

RX Herculink Elite[®] renal stent system: a review of its use for the treatment of renal artery stenosis

William R Colyer Jr

Division of Cardiovascular Medicine,
University of Toledo Medical Center,
Toledo, OH, USA

Abstract: The management of renal artery stenosis (RAS) remains controversial. While some evidence suggests that treatment with stent placement is beneficial, randomized trials have failed to demonstrate a significant benefit. Ongoing clinical trials should help to better define the role for stenting of RAS while avoiding limitations seen with earlier trials. When it comes to stenting for RAS, several stents have been used; however, many stents which have been used previously and which are still being used are biliary stents that are used “off-label.” These stents have typically come onto the market through the 510(k) pathway. To date, a total of five stents have been approved by the United States Food and Drug Administration for use in the renal arteries. Of the five stents that have received approval, the Bridge[™] Extra Support (Medtronic Cardiovascular, Santa Rosa, CA) and the Palmaz[®] (Cordis Corporation, Bridgewater, NJ) stents are no longer available. Currently, the Express[®] SD (Boston Scientific, Natick, MA), Formula[™] (Cook Medical, Bloomington, IN), and Herculink Elite[®] (Abbott Vascular, Santa Clara, CA) stents are Food and Drug Administration approved and available for use. The Herculink Elite is the most recently approved of the renal stents, having received approval in late 2011. The Herculink Elite stent is the only cobalt chromium stent approved for use in the renal arteries. Although trial data are limited and direct comparisons among renal stents is not possible, the Herculink Elite stent has demonstrated good performance. Additionally, the design of the Herculink Elite offers some advantages that may translate into improved outcomes.

Keywords: renal artery stenosis, stenting, FDA approval

Introduction

Renal artery stenosis (RAS) is a common manifestation of atherosclerosis. It is often seen in conjunction with other manifestations of atherosclerosis, such as coronary artery disease, aortoiliac disease, and carotid disease.^{1–5} The relationship between RAS and adverse clinical events, including increased mortality, has been well established for more than 40 years.^{6,7} Despite this, the optimal management of patients with RAS remains controversial.

Treatment options for RAS include medical therapy with or without adjunctive revascularization, which may be performed by either open surgical or percutaneous techniques. Surgical revascularization techniques for RAS include endarterectomy, patch angioplasty, extra-anatomic bypass grafting, and aortorenal bypass grafting.⁸ Percutaneous revascularization of RAS with balloon angioplasty was first reported in the 1970s.^{9,10} Although angioplasty is often able to achieve initial success in restoring renal blood flow, it is associated with a high rate of restenosis.¹¹ The introduction of stents has since improved immediate technical success rates, as well as reducing

Correspondence: William R Colyer Jr
University of Toledo Medical Center,
Division of Cardiovascular Medicine,
Mail Stop 1118, 3000 Arlington Avenue,
Toledo, OH 43614, USA
Tel +1 419 383 3697
Fax +1 419 383 3041
Email william.colyer@utoledo.edu

restenosis rates.¹¹ As a result of high technical success rates and lower rates of procedural complications as compared to open surgical repair, stenting has become the dominant strategy for revascularization of RAS.^{12,13}

While it is possible to effectively revascularize patients with RAS, it is not clear if this strategy offers benefit over treatment with optimal medical therapy. Specifically, as it relates to renal artery stenting, several registries and cohort studies have suggested that revascularization may lead to improvements in blood pressure control and/or renal function.^{14–18} However, to date there have been five randomized trials of renal artery angioplasty and stenting that have had largely disappointing results.^{19–23} The results of these randomized trials are summarized in Table 1. While disappointing, these trials have had limitations such as small sample sizes, the use of angioplasty without stenting in several, and the lack of core laboratory verification of the degree of RAS. As it relates to the largest of these trials, the ASTRAL (Angioplasty and Stenting for Renal Artery Lesions) trial, White provided an editorial detailing the limitations that has now become somewhat famous.²⁴ Currently, there are two ongoing trials of renal artery stenting, CORAL (Cardiovascular Outcomes in Renal Atherosclerotic Lesions) and RADAR (Comparison of Best Medical Treatment Versus Best Medical Treatment Plus Renal Artery Stenting), which will provide further insight into the potential benefits of stenting for RAS.^{25,26}

Despite the current controversy, renal artery stenting is still commonly performed. Guidelines for revascularization of RAS were published by the American College of Cardiology and the American Heart Association in 2005.²⁷ In 2011, a focused update of the guideline for the management of patients with peripheral arterial disease was published.²⁸ While the update acknowledged the results of new studies,

including ASTRAL, it did not change the recommendations of the 2005 guideline. The current recommendations for renal artery stenting are detailed in Table 2.

