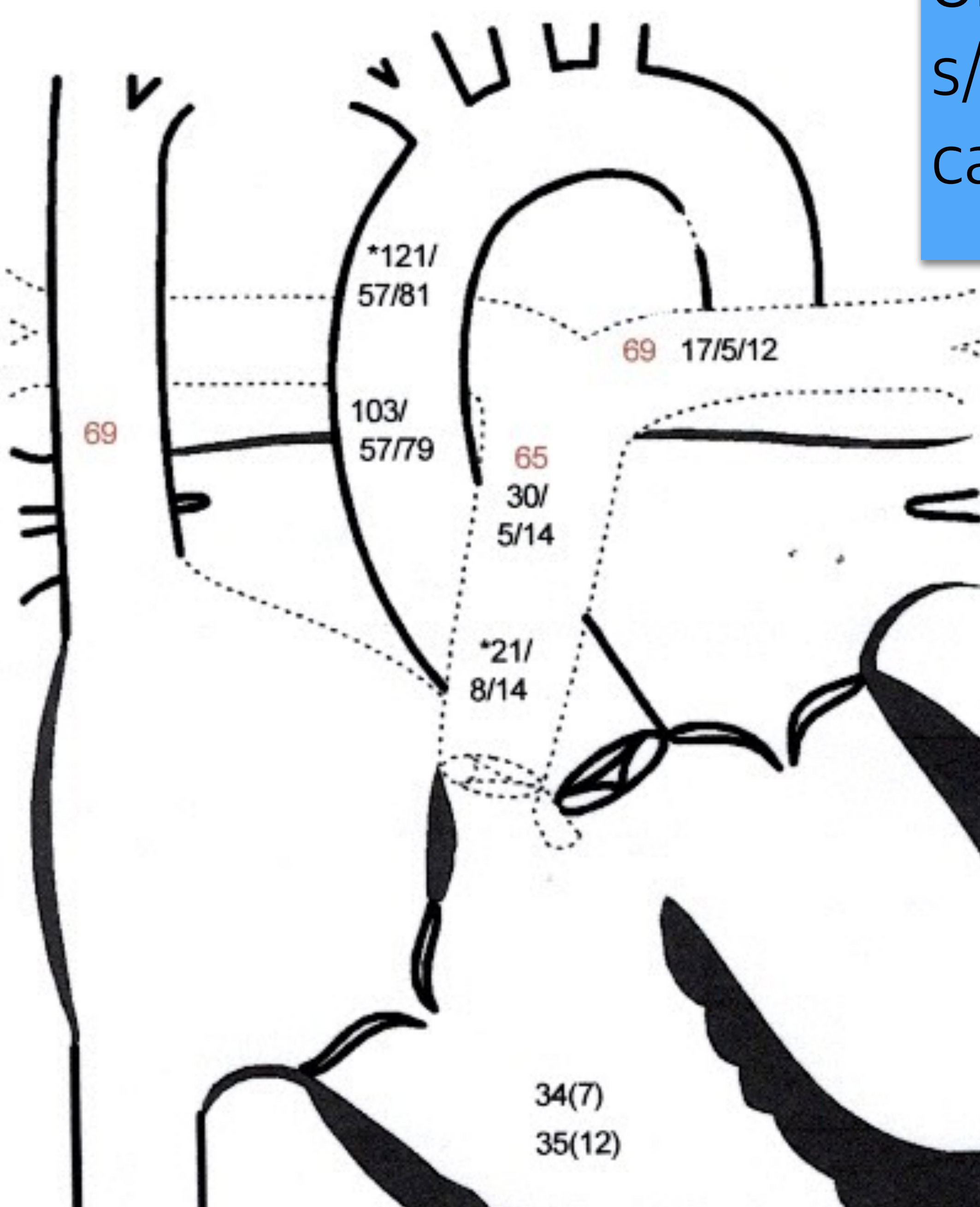
Genetic :

Wt : | Ht : | BSA :

Hgb : 11.4 | HR : 133 | VO2 :

ABGA : 7.395-34.2-94.7- *(Sat : 97.7%)*

*Post-BAP +Post-Stent



Diagnosis/Intervention

8M/F

s/p total repair of PA/VSD (19d)

cath for BAP of PA (3M)

