Percutaneous Coronary Intervention With Bioresorbable Scaffolds in a Young Child

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IMPORTANCE Although much less frequent than in adults, coronary artery disease requiring revascularization may develop in children because of homozygous familial hypercholesterolemia or other underlying conditions. Percutaneous coronary intervention (PCI) with a bioresorbable scaffold (BRS) may have advantages over metallic coronary stents in this population.

OBJECTIVE To present a case of the successful treatment of unstable, multivessel coronary artery disease in a child with PCI with BRS implantation. This case highlights the limitations of conventional metal stents and the potential benefits of using BRSs in children.

DESIGN, SETTING, AND PARTICIPANTS This is a case report from an academic tertiary care institution of a 3-year-old boy with homozygous familial hypercholesterolemia and unstable coronary artery disease requiring revascularization. We also briefly review the related literature.

INTERVENTIONS/EXPOSURES Intravascular imaging-guided PCI of the proximal right coronary artery and the left main and proximal left circumflex arteries was performed with BRSs.

MAIN OUTCOMES AND MEASURES The primary outcomes were acute procedural success and survival to liver transplant (3 months after PCI).

RESULTS Following BRS implantation, the patient recovered and remained free of cardiovascular symptoms 3 months after PCI. He subsequently underwent an orthotopic liver transplant for definitive treatment of homozygous familial hypercholesterolemia but died of noncardiac complications. A postmortem examination, including a histological assessment, revealed both BRSs to be patent with nonobstructive neointimal hyperplasia.

CONCLUSIONS AND RELEVANCE To our knowledge, this is the first report of PCI with BRSs in a child. This represents an application of a BRS with potentially important implications for the future treatment of coronary artery disease in children and warrants further study.

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Familial hypercholesterolemia (FH) is an autosomal dominant disorder of low-density lipid metabolism that, in its homozygous form, causes severe clinical manifestations, including cutaneous stigmata of hyperlipidemia and coronary artery disease in early childhood.\(^1,2\) Treatment options include 3-hydroxy-3-methyl-glutaryl-coenzyme A reductase inhibitors, cholesterol absorption inhibitors, and low-density lipid apheresis.\(^2,3\) Hepatic transplantation, through which defective low-density lipid receptors are replaced with functional receptors from a donor, has been used in highly affected individuals.\(^2\) Coronary revascularization may be required when symptom- or ischemia-producing coronary disease develop.

We present a case of a child with homozygous FH and symptomatic, severe coronary artery stenoses that were treated with percutaneous coronary intervention (PCI) with bioresorbable scaffolds (BRSs). Using a BRS in this clinical scenario may afford advantages as a revascularization strategy, including vessel scaffolding and drug elution without requiring a metal stent that may become undersized as the child grows.

### Clinical Case

#### Presentation

A 3-year-old boy weighing 12.4 kg with homozygous FH presented with chest pain after minimal exertion. He had been treated with 3-hydroxy-3-methyl-glutaryl-coenzyme A reductase inhibitor (rosuvastatin) and a cholesterol absorption inhibitor (ezetimibe). A coronary angiogram revealed critical stenoses of the left main and proximal right coronary arteries that were not present on surveillance angiography 18 months earlier (Figure 1). An echocardiogram demonstrated normal left ventricular function and moderate aortic sclerosis (mean gradient, 20 mm Hg).

A multidisciplinary team, including pediatric and adult cardiologists, lipidologists, and surgeons, discussed therapeutic options. A liver transplant was planned for definitive therapy of the homozygous FH but was deferred for urgent coronary revascularization. Options for revascularization included coronary artery bypass grafting or multivessel PCI with metallic stents or the Absorb BRS (Abbott Vascular). The potential benefits of BRSs, such as the avoidance of a permanent metallic implant, were compared with the potential risks, including the increased strut thickness of the device, the need for dual antiplatelet therapy, and the undefined risks of bleeding, restenosis, or thrombosis in the pediatric population. Based on these discussions, the family chose PCI with an Absorb BRS, which was performed according with the US Food and Drug Administration emergency use provision for investigational devices.

#### Procedural Details

Percutaneous coronary intervention was performed via femoral arteries with 6-French guiding catheters. Following predilation, 2.5-mm Absorb BRSs were implanted in the proximal right and left main coronary arteries, extending into the proximal left circumflex artery (Figure 1). Both scaffolds were postdilated with 2.75-mm noncompliant balloons. Scaffold sizing, placement, and expansion were guided by intravascular ultrasonography (Figure 2). The PCI was successful with adequate scaffold expansion (cross-sectional areas were approximately 5 mm\(^2\)), no residual coronary stenosis, and normal coronary flow. The post-PCI hospital course was uneventful.

