Smart Utility, Smart Outcomes

What do the data tell us about the role of the S.M.A.R.T.® Vascular Stent for treating SFA disease?

BY WILLIAM A. GRAY, MD

Since its introduction more than a decade ago, there has been a great deal of high-quality data generated for the use of the S.M.A.R.T.® Stent (Cordis Corporation, Bridgewater, NJ) in the superficial femoral/popliteal artery (SFA) circulations. From the more than 2,000 patient outcomes published or presented using the S.M.A.R.T.® Stent, it becomes possible to characterize this device with regard to its clinical utility and durability in a variety of lesion subsets, both in isolation and compared to other self-expanding nitinol stents, in some of the longest follow-up available for any SFA stent. This article reviews these data as a prelude to a discussion regarding the pivotal STROLL trial outcomes and draws conclusions regarding the place of the S.M.A.R.T.® Stent in the management of patients with occlusive SFA disease.

CLINICAL TRIALS AND REGISTRIES

The earliest controlled data on the S.M.A.R.T.® Stent come from the prospective SIROCCO study,[1] which randomized the bare S.M.A.R.T.® Stent to a drug-eluting sirolimus (DES) version. Although the DES version did not demonstrate a differential improvement in efficacy, the results of the study were nevertheless impressive, showing an 18-month primary patency rate for the bare S.M.A.R.T.® Stent of 87% for lesions of approximately 8 cm in length. The next set of data came from the BLASTER study,[2] which randomized patients receiving the S.M.A.R.T.® Stent for treatment with and without abciximab. Although there were no differences in outcomes as a result of the adjunctive pharmacology, in a population in which the mean length was approximately 12 cm, the clinical patency at 12 months was 83%, confirming the earlier SIROCCO results.

Early comparative data on the S.M.A.R.T.® Stent come, albeit retrospectively, from the FESTO study,[3] which reviewed the SFA outcomes of S.M.A.R.T.®, SelfX (Abbott Vascular, Santa Clara, CA), and Luminexx® (Bard Peripheral Vascular, Tempe, AZ) stents. In this analysis, the S.M.A.R.T.® Stent outperformed the other stents on 12-month patency as well as fracture resistance. In that study, fractures were associated with a loss of patency.

Some of the longest-term data on SFA stenting exists with the S.M.A.R.T.® Stent. The SIROCCO II trial[4] (a second-phase randomized DES study meant to assess changes in elution rates) enrolled 57 patients who were followed to 4 years. Both the DES and bare-metal S.M.A.R.T.® Stents demonstrated durable results, with a freedom from reintervention rate of approximately 74% at 4 years. In the retrospective J-SMART study[5] of 432 patients with lesion lengths of approximately 16 cm (approximately twice that of SIROCCO II), 5-year primary patency was a remarkable 66%. In fact, combined with other S.M.A.R.T.® Stent data, there appears to be an inverse relationship between lesion length and patency, not previously well demonstrated with a single-stent system.

THE STROLL TRIAL

It is on this background of a robust experience with the S.M.A.R.T.® Stent in the SFA that the pivotal STROLL trial[6] was conceived and executed in 250 patients at 39 sites in the United States. The STROLL trial was a multicenter, prospective, single-arm study of the S.M.A.R.T.® Stent in SFA/popliteal lesions, designed to gain an FDA vascular indication for the S.M.A.R.T.® Stent, which was achieved in November 2012 based on the strength of the STROLL data.

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STROLL demonstrated an excellent safety and efficacy profile when patients were treated for SFA/popliteal disease with the S.M.A.R.T.® Stent, with additional measures of long-term clinical efficacy tracking the sustained and durable patency results.

Patients eligible for the S.M.A.R.T.® Stent had to be Rutherford classification 2 through 4 with SFA/popliteal lesions between 4 and 15 cm in length and diameters between 4 and 6 cm. The primary efficacy endpoint of the study was patency (defined as the composite of the absence of both target lesion revascularization [TLR] and Doppler ultrasound-detected stenosis < 50%) at 12 months. There were important secondary endpoints that included 3-year clinical follow-up, functional and hemodynamic outcome measures, and protocol-driven core-lab radiographic evaluation of stent fracture. Follow-up is quite complete, with evaluable data on 234 subjects available at 1 year and on 224 subjects at 2 years.

Baseline patient characteristics are in keeping with other SFA trials, with a mean age of 68 years, two-thirds being men, and nearly 50% with diabetes. The average lesion length was approximately 8 cm, and one-quarter of the lesions were chronic total occlusions (CTOs).

Procedural results were excellent, with a technical success rate of 100% in relieving the stenosis, and no safety events (death, amputation, and TLR) within the first 30 days. Long-term follow-up of these acute results demonstrate primary patency, by Kaplan-Meier estimate, was 81.7% at 1 year and 74.9% at 2 years. Doppler ultrasound determination of patency was > 80% for both time intervals, as was the freedom from clinically driven TLR.

The careful radiographic assessment and core lab adjudication of stent strut fractures demonstrated that, of the five possible grades of fracture, S.M.A.R.T.® Stent usage in STROLL only resulted in fractures in four of 197 stents at 1 year, and no further fractures were noted at 2 years. Furthermore, only the simplest and most "benign" type of fracture was seen (type I, single-connector fracture), and no more complex fractures were noted. Last, there was no association with fracture and loss of patency in STROLL. These data were in contradistinction to previous data suggesting both higher rates of fracture with the S.M.A.R.T.® Stent, as well as an association with restenosis when fracture occurs.

Two populations within STROLL who are thought to be particularly at risk for device failure—patients with CTO or diabetes—had a prespecified analysis of efficacy outcomes. Interestingly, the presence of diabetes or CTO did not lead to any worse outcomes in patency after treatment with the S.M.A.R.T.® Stent when compared to patients without those conditions.

Increasingly, it is no longer adequate to simply demonstrate patency outcomes when treating claudicants. Specifically, patients must show benefit in hemodynamic and functional outcomes. Accordingly, these endpoints were built into the STROLL study. Mean ankle-brachial indices demonstrated marked and significant improvement from baseline (0.66 ± 0.15) to postprocedure (0.98 ± 0.14), and these improvements were durable to 2 years (0.93 ± 0.18). Similarly, > 80% of all patients were Rutherford-Becker class 0 or 1 at 2 years, whereas preprocedure, almost all patients were class 2 through 4.

SUMMARY

STROLL demonstrated an excellent safety and efficacy profile when patients were treated for SFA/popliteal disease with the S.M.A.R.T.® Stent, with additional measures of long-term clinical efficacy tracking the sustained and durable patency results. There were satisfying data on the at-risk populations with diabetes and CTOs that assured no difference in safety, efficacy, or durability of results.

These outcomes compare favorably with those obtained with other FDA-approved bare-metal and DES self-expanding nitinol stents, and place the S.M.A.R.T.® Stent results squarely among the treatment options available to physicians for the treatment of patients with SFA/popliteal disease. ■

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