mod PR no PS

Set1: BAS

Set2: Post-Stent

p(RV/Ao): 0.33 -> 0.29

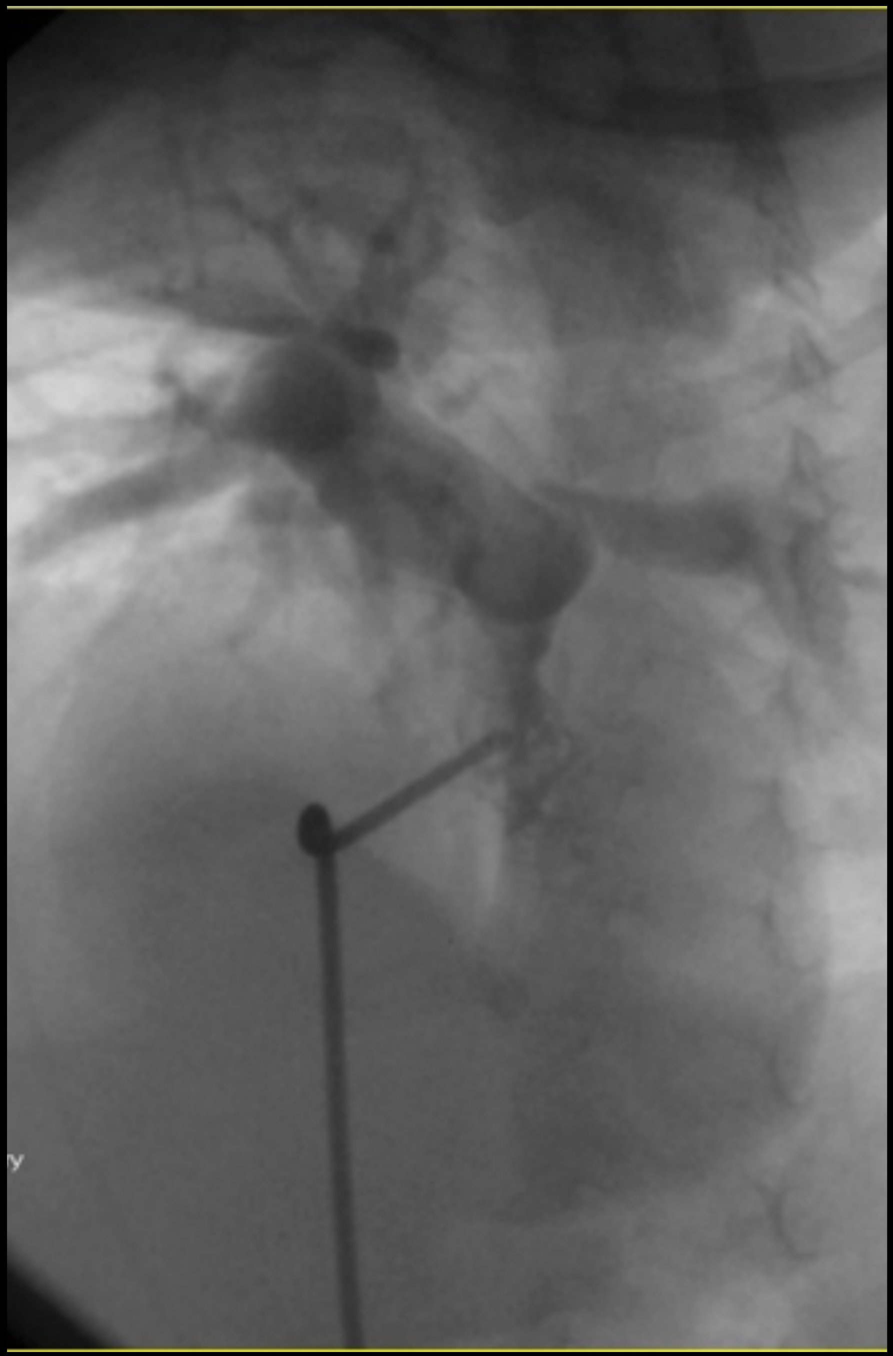
PG on LPA 13-->0

d=2.7-->8mm

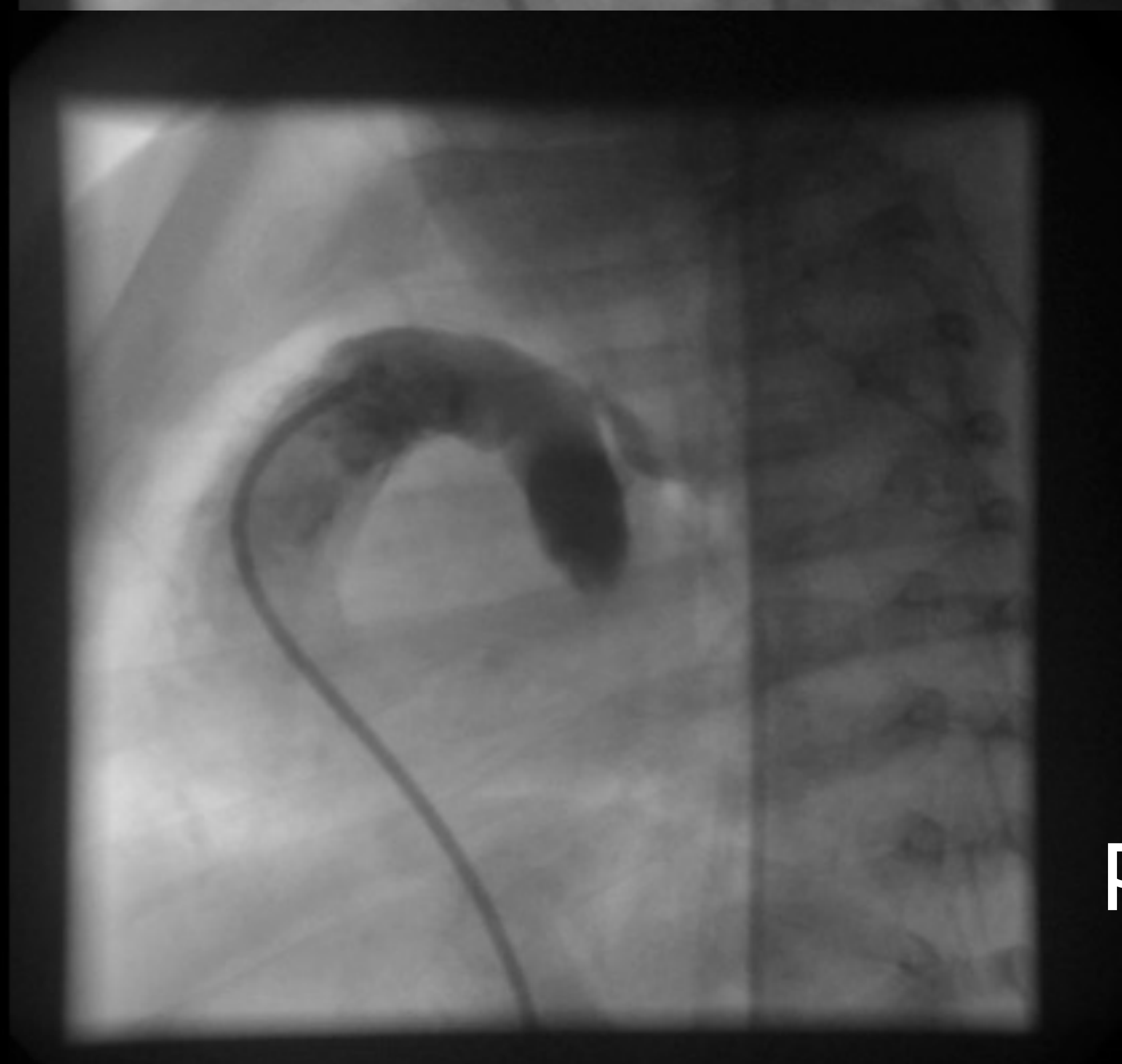
LPA origin stenosis, may be kinked

BAP with 8mm balloon, but d=2.7mm

stent (8mm*17mm) via 6F sheath on LPA origin

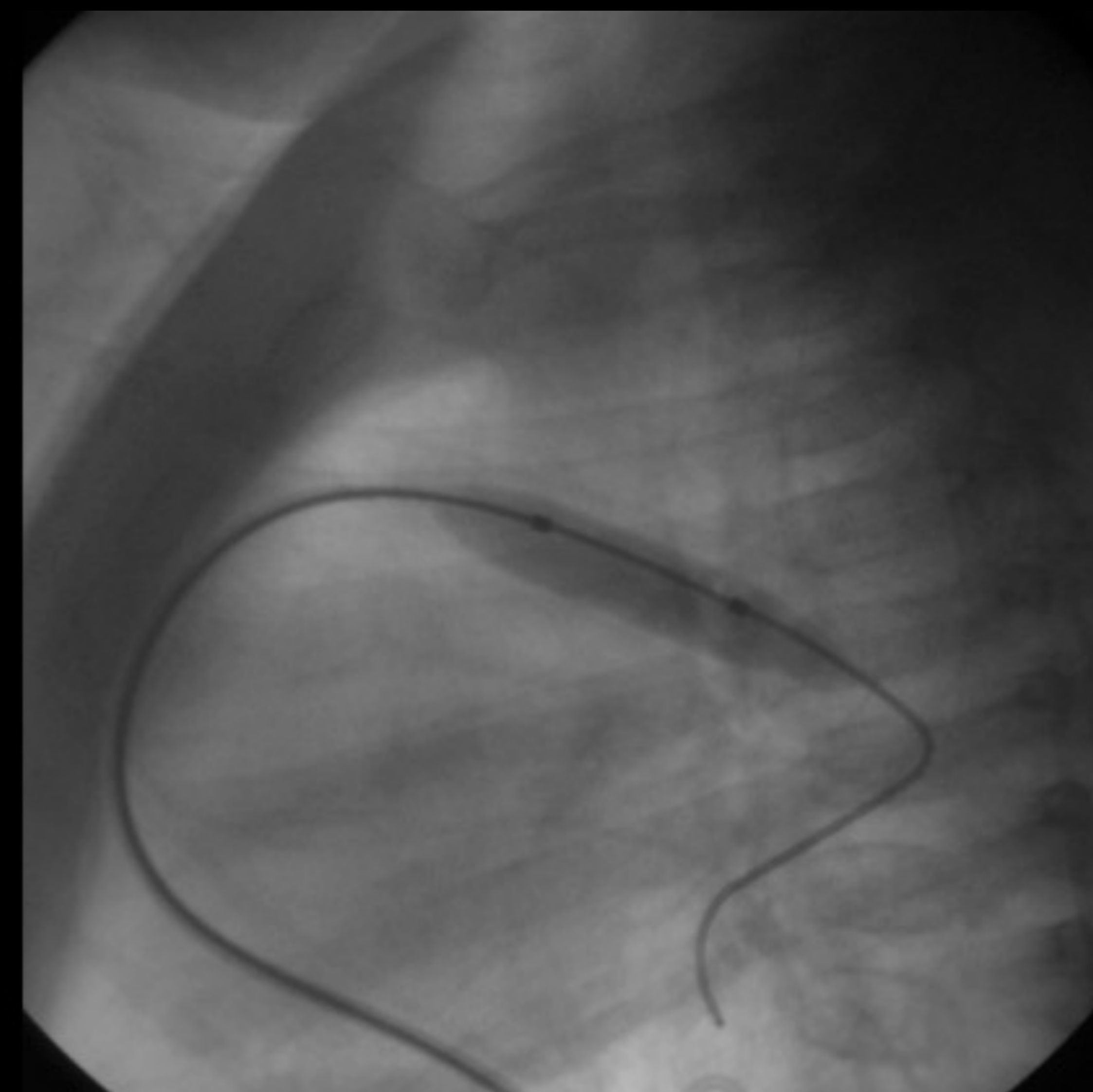


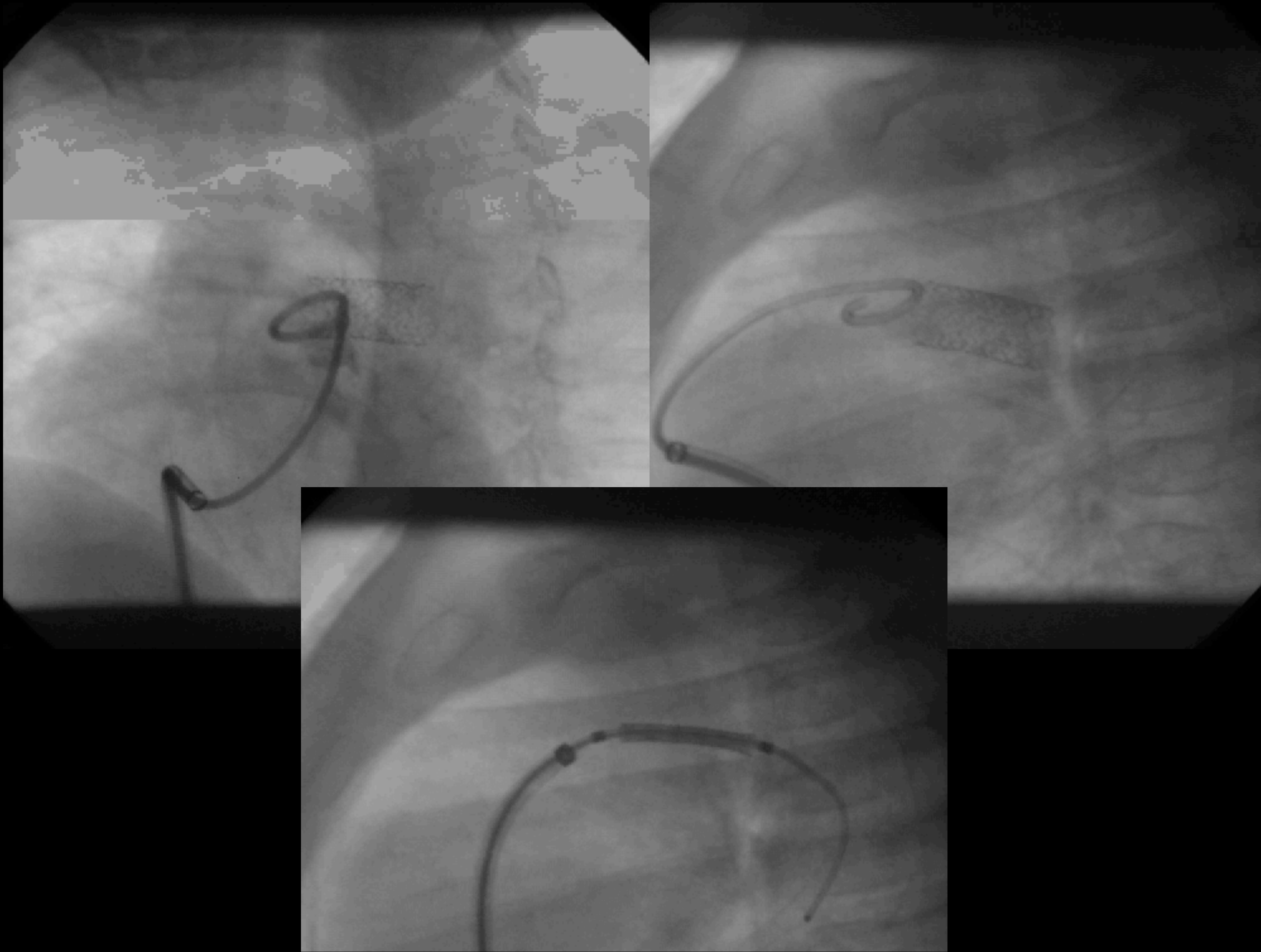

pre



post

8mm BAP





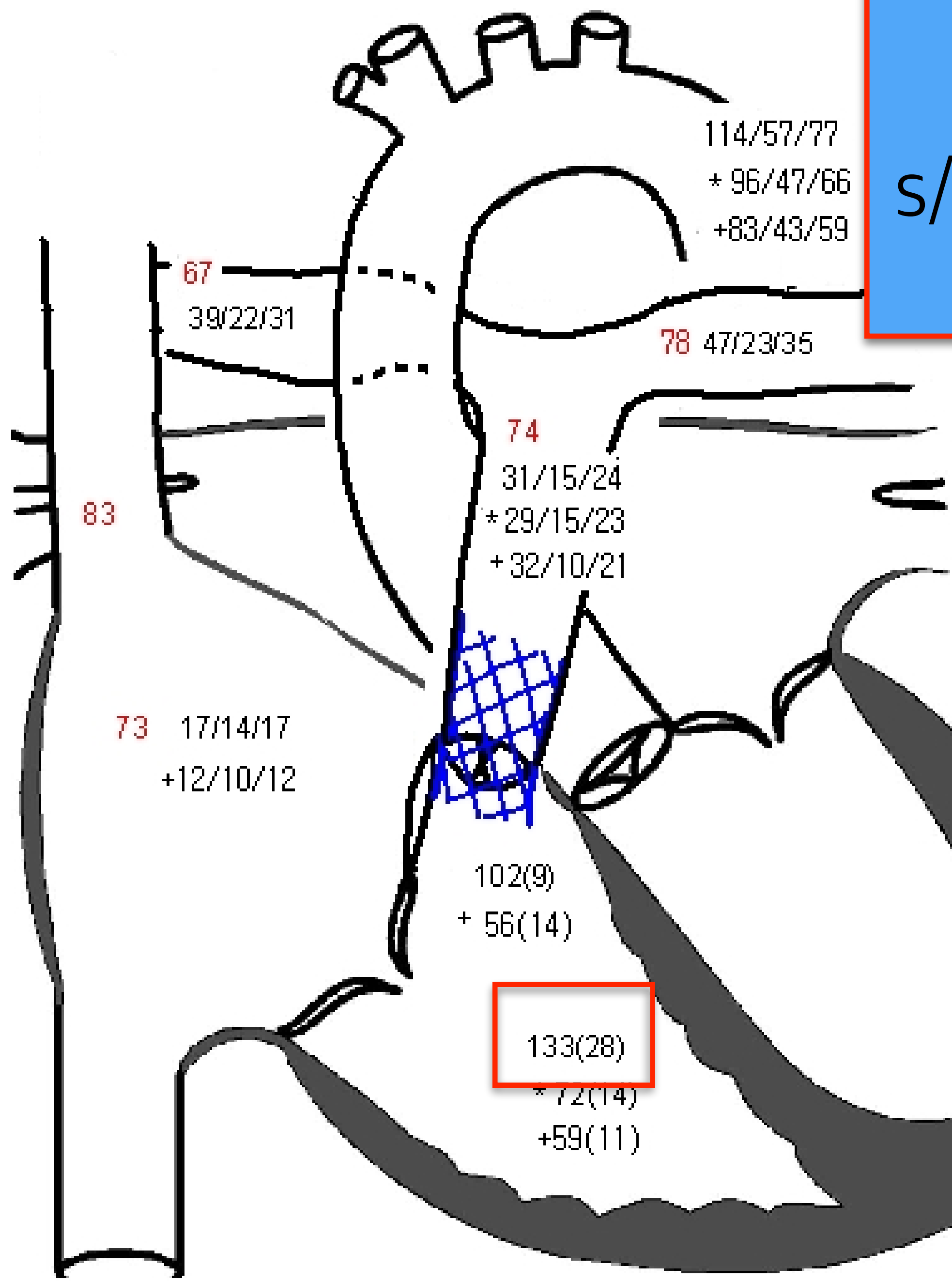
Cardiac Catheterization Report

No : 201320445 Name : _ _ _ Age/Sex : 1y11m/ Birth : 20130913
Date : 20150826 Cath No : 2015006194 Angio No : 72365
Physician : / / Fluoro : Dye :

