

New treatment of iliac artery disease: focus on the Absolute Pro[®] Vascular Self-Expanding Stent System

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Abstract: Management of iliac artery disease has evolved over the years, from a surgical-only approach to a primarily endovascular-only approach as the first line treatment option. This has been continuously improved upon with the advent of new devices and applied technologies. Most recently in particular, the literature has shown good, reliable outcomes with the use of self-expandable stents in iliac artery atherosclerotic lesions. Nevertheless, no device is without its limitations, and the Absolute Pro[®] Vascular Self-Expanding Stent System was designed with the intent of overcoming some of the shortcomings of other available stents while maintaining acceptable postprocedural outcomes. Based on preliminary industry-acquired data, it has achieved these goals and appears to be an emergent competitor for the treatment of both focal and complex iliac artery lesions.

Keywords: Absolute-Pro[®], iliac stent, self-expanding stents, atherosclerotic disease

Review: endovascular treatment of iliac artery atherosclerotic disease

Over the last 20 years, a significant paradigm shift has occurred in the treatment of atherosclerotic arterial disease. Endovascular interventions, including angioplasty and stenting, have become the first-line approach for the treatment of patients with simple and complex peripheral atherosclerotic lesions, including challenging-to-access iliac lesions. Initially, treatment was aimed at angioplasty of focal short segment lesions; however, as new stents and technical developments have been introduced, endovascular treatment has been expanded to include combined angioplasty and stenting of more complex, chronic lesions, with good long term results. The Abbott Absolute Pro[®] Vascular Self-Expanding Stent System (Abbott Laboratories, Abbott Park, IL, USA) was created with the intent to improve upon previous stent designs and to have the ability to be utilized as a first-line endovascular treatment for both simple and complex iliac artery lesions. This review addresses the change in the endovascular treatment of iliac atherosclerotic disease, with a specific focus on the Absolute Pro's new stent design and clinical effectiveness.

Iliac artery atherosclerotic disease can greatly impact patients' overall quality of life, limiting walking ability and leading to chronic pain and morbidity. Conventional treatment has been limited to an open surgical approach, generally associated with long hospital stays and significant perioperative morbidity and mortality.^{1,2} However, due to superior outcomes, most of these patients now undergo primary endovascular treatment. As previously mentioned, initial interventions focused on primary

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angioplasty of focal iliac lesions, which was evaluated by Becker et al.³ This group compiled the results of treatment with angioplasty alone reported in the literature, which showed an average technical success rate of 92%, a 2-year patency of 81%, and a 5-year patency of 72%. Over time, with the development of superiorly designed devices, catheters, and wires, the results of angioplasty alone for iliac stenosis continued to show improved results in the literature. Tegtmeier et al⁴ followed Becker's initial study with their own single-center series of 200 patients, in whom they found an initial technical success rate of 94.7% with angioplasty alone and a 7.5-year cumulative patency rate of 85%. In spite of these favorable results in the literature, iliac lesion type seemed to limit further improvements in patency with angioplasty alone. High rates of restenosis continued to be prevalent in published studies, especially in lesions with eccentric, calcified, or ulcerated plaques as well as in lesions found in patients with multilevel disease. Attention then turned to focus on evaluating primary stent placement versus primary angioplasty with selective stent placement. The Dutch Iliac Stent Trial⁴ was conducted for the purpose of addressing and evaluating which was the most effective treatment strategy. This study assigned 279 patients to undergo either primary stent placement or angioplasty with selective stent placement. The primary endpoints were vessel patency and symptomatic improvement. The researchers found that selective stent placement led to better long-term preservation of symptomatic relief; however, they found no difference in hemodynamic treatment outcome, iliac artery patency, or the quality of life between the groups. Other studies that followed the Dutch trial had results that showed a preference for primary stent placement, due to the reduced risk of vessel rupture and distal embolization as well as the superior long-term patency provided.⁵⁻⁷