#### Follow-up

The patient was treated with aspirin and clopidogrel (1-2 mg/kg, titrated by platelet reactivity testing), in addition to rosuvastatin and ezetimibe. He resumed normal activity and remained free of cardiovascular symptoms for 3 months, with normal left ventricular function confirmed with echocardiography. As planned, he underwent a liver transplant with continuation of dual antiplatelet therapy throughout the perioperative period. He tolerated surgery well, with no electrocardiographic or echocardiographic evidence of coronary ischemia. Unfortunately, he died 2 weeks later of perioperative complications, including delayed wound closure, peritonitis, and sepsis.

A cardiovascular postmortem examination was performed and revealed similar findings in the scaffolded segments of the left main and right coronary arteries. Both BRSs were patent with highly cellular, nonobstructive neointimal hyperplasia consistent with accelerated atherosclerosis of homozygous FH (Figure 3). The native coronary arteries beyond the scaffolds also had diffuse, nonobstructive atherosclerotic disease. Diffuse, predominantly subendocardial, acute infarction was observed in both ventricles and the septum, likely caused by terminal hypotension. There was no evidence of endocarditis.

#### Discussion

This report of PCI with BRSs in a young child with homozygous FH and unstable angina is the first, to our knowledge, to describe using BRSs in the pediatric population. Acute procedural success was achieved with the implantation of BRSs in...
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Figure 1. Angiography and Postintervention Angiography of the Coronary Arteries

Angiography

A | Left main coronary artery

B | Left main coronary artery

C | Right coronary artery

D | Right coronary artery

Angiography demonstrates severe stenosis (arrowheads) of the left main coronary artery (A) and the right coronary artery (C).

Postintervention angiography demonstrates no residual stenosis after percutaneous coronary intervention with the implantation of a bioresorbable scaffold extending from the proximal left circumflex to the ostium of the left coronary artery (B) and in the right coronary artery (D).

Recently, several case series have described promising acute results with PCI among young children.4,6,7

Using coronary artery stents presents unique challenges among young children. The risk of in-stent restenosis may be increased, either because of the small diameter of the stents required or because of undefined differences in vascular healing responses in this population.7 Furthermore, a metallic stent may become undersized because of a child’s growth: a 4-fold increase in the diameter of the left main coronary artery (1-4.5 mm) occurs between infancy and 17 years of age.8 Finally, the presence of a metallic stent may permanently alter the coronary physiology.

Bioresorbable scaffolds address some of the limitations of metallic coronary stents.9,10 A BRS implanted after balloon angioplasty provides acute scaffolding of the vessel wall before being completely resorbed.11 The Absorb BRS is a polylactide scaffold that elutes an antiproliferative drug (everolimus) to limit neointimal hyperplasia and decrease restenosis.9 This BRS maintains structural integrity and radial strength for approximately 3 months before becoming discontinuous via hydrolysis and being fully resorbed within 36 months.9,11
The clinical performance of the Absorb BRS in adults has been studied in registries and randomized trials that have demonstrated noninferior safety and efficacy relative to second-generation drug-eluting stents. The experience of these studies has provided important technical lessons relevant for using BRSs in children, including the necessity of adequate vessel preparation and postdilation, 1 to 1 vessel to scaffold sizing, and avoidance of small target vessels (<2.5 mm). An important theoretical advantage of using BRSs in children is the potential to minimize interference with normal coronary artery growth, development, and physiology. Using a resorbable scaffold could potentially obviate the need for additional interventions because of a child’s normal growth. In addition, BRS resorption has the potential to restore normal coronary vasomotor tone.
Uncertainties exist regarding the use of BRSs in the pediatric population. Bioresorbable scaffolds have not been tested in children, so caution must be applied—this case was performed on an emergency basis with notification of the US Food and Drug Administration. Neointimal hyperplasia was noted at 3 months, and although late-lumen loss of the Absorb BRS has been shown to be noninferior to modern drug-eluting stents in adults, the risk of restenosis in children requires further study. In addition, the strut size of the Absorb BRS is larger than conventional metallic stents and may be predisposed to scaffold-related thrombosis in the setting of small or underexpanded scaffolds. Finally, dual antiplatelet therapy is required to prevent scaffold-related thrombosis and carries a risk of hemorrhage, which has not been well studied in children.

Conclusions

We present the first case, to our knowledge, of PCI with BRS in a young child with homozygous FH and symptomatic, severe coronary artery disease. Percutaneous coronary intervention in this case resulted in acute procedural success with resolution of the acute coronary syndrome and a favorable intermediate-term clinical outcome with survival to liver transplant.

REFERENCES