Pt alertness: Ventilator applied
Clinical : Genetic :
Comment : Wt : 7.4 kg Ht : 68 cm BSA : .36
Complication : Hgb : 9.1 HR : 146 VO2 : 170 ml/min/

ABGA : 7.189-85.2-185- *(Sat : 99.5%)*

*Post-PVP +Post-Stent



---Post-pvp---
MPA 29/15/23
RV 72(14)
AO 96/4766

Diagnosis/Intervention
Truncus arteriosus (CE I), VSD

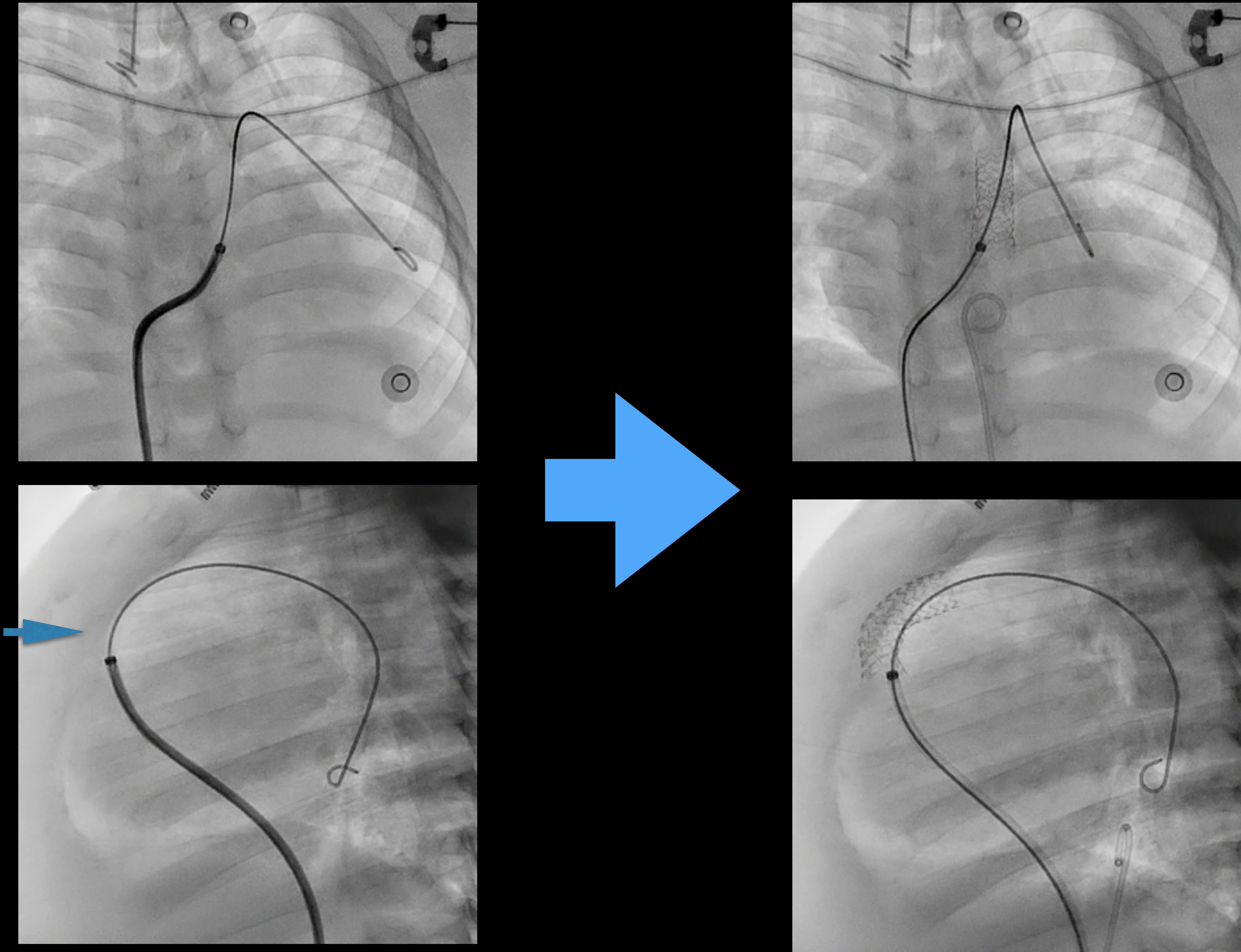
s/pTA type I (10d)
s/p PVR(Goretex bicuspid 12mm)(5M)

(2014-02-17, 5m4d)
home vent. support, medi
2015-07-22

1. Severe stenosis of bicuspid Gortex valve on conduit PG 70mmHg
2. Mild both PA stenosis PG<10mmHg

Baseline > Post-PVP > Post-Stent
Qp/Qs: 0.6, Qp: 5.5, Qs: 8.6
p(RV/Ao): 1.17 -> 0.75 -> 0.7

1.BAP on conduit with 12*2 Armada
- little effective
2. stent on conduit with 10mm*29mm stent
follwed by 12*2 balloon
PG 70->20mmHg
Prv/ao 1.17->0.7



Br Heart J 1995;74:689–695

AUDIT

Endovascular stents in children under 1 year of age: acute impact and late results

Yoshiho Hatai, David G Nykanen, William G Williams, Robert M Freedom, Lee N Benson

- **1989 - 1994**
- **26 infants**
- **4.7M (2d - 1Y)**
- **5.3kg (2.2 - 9.5)**
- **success in 31 of 37 stents (84%)**
- **large diameter stent(iliac)- not feasible**
- **Cx: malposition(5), balloon rupture(1), bleeding at puncture site(1)**

Issues of stenting in infants with CHD

- There have been concerns that stenting in infants may be difficult and have more complications because of the smaller vessels.
- Stents implanted in infants become fixed stenoses as the body grows.
- Although stents can be post-dilated to accommodate growth, balloon-mounted stents with a low profile to implant in infants usually lac the capacity to expand to adult size.

Solutions of stenting in infants with CHD

- Valeo or Formula stents
- bioabsorbable stent
- Unzipping with UHPB
- breakable stent

Catheterization and Cardiovascular Interventions 74:905–912 (2009)

A Premounted Stent that can be Implanted in Infants and Re-Dilated to 20 mm: Introducing the Edwards Valeo Lifestent

Herbert J. Stern,* MD, FACC, FSCAI and Christopher W. Baird, MD

Intravascular stenting (IS) for vascular stenoses in congenital heart disease provides superior gradient relief and angiographic results over balloon angioplasty (BA) alone. The advantages of IS, however, are difficult to apply to infants, toddlers, and small children due to technical challenges in placing large, long sheaths and the risk of creating future stenoses in stents that cannot be re-dilated to keep pace with somatic growth. This report highlights the Edwards premounted re-dilatable biliary stent, which was safely placed in four infants and small children with excellent hemodynamic and angiographic results. Bench testing revealed the stent has adequate radial strength and can be re-dilated to a maximal diameter of 20 mm.

Fig. 1. The triple helix design of the Valeo stent.

Bard Valeo stent (Bard Peripheral Vascular, Tempe, AZ)
stainless steel triple helical stent
open cell design - dilation of side branch
premounted
0.035-inch guide wire
balloon burst pressure - 14 atm
medium sized Valeo stent 6-8mm balloon 6F sheath upto 13mm
larger sized Valeo stent 9-10mm balloon 7F sheath upto 20mm

Catheterization and Cardiovascular Interventions 84:197–203 (2014)

Implantation and Preliminary Follow-Up of the Bard Valeo Stent in Pulmonary Artery Stenosis

Vikram Kudumula,[1] MRCPCH, Patrick Noonan,[2] MRCPCH, Demetris Taliotis,[1] MRCPCH, and Christopher Duke,[1*] FRCP

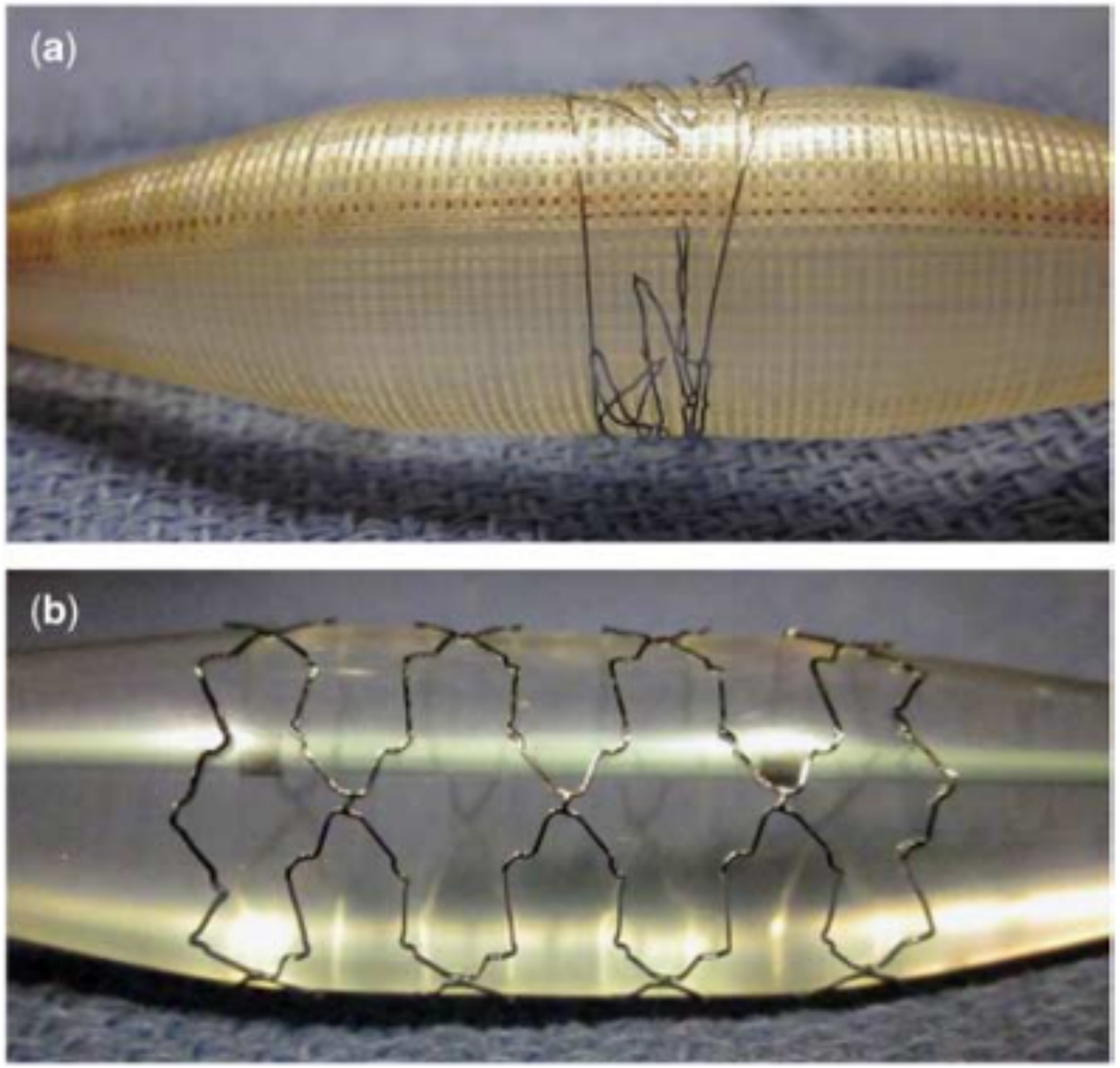
2011-2013
12 stents in 10 pts (branch jailing, 6)
success and no Cx in all pts
median recoil : 5.5(0 -21)%
resistant to dilation 2pts
Bench testing radial force :