Proceeding forward, studies focused on the stent type as the limiting variable for interventional success. Among the stents used, the Palmaz® Balloon Expandable Stent (Johnson & Johnson Interventional Systems, Warren, NJ, USA) and the self-expandable WALLSTENT® Venous Endoprosthesis with Unistep® Plus Delivery System (Boston Scientific Corp, Natick, MA, USA) resulted in a 1-year primary patency of 87% and 78%, respectively, with secondary patency rates of 91% and 86%, respectively.^{8,9,10} Primary patency, in these studies, appeared to be limited by intimal hyperplasia and progressive atherosclerotic disease as well as by technical limitations, including imprecise placement and difficulty with intra-arterial deployment of the stent in complex iliac lesions.¹¹ Other trials then looked at covered stents

versus bare-metal stents, in the treatment of iliac disease. A multicenter, prospective, randomized, controlled trial was conducted by Mwiipatayi et al¹² to evaluate covered balloon-expandable stents vs bare-metal stents, in the treatment of iliac artery atherosclerotic disease. This study involved 125 iliac artery lesions, with results showing no difference in TransAtlantic Inter-Society Consensus (TASC) type B lesions; however the researchers did find that covered stents had higher long-term patency rates in both TASC type C and D lesions.¹² The major disadvantage in this study was that the covered stents that were used required larger delivery systems, exposing the patient to a higher risk of groin complications, including pseudo aneurysm and hematoma formation.

In addition to covered stents, another alternative to balloon-expandable stents that was hypothesized to have superior long-term patency was the class of flexible self-expandable stents. Self-expanding stents are often used for treatment in femoropopliteal disease, where stent fracture of the stiff balloon-expandable stents usually used in this area is an issue of major concern, leading to in-stent restenosis and reduced patency. Higashiura et al¹³ chose to further investigate the prevalence of stent fractures in self-expanding stents used in iliac artery lesions and found these to be very rare in this location (5% in nitinol stents). Their findings revealed that stent placement in chronically occluded lesions was a risk factor for stent fracture in iliac lesions; although, compared with the occurrence in femoropopliteal lesions, fracture rarely negatively affected vessel patency. The effectiveness, safety, and patency of self-expanding nitinol stents, in particular, of the JOSTENT SelfX Stent System (Abbott Laboratories) were also evaluated in an independent project by Hamer et al.¹⁴ Twenty-seven patients, with 34 lesions involving the common and external iliac arteries, were treated in their study. The inclusion criteria was defined as the presence of a clinically relevant stenosis in either the common or external iliac artery, with a lumen narrowing of >50%, or a mean translesion pressure gradient of >10 mm. Measured results found immediate technical success rates of 94%, with 96% of patients reporting clinical improvement of at least one Rutherford category¹⁴ after the initial procedure. At 6-month follow up, results showed 85% of patients presented with sustained improvement by at least one clinical category, and the primary patency was measured as 96%. This was comparable with the results of other self-expandable stents reported in the literature; such as of the WALLSTENT (93%–97%), the Cragg Endopro System I stent (94–98%) (Mintec™ Minimally Invasive Technologies

SARL, La Ciotat, France) and the Memotherm Stent (CR Bard Inc, Covington, GA, USA) (95%–98%).^{15–19} Despite favorable results, a few disadvantages of the JOSTENT SelfX were noted by operators, including poor visibility of the stent during fluoroscopy, as well as the inability to correct stent localization after commencing the stent deployment.

Abbott's Absolute Pro: design and features

The reviewed literature shows that stent placement, whether primary or selective, is a valuable tool in the treatment of iliac atherosclerotic disease; however, long-term results could still be improved by improved stent design and delivery.^{5,6,8–10,14,15,18} Abbott's stent design for the Absolute Pro was aimed at overcoming some of the shortcomings in the design of previously available stent and deployment systems. The Absolute Pro, a self-expanding nitinol stent system, is made of a flexible material to allow the stent to conform to challenging and complex iliac lesions. Its design also incorporates technology to enhance stent visibility, and a delivery system designed for minimal friction during stent deployment as well as for precision of stent placement, providing the user the ability to reposition or remove stent during initial deployment. This device is compatible with a small 6F sheath, with available stent diameters ranging from 6–10 mm and available length sizes between 20–100 mm.