While there is controversy regarding the role for stenting in RAS, there is even less information available to help a physician make a decision about what equipment to use. Historically, many stents that were used for the treatment of RAS in the United States were approved as biliary stents and used “off-label” to treat RAS. This holds true today, as stents such as the Palmaz® Genesis™ and Blue™. 014 peripheral stent systems from Cordis Corporation (Bridgewater, NJ) are not approved for this indication by the Food and Drug Administration (FDA). Although, it should be noted that the Genesis stent has been studied in RAS in the GREAT (Palmaz Genesis Peripheral Stainless Steel Balloon Expandable Stent in Renal Artery Treatment) trial.²⁹ Overall to date, the FDA has approved five stents for the treatment of RAS as summarized in Table 3. The clinical data related to these stents will be reviewed in some detail below, with particular attention to the Herculink stent, which is the most recently approved.

FDA approved stents for treatment of RAS

Bridge™ Extra Support Over-the-Wire (Medtronic CardioVascular, Santa Rosa, CA)

The Bridge stent is a 316 L stainless steel stent that was manufactured by Medtronic. It was approved by the FDA in 2002; however, it is no longer for sale in the United States. FDA approval of the Bridge stent was based upon the results of the SOAR (Suboptimal Renal Angioplasty Results) trial.³⁰ A total of 188 patients were enrolled in the SOAR trial between April 1999 and May 2002. Inclusion criteria

Table 1 Summary of randomized trials of revascularization versus medical therapy in renal artery stenosis

Study	Year of publication	Subjects (N)	Strategy compared	Follow-up	Primary outcome	P value
EMMA ¹⁹	1998	49	PTA versus medicine	6 months	24 hour ambulatory blood pressure	NS
Scottish and Newcastle ²⁰	1998	55	PTA versus medicine	3–54 months	Change in SBP (34 mmHg versus 8 mmHg PTA better)	0.018
DRASTIC ²¹	2000	106	PTA versus medicine	12 months	Change in serum Cr	NS
STAR ²²	2009	140	Stenting versus medicine	24 months	Change in SBP and DBP	NS
ASTRAL ²³	2009	806	PTA ± stenting versus medicine	60 months	≥20% decrease in estimated Cr clearance	NS
					Change in renal function (trend favors revascularization)	0.06

Abbreviations: ASTRAL, Angioplasty and Stenting for Renal Artery Lesions; Cr, creatinine; DBP, diastolic blood pressure; DRASTIC, Dutch Renal Artery Stenosis Intervention Cooperative Study Group; EMMA, Essai Multicentrique Medicaments vs Angioplastie; NS, not significant; PTA, percutaneous transluminal angioplasty; SBP, systolic blood pressure. STAR, Stent placement in patients with atherosclerotic renal artery stenosis and impaired renal function.

Table 2 Summary of current guidelines for revascularization in patients with renal artery stenosis

Class I	Class IIa	Class IIb
1. Hemodynamically significant RAS and unexplained CHF or sudden unexplained pulmonary edema (Evidence level B)	1. Hemodynamically significant RAS and accelerated HTN, resistant HTN, HTN with unexplained unilateral small kidney, and HTN with medication intolerance (Evidence level B) 2. Bilateral RAS or RAS of solitary functioning kidney and progressive CKD (Evidence level B) 3. Hemodynamically significant RAS and unstable angina (Evidence level B)	1. Asymptomatic bilateral or solitary viable kidney with hemodynamically significant RAS (Evidence level C) 2. Unilateral hemodynamically significant RAS in a viable kidney (Evidence level C) 3. Unilateral RAS and CKD (Evidence level C)

Abbreviations: CHF, congestive heart failure; CKD, chronic kidney disease; HTN, hypertension; RAS, renal artery stenosis.

included a $\geq 70\%$ ostial RAS and “significant chronic or new onset hypertension.” This degree of hypertension was defined as a blood pressure of $> 140/90$ on two medications, or a blood pressure of $< 140/90$, but requiring three or more medications to achieve this level of control. Patients in the trial also had to have normal to moderately reduced renal function, defined as a serum creatinine of ≤ 1.9 mg/dL. Patients were initially treated with angioplasty with stenting reserved for suboptimal results, defined as a residual stenosis of $\geq 50\%$, visible dissection, or a significant pressure gradient. A significant pressure gradient was defined as a ≥ 20 mmHg peak systolic gradient or a ≥ 10 mmHg mean gradient. Angiograms were assessed by a core laboratory. The primary endpoint of the SOAR trial included the binary restenosis rate at 9–12 months as determined by duplex ultrasound analysis.³⁰ Secondary endpoints included acute success defined as a residual stenosis of $\leq 30\%$ and a residual gradient of < 5 mmHg, as well as blood pressure and renal function endpoints.