- 8*36mm Valeo - 34 g/mm
- ev3 Intrastent double strut LD - 26 g/mm
- 8mm Palmaz P308 - 15 g/mm

The Valeo stent: a pre-mounted, open-cell, large stent for use in small children with CHD

Frances C. Travelli, Patrick M. Sullivan, Cheryl Takao, Frank F. Ing

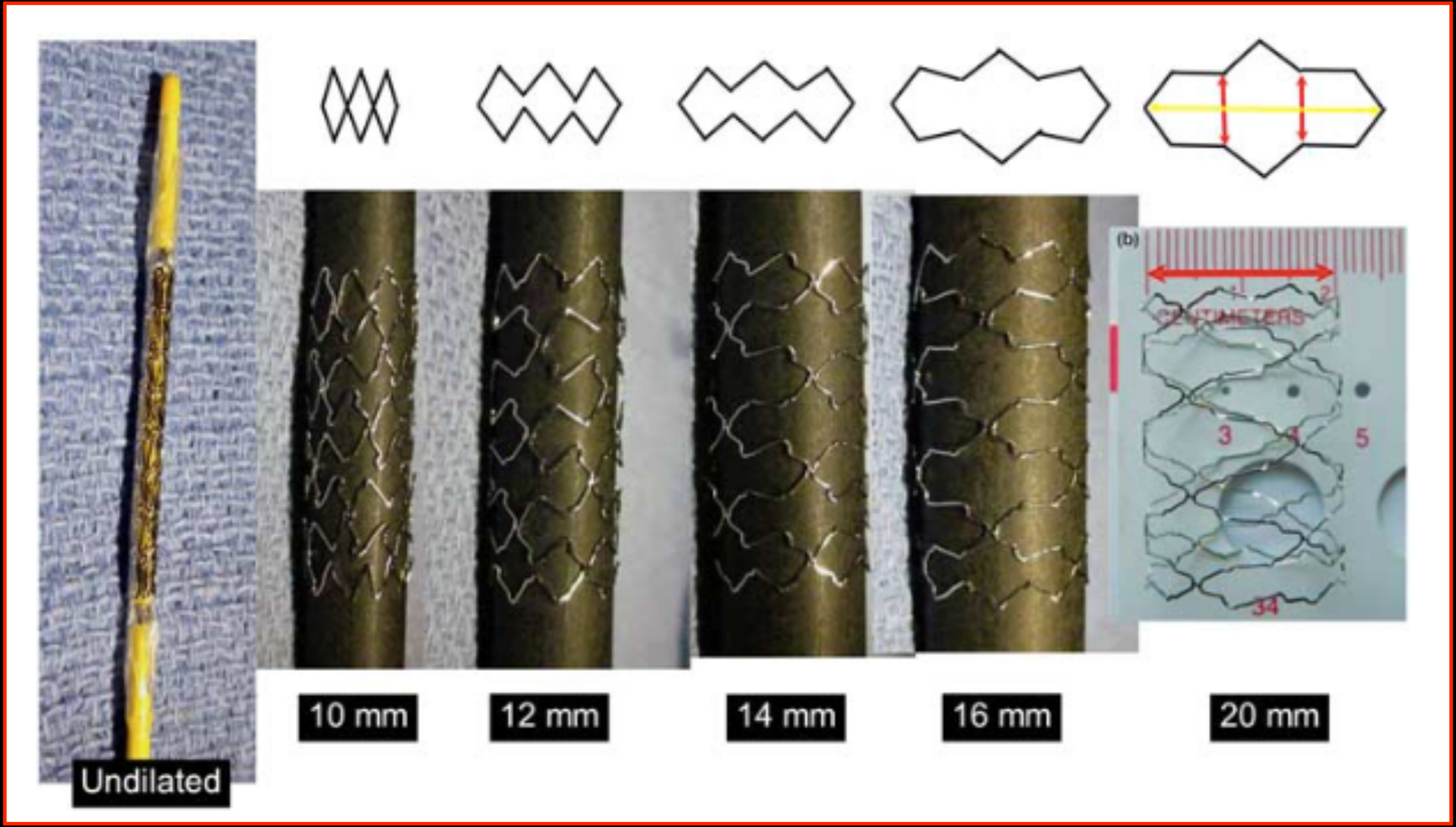
Department of Pediatrics, Keck School of Medicine, Division of Cardiology, Children's Hospital Los Angeles, University of Southern California, Los Angeles, California, United States of America



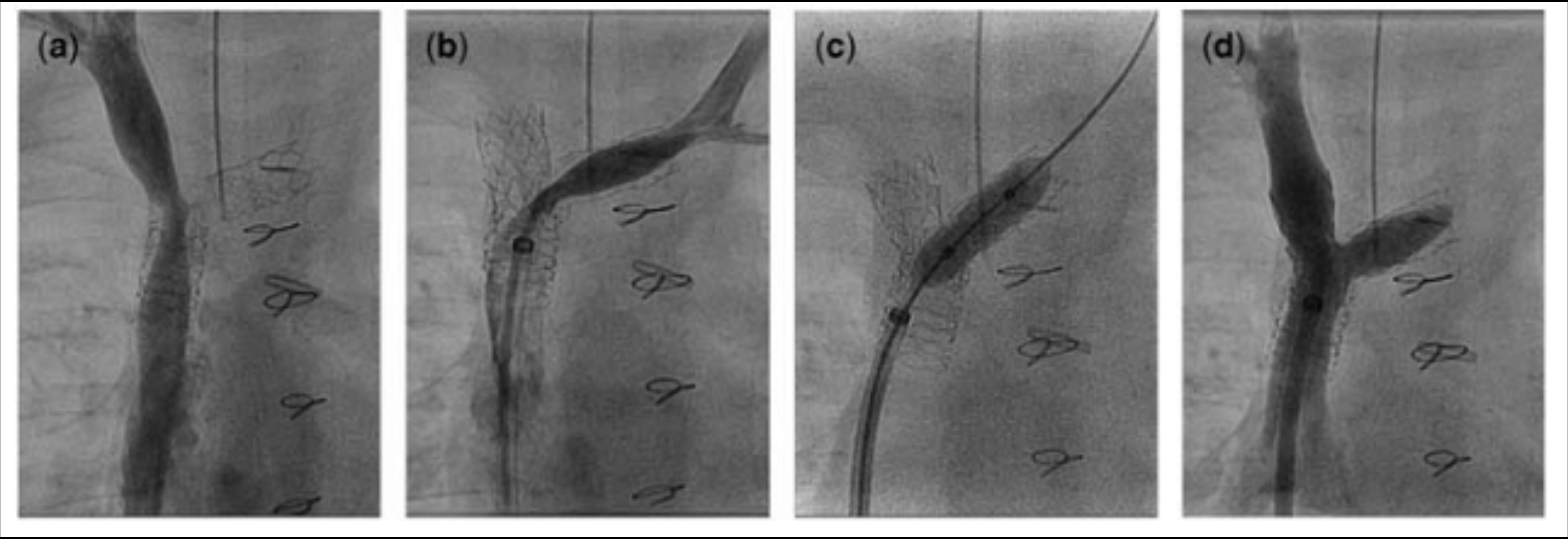
Bench testing with 16mm balloon

medium sized Valeo stent
premounted on 6-8mm balloon
6F sheath
upto 13mm

larger sized Valeo stent
premounted on 9-10mm balloon
7F sheath
upto 20mm



Travelli et al, Cardiology in the Young 2015; Page 1 of 7



Travelli et al, Cardiology in the Young 2015; Page 1 of 7

2012-2014
81 Valeo stents in 61 pts
58.9M(3.7M- 19.8Y)
15.3kg (4.6 - 110kg)
Foreshortening : 2.5±2.3%
Recoil : 5.9±3.4%
re-mounting   7 cases
side-cell dilation 4 cases

Table 1. Diameter increase of the Valeo stent.

Diameter increase (mm)	Minimum	Maximum	p
All patients	4.1 ± 1.8	7.7 ± 1.7	<0.0001
Systemic veins	4.4 ± 0.3	7.6 ± 0.3	<0.0001
Single ventricle (PAs)	3.9 ± 1.6	4.3 ± 1.3	<0.0001
Two-ventricle (PAs)	3.7 ± 2.1	7.4 ± 1.9	<0.0001
Aorta	5.3 ± 1.4	9.1 ± 1.6	0.01

Table 2. Gradient reduction of the Valeo stent.

Gradient reduction (mmHg)	Pre	Post	p
All patients	16.6 ± 18	5.7 ± 9.1	<0.0001
Systemic veins	6.0 ± 1.8	0.3 ± 0.3	0.09
Single ventricle (PAs)	3.9 ± 10.5	0.3 ± 0.6	0.16
Two-ventricle (PAs)	28.2 ± 17	12.5 ± 9.9	<0.0001
Aorta	17.4 ± 11	4 ± 2.6	0.11

Travelli et al, Cardiology in the Young 2015; Page 1 of 7

Catheterization and Cardiovascular Interventions 86:432–437 (2015)

PEDIATRIC AND CONGENITAL HEART DISEASE

Original Studies

The Edwards Valeo Lifestents in the Treatment and Palliation of Congenital Heart Disease in Infants and Small Children

Gianfranco Butera,* MD, PhD, FSCAI, Luca Giugno, MD, Domenica Basile, MD, Luciane Piazza, MD, Massimo Chessa, MD, PhD, FSCAI, and Mario Carminati, MD, FSCAI

25 pts, 2012-2014
39±35 M, 10.4±6.7kg
35 stents
Prv/ao 1.0±0.2->0.6±0.2
Cx : 12% (3/25)-hypotension, lung bleeding
FU 18M - no Cx

Catheterization and Cardiovascular Interventions 86:432–437 (2015)

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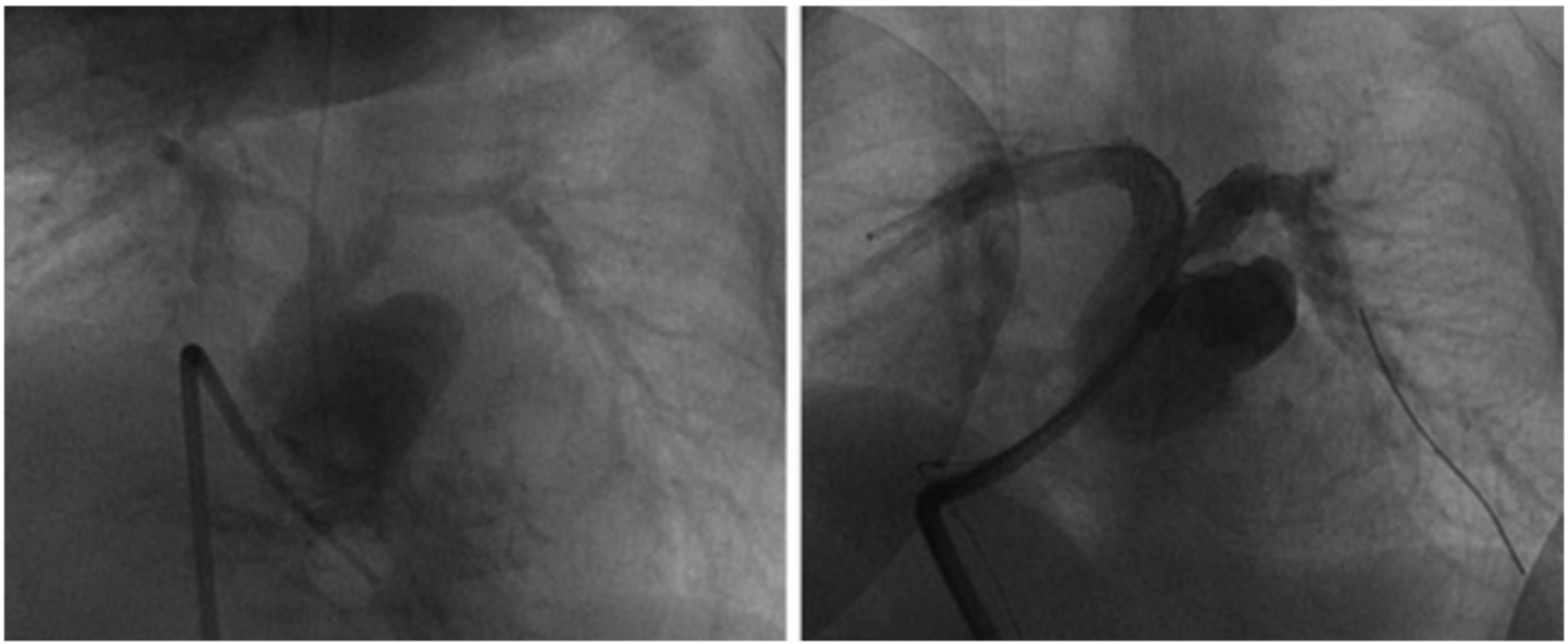


Fig. 2. Antero-posterior view with cranial angulation showing severe pulmonary artery stenosis and hypoplasia (left). After two 6 × 18 mm^2 Valeo stent implantation a significant increase of pulmonary arteries diameter is shown.