The Absolute Pro received FDA approval following the results of the MOBILITY trial,²⁰ a company-sponsored, nonrandomized, two-arm, multicenter study that evaluated the safety and effectiveness of the Absolute Pro and Omnilink Elite® (Omnilink Elite Vascular Balloon-Expandable Stent System; Abbott Laboratories) stents. In the Absolute Pro arm, all subjects enrolled had symptomatic peripheral arterial disease with 76% of lesions treated located in the common iliac artery, and 62.8% were severely calcified. A total of 151 patients were enrolled in the Absolute Pro arm of the study. The primary endpoint evaluated was the occurrence of major adverse events at 9 months, defined as death, myocardial infarction, restenosis, need for open revascularization, or limb loss. The secondary endpoints included device, technical, and procedure success (defined as achievement of successful delivery, deployment and removal of stent with final in-stent residual stenosis of less than 30%) as well as improvement in Ankle-Brachial Index (ABI), walking capacity, Rutherford and Becker clinical category. The study results showed the major adverse event rate of the Absolute Pro was 6.1%, well below the study's goal of 19.5% (determined based on the existing literature

and previous published studies). Serious adverse events for the first 30 days after procedure, found dissection to be the most prevalent event at 2.6%. For events between 31 days and 326 days after procedure, the most prevalent events included restenosis (5.3%), "other peripheral vascular disease, not otherwise specified" (4%), and angina (3.3%). Analysis of the secondary endpoints showed that 95.9% of lesions had a 9-month hemodynamic success (defined as ABI improvement greater than 0.1 compared with baseline or deterioration less than 0.14 compared with postprocedure values). Restenosis, defined as greater than 50% stenosis, occurred in 13/151 (8.4%) lesions. The study device success was found to be 96.4%, with seven device malfunctions among the 193 devices. The technical success, on a per lesion basis, was 87.3%, with no major adverse effects occurring through postprocedure day 2. The overall procedure success was then measured to be 85.4%.²⁰

Following the MOBILITY trial came a second study investigating the Absolute Pro stent, the BRAVISSIMO trial.²¹ This was a prospective, nonrandomized, multinational, multicenter, controlled trial centered in Belgium and Italy. The purpose of the BRAVISSIMO study was to validate both the Omnilink Elite and the self-expanding nitinol Absolute Pro stent in TASC type A and B lesions as well as to evaluate their expanded use in TASC type C and D iliac lesions. The primary endpoint in this study was primary patency at 12 months, as determined by duplex ultrasound. There were a total of 325 patients enrolled into the study; of these, 190 were in the TASC A/B group and 135 in the TASC C/D group. The baseline risk factors were comparable in all groups. In the TASC A/B group, 88% of patients were claudicants, with 12% found to have critical limb ischemia. In the TASC C/D group, 74% were claudicants, and 26% had critical limb ischemia. In the TASC A/B group, the 12-month primary patency was 97.1% for lesions treated with the Absolute Pro stent. In the TASC C/D group, the preliminary 12-month primary patency results show 95% primary patency for the Absolute Pro stent. These results support an endovascular-first approach for TASC A/B as well as for TASC C/D aortoiliac lesions.

Conclusion

Based on the preliminary industry-sponsored data, the Absolute Pro appears to be another good option for the treatment of both focal and complex iliac atherosclerotic lesions. The design is easy to use, allows for a low profile access system with good visualization on imaging, and has the ability to be repositioned – qualities that show the benefit of improvements compared with other available models. Also,

the reviewed literature which demonstrates excellent long-term results for stents with similar designs as the Absolute Pro, shows strong support for the use of this new competitive product. Irrespective of which stent model or device design is chosen, the endovascular treatment of iliac artery disease has emerged as the new standard of care and will continue to evolve with the advent of innovative devices and newly generated technologies.

Disclosure

The authors report no conflicts of interest in this work.

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