Among the 188 patients enrolled in SOAR, 159 had follow-up duplex ultrasound analysis for restenosis. The restenosis rate among the analyzed patients was 16.4%. The systolic blood pressure decreased from a baseline of 160 mmHg to 147 mmHg at the 9–12-month follow-up. The diastolic blood pressure decreased from 77 mmHg to 74 mmHg. The number of antihypertensive medications decreased from 2.7 to 2.5, which, although a small difference, was statistically significant. Serum creatinine levels increased

from 1.15 mg/dL to 1.22 mg/dL.³⁰ These results are summarized in Table 4, along with the results of trials leading to the approval of the other FDA approved stents.

Palmaz

The Palmaz stent is a 316 L stainless steel stent that was manufactured by Cordis Corporation. It was approved by the FDA in 2002; however, like the Bridge stent, it is no longer for sale in the United States. FDA approval was based upon the results of the ASPIRE-2 (A Study to Evaluate the Safety and Effectiveness of the Palmaz Balloon Expandable Stent in the Renal Artery After Failed Angioplasty) trial.³¹ A total of 208 patients were enrolled between December 1997 and May 1999. Inclusion criteria included a $\geq 70\%$ RAS, a serum creatinine of ≤ 3.0 mg/dL, and uncontrolled hypertension. Uncontrolled hypertension was defined as a blood pressure of $> 140/90$ with “two or more antihypertensive agents administered in appropriate doses.” Patients were treated with angioplasty and were eligible for enrollment in the clinical trial and stent placement if there was a $\geq 50\%$ residual stenosis, a peak systolic pressure gradient of ≥ 20 mmHg, or a flow limiting dissection following angioplasty. Angiograms were assessed by a core laboratory. The primary efficacy endpoint of the trial was the rate of binary restenosis at 9 months. This was determined by repeat angiography in the first 65 patients and by duplex ultrasound in the remaining patients. Secondary endpoints included acute success, defined as $< 30\%$ residual stenosis and ≤ 5 mmHg residual

Table 3 Summary of stents approved by the United States Food and Drug Administration for the treatment of renal artery stenosis

Stent	Manufacturer	Year approved	Clinical trial	Material
Bridge Extra Support	Medtronic CardioVascular	2002	SOAR	Stainless steel
Palmaz	Cordis Corporation	2002	ASPIRE-2	Stainless steel
Express SD Renal	Boston Scientific	2008	RENAISSANCE	Stainless steel
Formula 414 and 418	Cook Medical	2011	REFORM	Stainless steel
Herculink Elite	Abbott Vascular	2011	HERCULES	Cobalt chromium

Table 4 A summary of the results of trials leading to United States Food and Drug Administration approval of stents for use in the renal artery

Stent	Trial	Binary restenosis rate	Change in SBP (mmHg)	Change in DBP (mmHg)	Change in sCr (mg/dL)
Bridge	SOAR	16.4%	-13	-3	+0.07
Palmaz	ASPIRE-2	17.4%	-19	-5	+0.04
Express	RENAISSANCE	21%	-8	-1	+0.01
Formula	REFORM	8%***	-10	+4	Not reported
Herculink Elite	HERCULES	11%	-17	-3	Not reported

Notes: Head to head comparisons cannot be made as each result was obtained from a different trial; ***the REFORM trial reported a primary patency rate of 92%, but did not report a restenosis rate.

Abbreviations: DBP, diastolic blood pressure; SBP, systolic blood pressure; sCr, serum creatinine.

pressure gradient, as well as blood pressure and renal function outcomes.³¹

The restenosis rate among patients who had follow-up data available at 9 months was 17.4%. Systolic blood pressure decreased from 168 mmHg at baseline to 149 mmHg at 9 months. Diastolic blood pressure decreased from 82 mmHg to 77 mmHg. The number of antihypertensive medications decreased from 2.8 to 2.4. All of these changes were statistically significant. Serum creatinine increased from 1.36 mg/dL to 1.40 mg/dL; however, this difference was not statistically significant.³¹ These results are summarized in Table 4.