Catheterization and Cardiovascular Interventions 85:259–266 (2015)

Initial Experience with the Cook Formula Balloon Expandable Stent in Congenital Heart Disease

Daniel Quandt, MD, Bharat Ramchandani, MD, MRCP, Vinay Bhole, MD, MRCPCH, Gemma Penford, MRCP, Chetan Mehta, MD, MRCP, Rami Dhillon, MRCP, and Oliver Stumper*, MD, PhD

Introduction: Balloon expandable stents are an integral part in the catheter treatment of congenital heart disease. In the growing child, stents require dilatation to greater diameters over time. The Cook Formula stent is a recent 316 stainless steel open-cell design licensed for peripheral vascular work. Methods: Following extensive ex vivo studies, 112 stents were implanted in 97 children [median age 3.9 (0.01–17.6) years; median weight 13.7 (2.4–62.8) kg] over a 27-month (Oct 2011–Dec 2013) period. Results: Bench testing revealed that there was no stent shortening for dilatation to nominal diameter and beyond. The 5 mm stents could be dilated up to 10 mm, and the 10 mm stents to 20 mm. Stents were implanted through 4–7F sheaths or guide catheters over appropriate wires. Stent tracking and delivery was excellent. Twenty-three stents were implanted in the right ventricular outflow tract in Fallot-type lesions, 53 for branch pulmonary artery stenosis (22 post cavopulmonary shunt/Fontan), 14 conduit stenosis, 13 Fontan fenestrations, 3 PDA in hybrid stage I Norwood, 5 in coarctation, and 1 for SVC obstruction. Sixty-one stents (54%) were overdilated. There were no stent fractures. Radial strength was very good, whereas stent conformability was limited. Conclusions: The Cook Formula stent is a premounted balloon-expandable stent that can be significantly overdilated with virtually no shortening allowing for precise placement and minimal protrusion into adjacent vessels. The Formula stent is a very versatile addition to the range of stents for use in the catheter treatment of complex congenital heart disease in children.

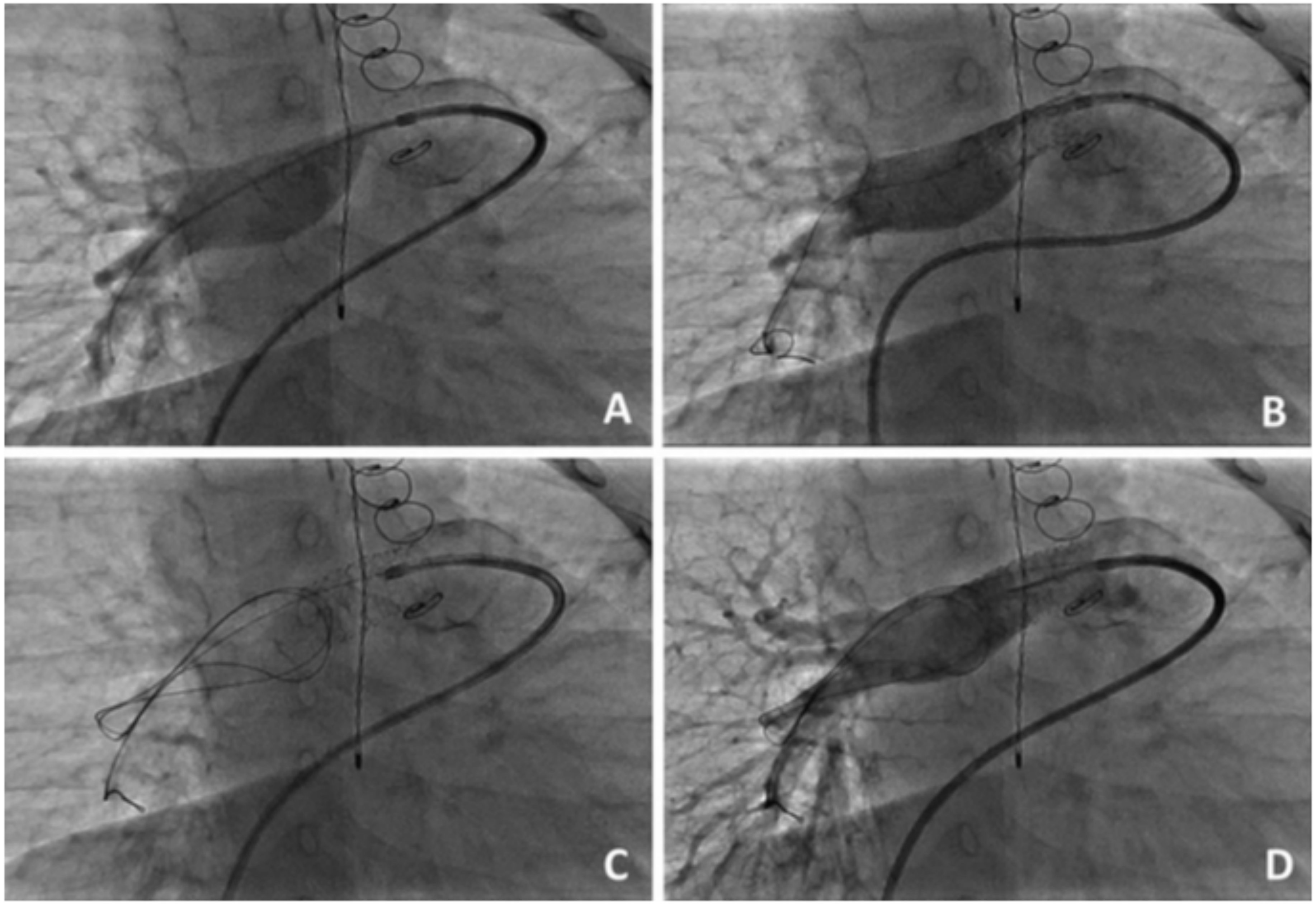


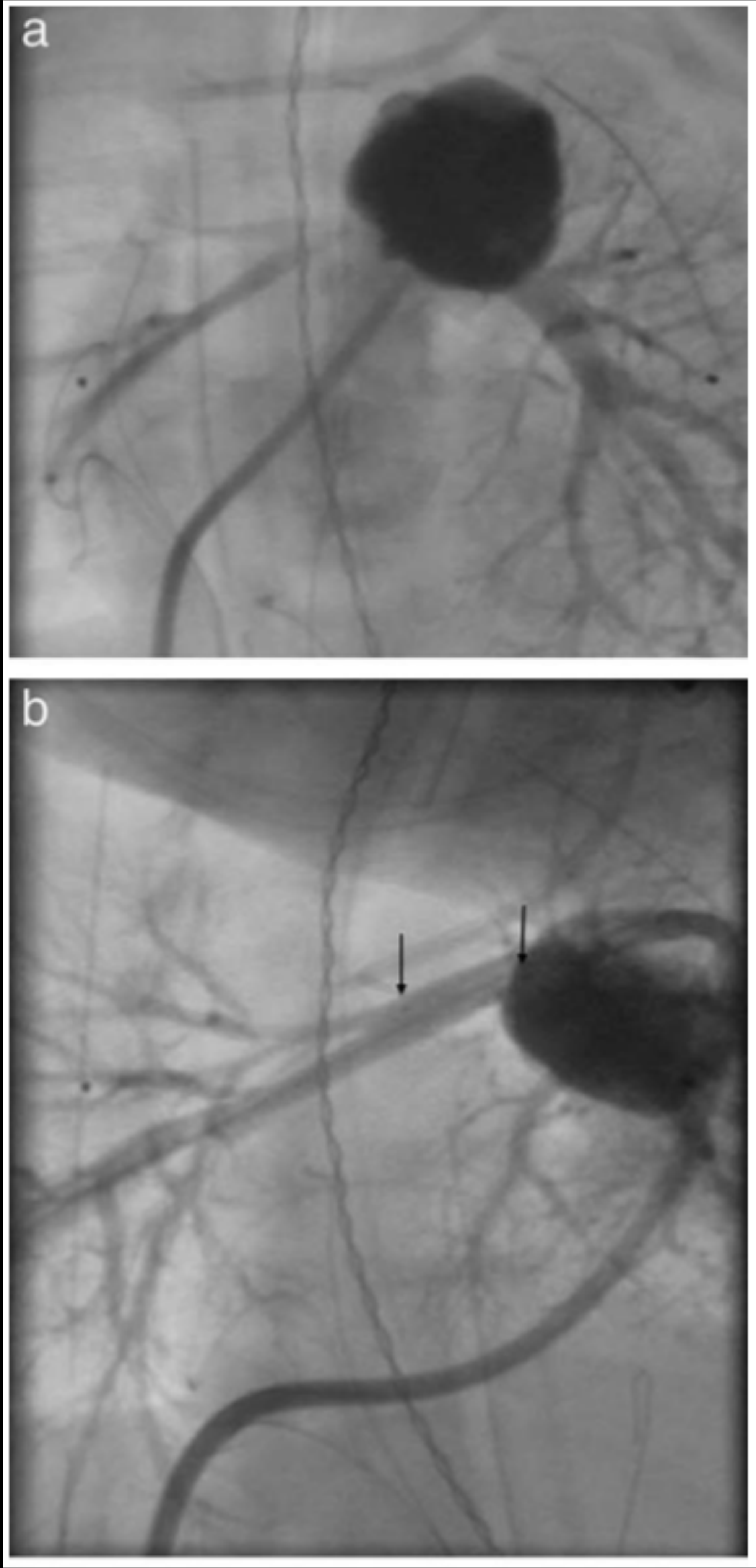
Fig. 4. Stenting of right pulmonary artery stenosis in a 3-year-old (13 kg) patient after complete repair of a common arterial trunk with a 15 m aortic homograft (RV/PA conduit). A: RPA origin stenosis, B: initial stenting with Cook formula 414, 7 × 20 mm stent. C: Overdilation of stent with 10 × 20 mm balloon with no stent shortening, D: Final result.

First Reported Use of Drug-Eluting Bioabsorbable Vascular Scaffold in Congenital Heart Disease

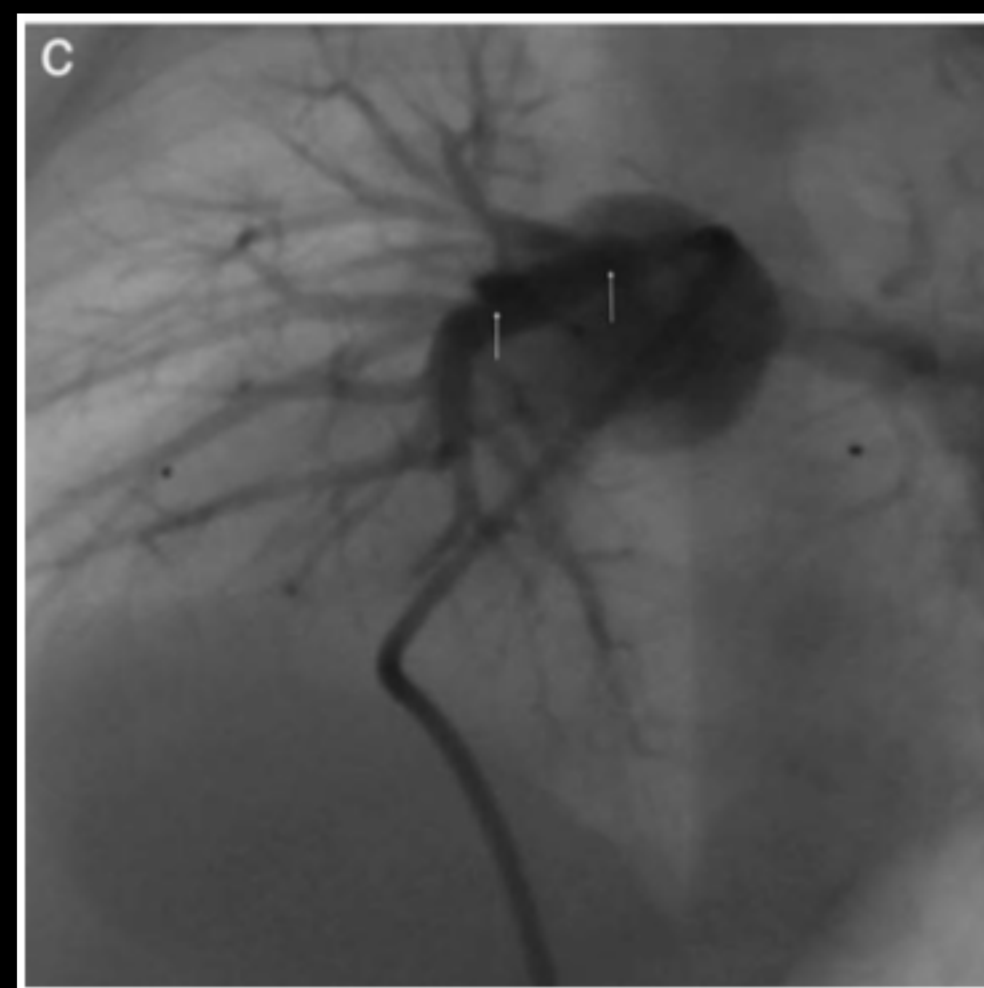
B.A. McCrossan,* MD, MRCPCH, C.J. McMahon, MRCPI FAAP, and K.P. Walsh, MD, FRCPI

The aim of catheter intervention for vascular stenosis is the restoration of lumen area and optimization of distal blood flow. In pediatric practice, this has traditionally been a compromise between less effective balloon angioplasty and bare metal stent insertion with its attendant limitations of size. Bioabsorbable stents offer short-term relief of stenosis, radial support of the healing lesion, return of endothelial function and crucially, in children, the potential for long-term growth. Initial experience, in pediatric practice, with metal-based bioabsorbable stents was relatively disappointing with frequent restenosis secondary to early reabsorption. Design modifications resulting in polymer-based, drug eluting, bioabsorbable vascular scaffolds (BVS) have reportedly overcome some of these faults. We describe the first reported use of a drug eluting BVS in three patients with: (1) A newborn with severe right pulmonary artery (RPA) stensosis post repair of type two common arterial trunk. (2) A child with pulmonary atresia/ventricular septal defect (VSD) and major aorto-pulmonary collateral arteries (MAPCAs), and (3) An infant with severe left pulmonary artery (LPA) stenosis in the setting of an LPA sling.

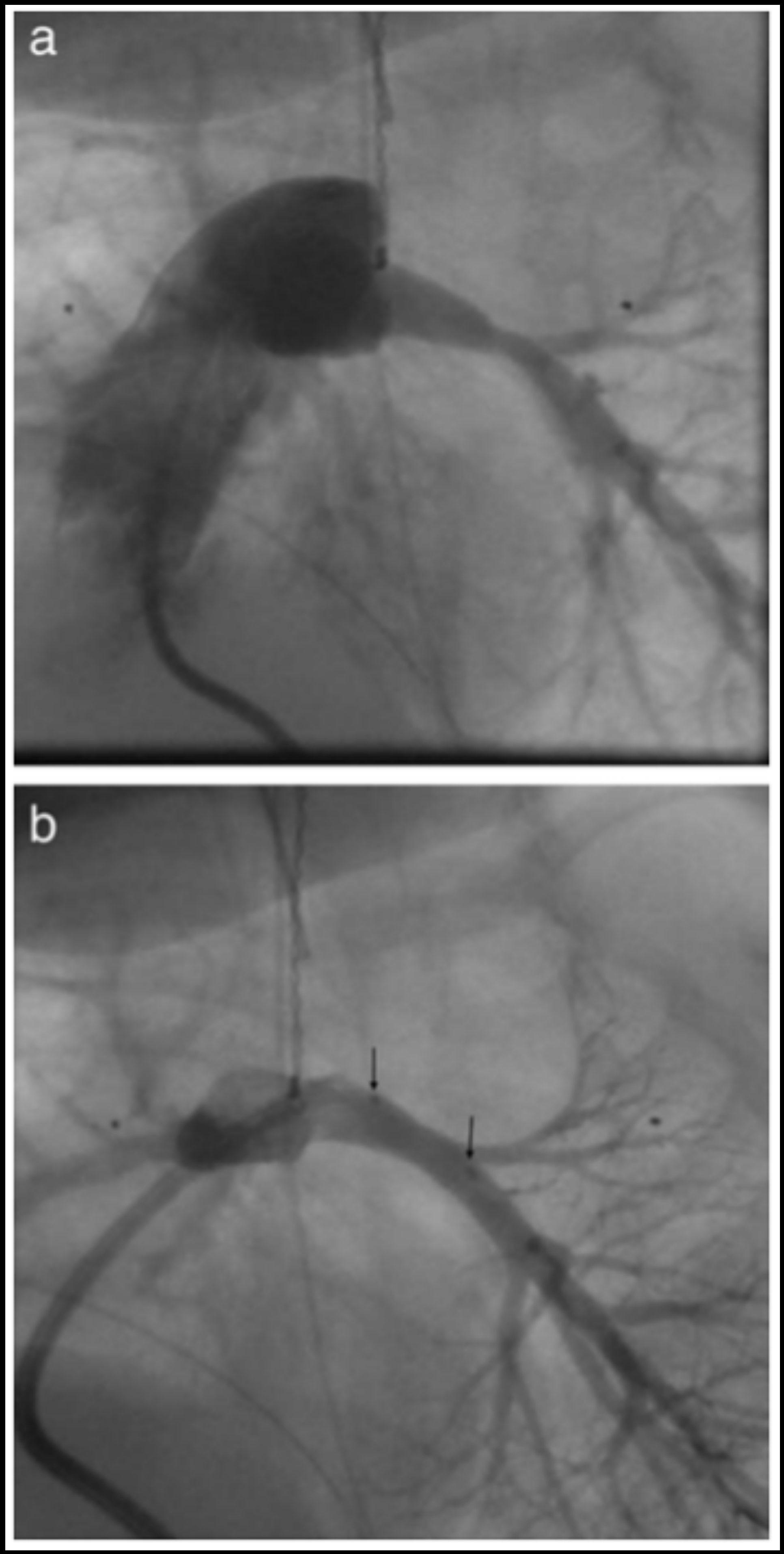
- Biodegradable stents for >10 years.
- Stents should provide radial strength for up to 3 months,
- Earlier magnesium-based biodegradable stents lose radial strength within weeks and are resorbed within four months.
- The latest polymer-based, drug eluting BVS have been shown to provide radial strength for at least three months.



11-day-old baby girl, TA (type 2)
repair on day 6 of life with a 12 mm Contegra homograft.
POD#5,
3.5*12 mm Absorb Bioresorbable Vascular Scaffold System (Abbott, IL)
Abbott Vascular Multi-link Ultra 5.0*13 mm stent in 2M



McCrossan et al, Catheterization and Cardiovascular Interventions 87:324-328 (2016)



4.1kg, 3M, s/p LPA sling
3.5*12mm Absorb BVS System

McCrossan et al, Catheterization and Cardiovascular Interventions 87:324-328 (2016)

Ultra-High-Pressure Balloon Angioplasty for Treatment of Resistant Stenoses Within or Adjacent to Previously Implanted Pulmonary Arterial Stents

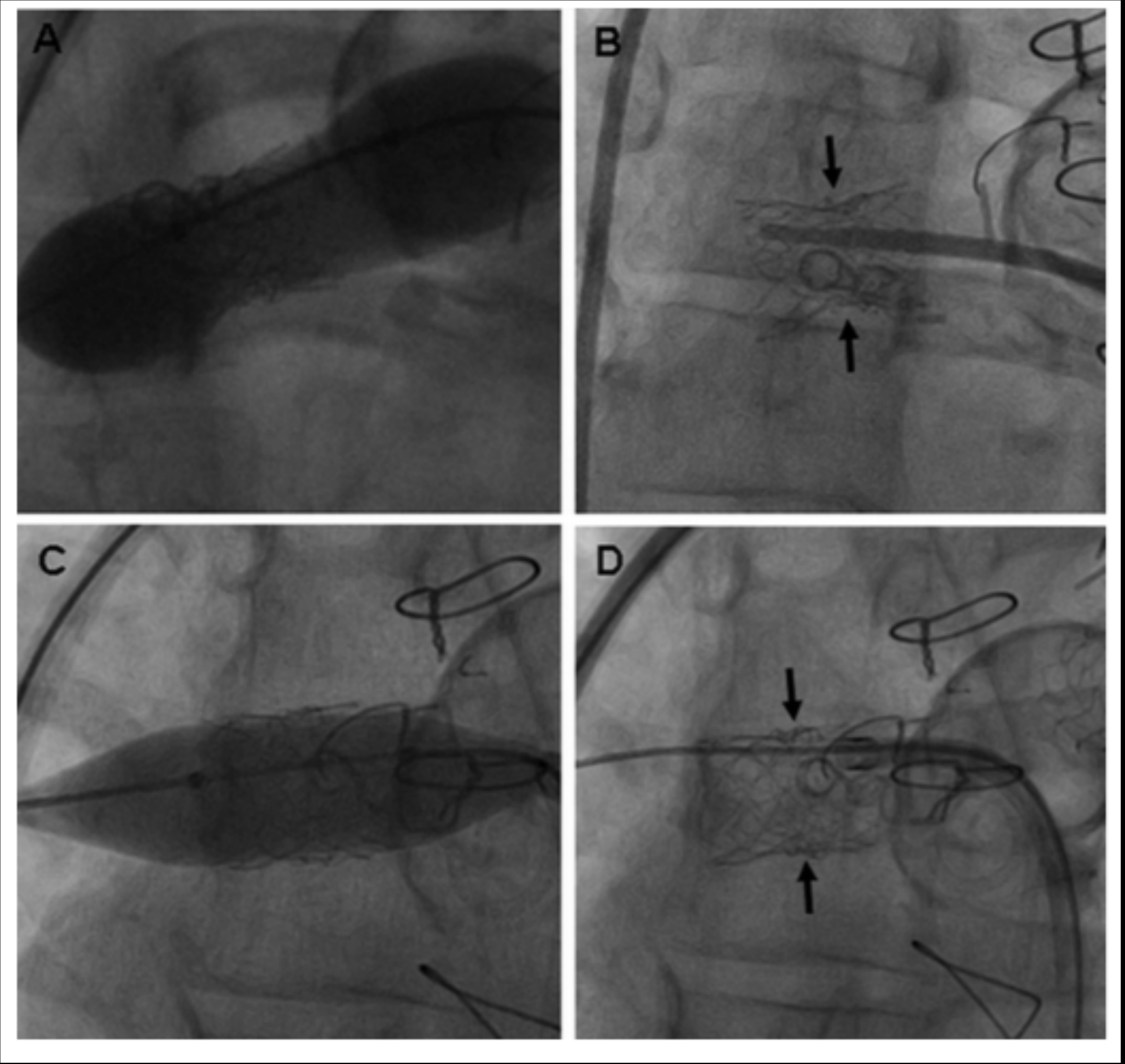
Jessica Maglione, BA; Lisa Bergersen, MD; James E. Lock, MD; Doff B. McElhinney, MD

Background—Stents are essential tools in the management of pulmonary arterial (PA) stenosis in patients with congenital heart disease. Although stents can usually be reexpanded as children grow, resistant in-stent or peri-stent obstruction can complicate the management of PA stents. Angioplasty with ultra-high-pressure (UHP) balloons may facilitate successful treatment of stent-associated PA stenoses that are resistant to high-pressure dilation.