Express[®] SD (Boston Scientific, Natick, MA)

The Express SD stent is a 316 L stainless steel stent manufactured by Boston Scientific. It was approved for use by the FDA in 2008 based upon the results of the RENAISSANCE (Renal Artery Stenting with Noninvasive Duplex Ultrasound Follow Up) trial.³² A total of 100 patients were enrolled in the trial between January and August 2004. Inclusion criteria included a $\geq 70\%$ RAS and “hypertension, renal dysfunction, flash pulmonary edema, or any combination thereof.” Although renal dysfunction was an inclusion criterion, serum creatinine had to be < 3.0 mg/dL. No blood pressure criteria were described in the published results of the trial.³² All enrolled patients received a stent. The primary endpoint was the binary restenosis rate at 9 months of follow-up, as assessed by duplex ultrasound with confirmatory angiography. Binary restenosis was defined as $\geq 50\%$ stenosis on the confirmatory angiogram. Angiograms were assessed by a core laboratory. Secondary endpoints included technical success, defined as $\leq 30\%$ residual stenosis, as well as blood pressure and renal function outcomes.

Nine-month follow-up data was available in 93% of patients with a restenosis rate of 21%. Systolic blood

pressure decreased from 157 mmHg at baseline to 149 mmHg at 9 months. Diastolic blood pressure decreased from 75 mmHg to 74 mmHg. The number of antihypertensive medications was not reported. Serum creatinine was essentially unchanged from baseline (1.39 mg/dL) to 9-month follow-up (1.40 mg/dL).³² These results are summarized in Table 4.

Formula[™] 414 and 418 (Cook Medical, Bloomington, IN)

The Formula 414 and 418 stents are 316 L stainless steel stents manufactured by Cook Medical. The only difference between the stents is the delivery system, with the Formula 414 being compatible with a 0.014-inch delivery system and the Formula 418 being compatible with a 0.018-inch delivery system. The Formula stent was approved for use by the FDA in 2011 based upon the results of the REFORM (Treatment of RAS With the Formula Balloon-Expandable Stent) trial, which has not been published. Data from the REFORM trial are detailed in the instructions for use, which are available on the FDA website.³³ The REFORM trial enrolled a total of 100 patients. The primary endpoint was primary patency at the 9-month follow-up, defined as $\leq 60\%$ stenosis as determined by duplex ultrasound.³³ Secondary endpoints included renal function and blood pressure outcomes.

The primary patency rate at the 9-month follow-up was 92%. Systolic blood pressure decreased from 150 mmHg at baseline to 141 mmHg at 9 months. Diastolic blood pressure increased from 74 mmHg to 78 mmHg. The number of antihypertensive medications decreased from 2.7 to 2.5.³³ The instructions for use indicate that “renal function was maintained (ie, did not worsen)” from baseline to follow-up; however, the actual renal function data is not provided. These results are summarized in Table 4.

RX Herculink Elite® (Abbott Vascular, Santa Clara, CA)

The Herculink Elite is an L605 cobalt chromium stent manufactured by Abbott Vascular. It was approved by the FDA in 2011 based upon the results of the HERCULES (A Safety and Effectiveness Study of the Herculink Elite Renal Stent to Treat RAS) trial, which has not been published. A summary of the results of the HERCULES trial is included in the instructions for use, which are available on the Abbott website.³⁴ The HERCULES trial enrolled 202 patients. Inclusion criteria included $\geq 60\%$ RAS and uncontrolled hypertension, defined as a systolic blood pressure of ≥ 140 mmHg, a diastolic blood pressure of ≥ 90 , or both on two or more antihypertensive medications. Patients were initially treated with angioplasty and were eligible for stenting if the angioplasty result was suboptimal. A suboptimal angioplasty result was defined as $\geq 50\%$ residual stenosis, ≥ 20 mmHg peak systolic translesional pressure gradient, ≥ 10 mmHg mean translesional pressure gradient, or a flow limiting dissection. The primary endpoint was the 9-month follow-up binary restenosis rate, defined as $\geq 60\%$ stenosis measured by duplex ultrasound. Secondary endpoints included blood pressure and renal function measures.