Methods and Results—We reviewed patients who underwent UHP angioplasty of in-stent or peri-stent PA stenoses that were resistant to high-pressure redilation. A resistant stenosis was defined as a residual balloon waist during high-pressure redilation of the stent, along with a pressure gradient and/or angiographic stenosis. Thirty-four lesions in 29 patients, including 8 with multiple concentric, overlapping, or adjacent stents, were included. The median age at UHP angioplasty was 9 years, and a median of 4 years had elapsed since unsuccessful high-pressure angioplasty. Thirty-one of the 34 (91% [81% to 100%]) UHP angioplasty procedures were successful in relieving the resistant stenosis. Balloon:waist diameter ratios were conservative (median 1.26), reflecting the ability of UHP balloons to "fracture" nearly all obstructions. After UHP dilation, lesion diameter increased by a median of 3.1 mm (36%), significantly more than after previous high-pressure dilation (1.3 mm, 19%; $P<0.001$). In 5 lesions, UHP angioplasty fractured the stent, allowing further vessel expansion. There were no vascular or other complications.

Conclusions—UHP angioplasty was safe and effective for treatment of stent-related resistant PA stenosis in this series; the ability to fracture maximally expanded stents may extend the utility of stents in the pediatric population.

(*Circ Cardiovasc Intervent*. **2009;2:52-58.**)



A, A 15-mm balloon expanded to high pressure was unable to relieve the waist in this lesion with 2 concentric stents, which is caused by complete expansion and shortening of a Palmaz P154 stent, across which a Palmaz P188 stent has been placed. B, The waist and the fully expanded outer stent can be appreciated in this fluoroscopic image (arrows). C and D, A 12-mm Atlas balloon inflated to 28 atm was successful at relieving the resistant waist in the stents and fracturing the fully expanded and shortened Palmaz P154 stent (arrows).

UHPB

- **layered with woven ultrahigh molecular weight polyethylene (UHMWPE)**
- **burst pressures as high as 27 atm**
- **Conquest (5-12) Atlas (12-26 mm)**

Maglione et al, Circ Cardiovasc Intervent. 2009;2:52-58

Catheterization and Cardiovascular Interventions 85:249–258 (2015)

Unzipping of Small Diameter Stents: An In Vitro Study

Shyam K. Sathanandam,* MD, Lauren M. Haddad, MD, Saradha Subramanian, MD,
Dena Wright, RN, Ranjit Philip, MD, and Benjamin Rush Waller, MD

55 stents d ≤ 6mm
(34 coronary, 11 biliary, 10 nitinol)

predictors for unzipping
stainless steel alloy, closed -cell design

Palmaz Genesis stent d=4-6mm
fracture diameter (x Nominal)
: 3 (2.3-3.5)

s can be
in infant
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d to the
e dilated
er (dL/dD
hirty-four
4, 5, and
(SS) CS
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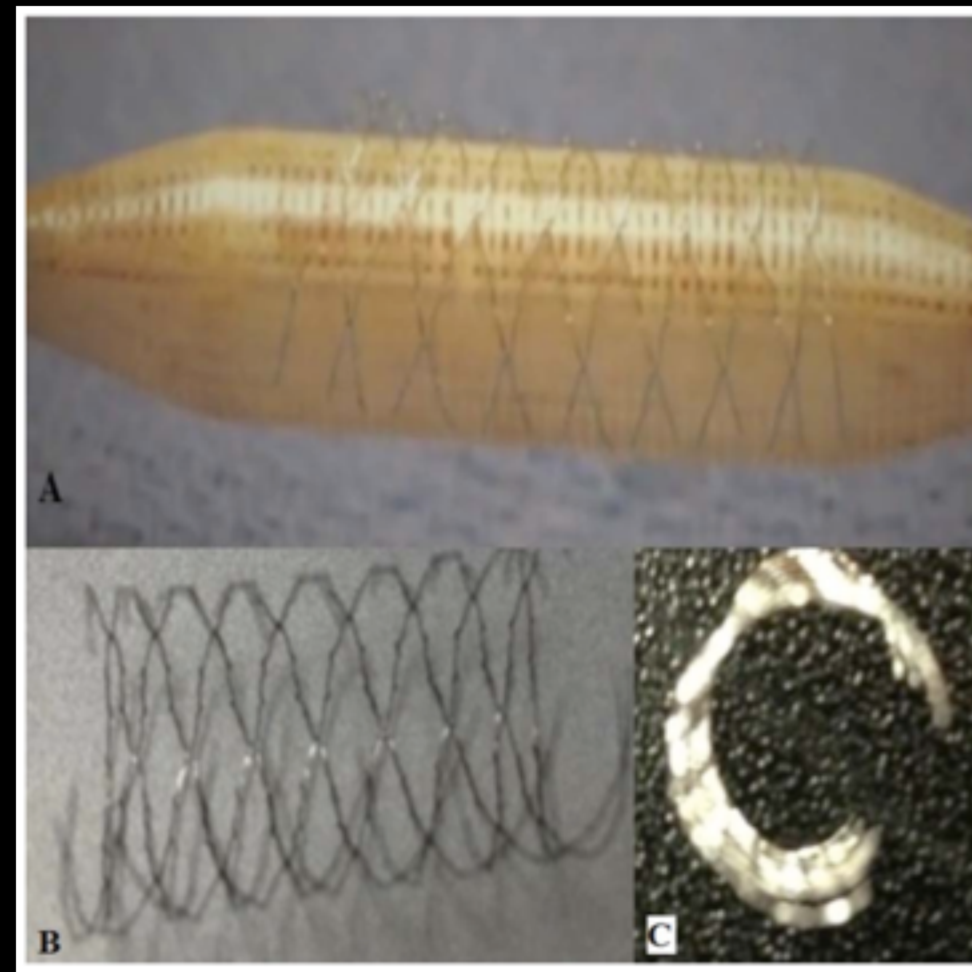

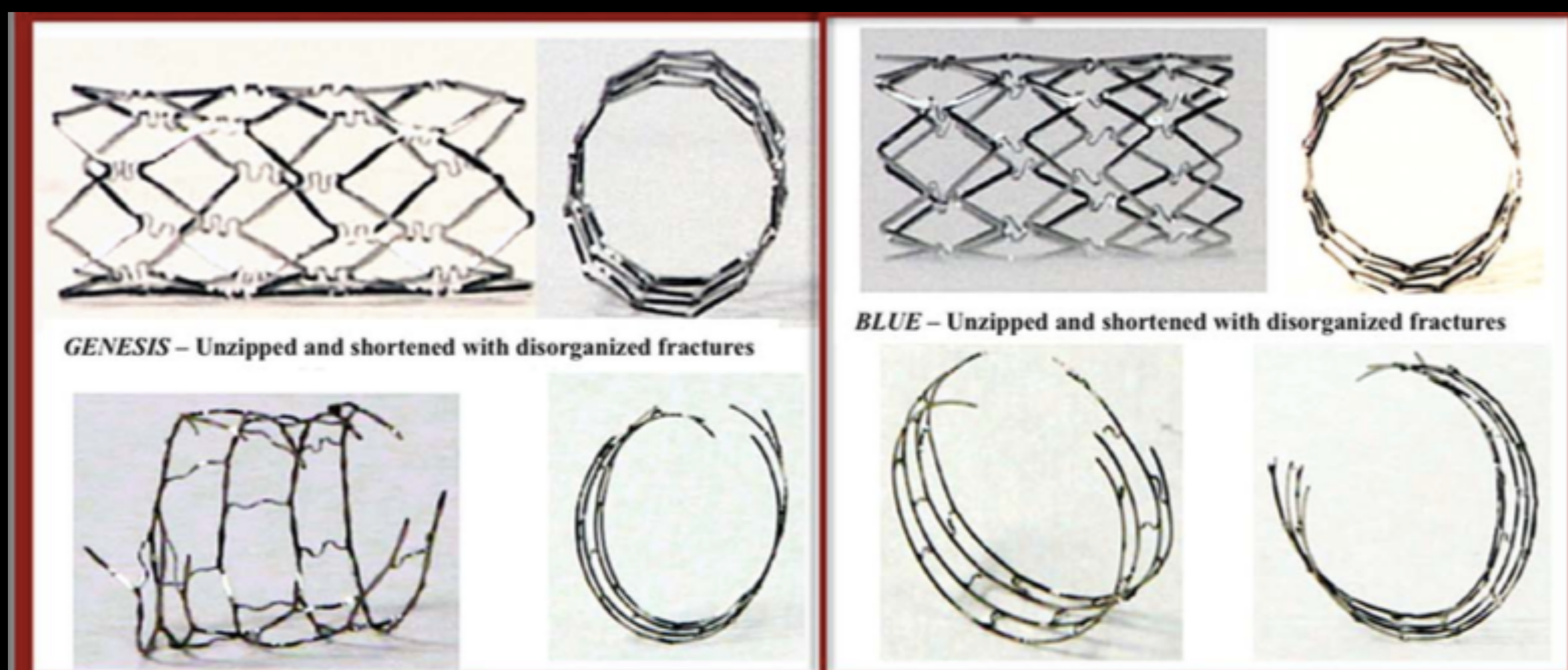

Satanandam et al, Catheterization and Cardiovascular Interventions 85:249–258 (2015)

Catheterization and Cardiovascular Interventions 87:E143–E150 (2016)

PEDIATRIC AND CONGENITAL HEART DISEASE

Original Studies

A New Breakable Stent for Recoarctation in Early Infancy: Preliminary Clinical Experience

Jochen Grohmann,[1*] MD, Matthias Sigler,[2] MD,
Matthias Siepe,[3] MD, and Brigitte Stiller,[1] MD

Objectives: Transcatheter treatment of aortic coarctation (CoA) via stent implantation has become an established treatment option depending on the patient's age and CoA type. Background: The Osypka BabyStent® is a low-profiled, balloon-expandable cobalt-chrome stent to treat aortic CoA in infants, which is breakable to permit unrestricted growth. We hereby evaluated our initial clinical experience to demonstrate the feasibility and efficacy of this new nonlicensed device, which we have occasionally implanted in critically ill patients or when redo-surgery would entail an excessively high risk. Methods: Retrospective single-center analysis of all available data during and after treatment with a BabyStent implanted in infants with considerable re-CoA or reobstruction of the aortic arch after former surgery. All interventions took place under fluoroscopy and conscious sedation with local anesthesia or general anesthesia. Results: Five BabyStents were implanted in four infants with technical success in all of them—median age 10 weeks (range 5–21), median bodyweight 3.8 kg (range 2.7–4.5). Aortic diameters enlarged from median 2.25 mm (range 1.5–3.3) to median 5.3 mm (range 4.6–6.0). The follow-up period lasting up to 26 months (median 8.5, range 2–26) was uneventful concerning stent-related complications. Conclusions: BabyStent® implantation for recoarctation was effective. However, our initial experience with the device is limited to short- and midterm follow-up only. None of the stents was subsequently overdilated with the intention to break due to our patients' limited somatic growth so far. A multicenter survey has been initiated to justify device approval.

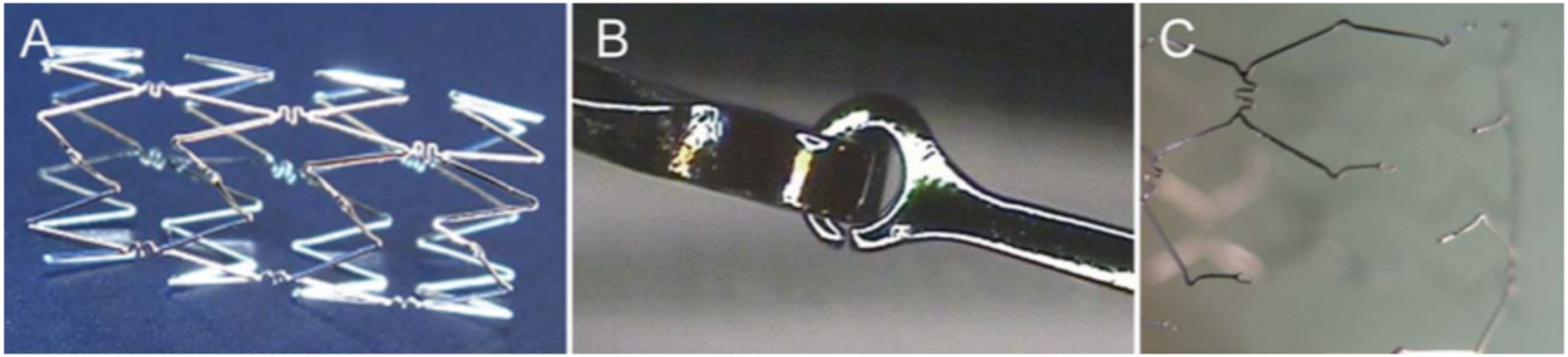

Fig. 1. The stent design includes elastic joints between the cells as well as hook and eye connections (A and B) which can be opened when the balloon's diameter exceeds 12 mm (C).

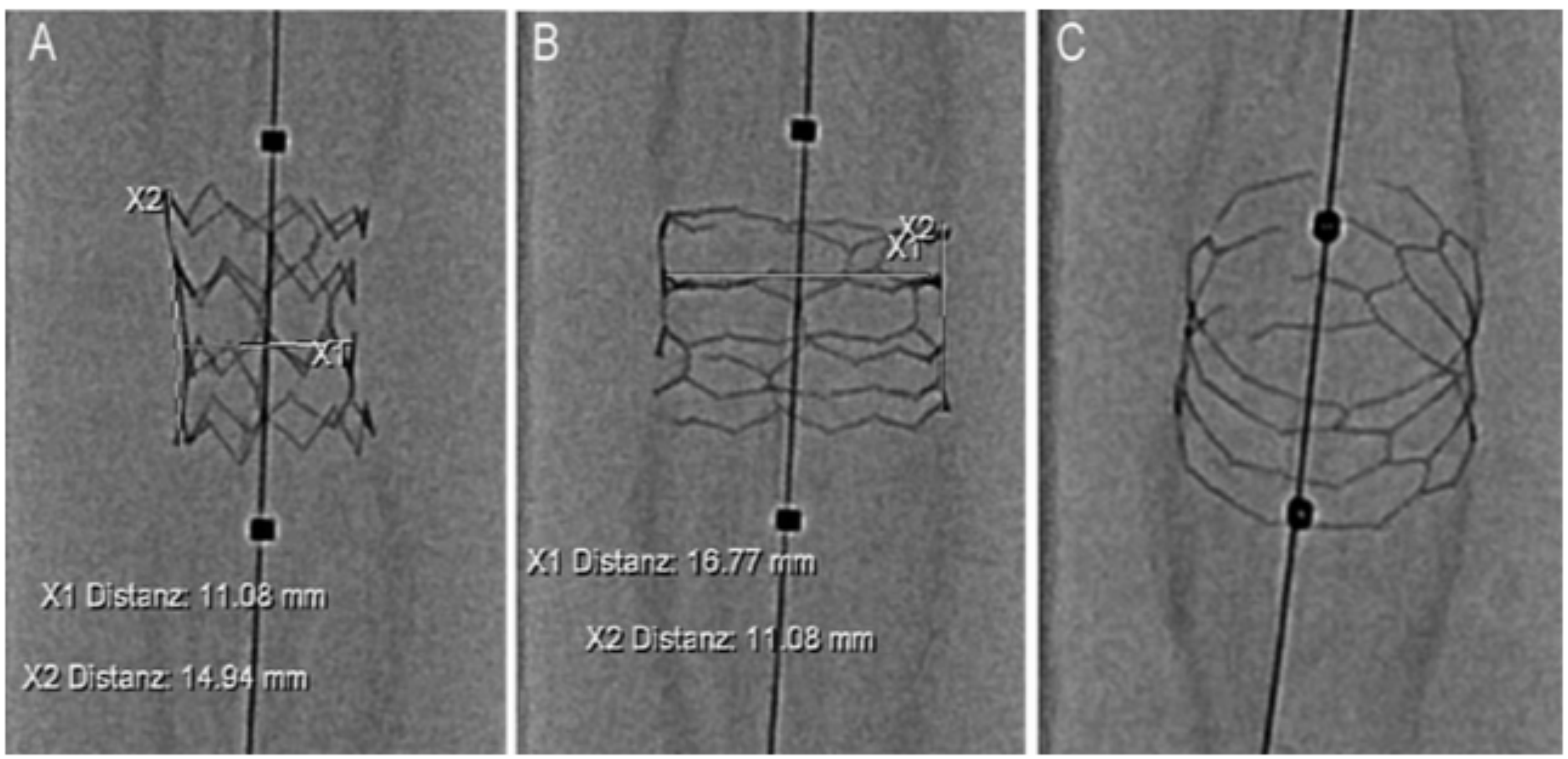

Fig. 2. (A) Bench test with the BabyStent dilated up to 11 mm. (B and C) Locking mechanisms of all the 4 strut rows opened after redilation with a noncompliant 18 mm balloon.

Graham et al, Catheterization and Cardiovascular Interventions 87:E143–E150 (2016)

Baby Stent

15mm long
6 - 12mm by balloon
0.018” wire
4F sheath
open locking by balloon>12mm
off-labeled, investigational only

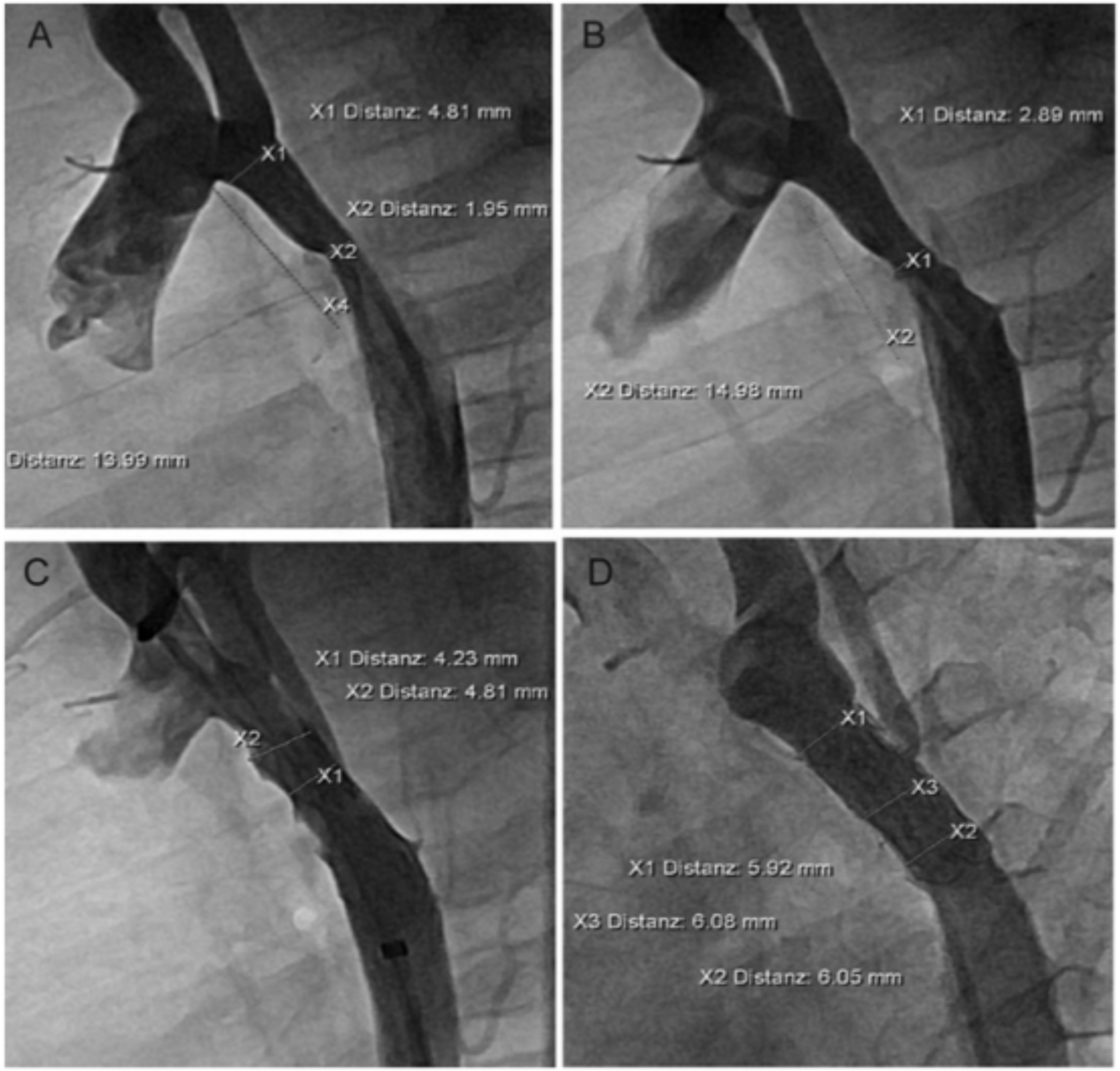

Fig. 5. Patient 4: (A) Re-CoA with a minimal diameter around 2.0 mm. (B) Balloon-angioplasty resulted in some improvement up to 2.9 mm. (C) More favorable result after recanalizing the left subclavian artery and BabyStent implantation with a stented lumen of at least 4.2 mm. (D) Follow-up result with diameters around 6 mm after reballooning 10 months later.

Graham et al, Catheterization and Cardiovascular Interventions 87:E143–E150 (2016)

Conclusions

- Endovascular stenting in infants has several limitations such as a smaller vessel, no growth potential of stent as the body grows, and no capacity to expand it to the adult size etc.

- These limitations can be overcome by using Valeo or Formula stents, breakable stent, and bioabsorbable stent or by unzipping of stent with UHPB.