The 9-month follow-up restenosis rate was 11%. Systolic blood pressure decreased from 162 mmHg at baseline to 145 mmHg at 9 months. Diastolic blood pressure decreased from 78 mmHg to 75 mmHg. The instructions for use state that “renal function was maintained (ie, did not worsen)” from baseline to follow-up; however, as with the Formula stent, the actual renal function data is not provided.³⁴ These data are summarized in Table 4.

Based upon the available data, the Herculink Elite stent performs in a comparable manner to other stents that have been FDA approved for the treatment of RAS; however, it is important to note that no direct comparisons of the efficacy of each stent can be made. One clear difference between the Herculink Elite and other stents is that it is the only stent that is not made of stainless steel. The use of a cobalt chromium alloy may lead to some performance advantages with the Herculink stent. Specifically, the use of cobalt chromium allows for thinner stent struts, which may lead to a lower rate of restenosis. This has been well documented in the arena of coronary artery stenting. The ISAR-STEREO (Intracoronary Stenting and Angiographic Results: Strut Thickness Effect on Restenosis Outcome) trial demonstrated that a thin strut stent had a lower rate of restenosis than a thick strut stent of similar design.³⁵ Similar results were found in several other trials.^{36–38}

In addition to thinner struts, cobalt chromium stents tend to be more deliverable; however, this is likely to be less of an issue in the renal artery than in coronary arteries, as the lesion is typically ostial so there is typically not a need to deliver a stent to a more distal location through a tortuous vessel.

Importance of FDA approval

A reasonable question to ask is whether FDA approval of a stent specifically for the treatment of RAS matters. Many devices used by interventional physicians are used off-label. Indeed, it is important that physicians are able to use devices as well as drugs in a manner that will allow them to best treat their patient. Given that trials that lead to FDA approval have very specific inclusion and exclusion criteria, the instructions for use of the approved product have similarly specific labeling, which would preclude the use of the device in many patients who may derive benefit from it. However, a distinction can be made between using a stent approved for treating RAS for a lesion that is not defined in the package insert, such as a nonostial stenosis, and the use of a device that is not approved for use in the vascular system. In order to appreciate this, it is helpful to understand how the FDA classifies medical devices and clears or approves a device for use.

The FDA classifies medical devices into three categories. Class I devices are low-risk devices with well-established safety and efficacy. These devices require “general controls.” Examples of class I devices include drainage catheters. Class II devices are intermediate risk and require “special controls.” These devices are not “approved,” but are ultimately “cleared” via the 510(k) pathway. Devices submitted for 510(k) clearance must demonstrate “substantial equivalence” to a “predicate” device. As it relates to stenting for RAS, the 510(k) pathway has been used to obtain clearance for biliary stents, which have been used for RAS as well as many other peripheral vascular applications.³⁹ Class III devices are first of a kind or high-risk products for which a manufacturer must submit a premarket application demonstrating the safety and efficacy of the device. In addition to a premarket application, class III devices are subject to annual reports and often post approval studies following the initial approval.

In 2007, the FDA met with biliary stent manufacturers to address off-label promotion. Since that time, the FDA has worked to help manufacturers design trials to allow for approval of devices such as stents to treat RAS. Indeed, this is how the Formula and Herculink Elite stents were ultimately

approved for treating RAS. This represents a step forward compared to simply using a 510(k) pathway to approve a biliary stent with the ultimate intent of using it in the vascular system; however, there is still progress to be made. Specifically, the REFORM and HERCULES trials used predefined objective performance criteria rather than an active control. While this provides data that the devices are safe and effective for reducing a renal artery narrowing, it does little to show that clinical outcomes are improved.

Future perspectives

Currently, the clinical utility of stenting for RAS remains incompletely defined, although trials such as CORAL and RADAR will ultimately provide additional clarification of this issue. If stenting for RAS is proven to provide benefits over medical therapy alone, then having stents – which have been tested and approved for this indication – will be important. Given this, future studies of new renal stents will need to be compared to those that have been approved by the FDA.

Conclusion

While the management of RAS remains controversial, there is currently a role for stenting. While historically physicians wanting to treat RAS with a stent often used a biliary stent off-label, there are currently three stents approved by the FDA for this indication. Therefore, when selecting a stent, physicians should choose one that has been FDA approved. While direct comparisons cannot be made among FDA approved stents for use in the renal arteries, the Herculink Elite performs comparably to the other FDA approved stents. Additionally, its unique cobalt chromium design may offer specific advantages in theory and possibly in practice.

Disclosure

The author reports no conflicts of interest in this work.

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