

INTERVIEW

Evaluating the Auryon Laser Atherectomy System in Diabetic Patients: A Subgroup Analysis

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At the 2024 Amputation Prevention Symposium, interventional radiologist John Rundback, MD, from Advanced Interventional & Vascular Services in New Jersey, spoke with Vascular Disease Management about his AMP 2024 presentation on a subgroup analysis of the PATHFINDER Registry, which is a prospective, nonrandomized, multicenter study that evaluated the performance and outcome of the Auryon laser atherectomy system (Angiodynamics). Below is an edited transcription of the video Dr. Rundback recorded for us at AMP, which you can watch [here](#).

**John Rundback, MD**

Advanced Interventional & Vascular Services, Teaneck, New Jersey

I'm Dr. John Rundback, and today I have an opportunity to talk about the subgroup analysis of diabetics in the in the Pathfinder registry utilizing the Auryon laser platform. This is a great opportunity to do this and obviously a great opportunity to be here at AMP, which is the preeminent meeting for doctors interested in limb salvage and treating patients with complex disease. This study and the Auryon laser platform fit very nicely into this overall concept of what we can do to improve limb salvage, particularly in susceptible diabetic high-risk individuals.

The PATHFINDER Registry had just over 100 patients. A little more than half of that cohort were diabetics, and what we did in this particular analysis is we compared the diabetic cohort to the overall group to see if there were measurable differences in procedures in terms of major adverse events, as well as out to 24 months in clinical parameters, such as walking impairment questionnaire, Rutherford score, and so forth. And what we found is that in terms of patient characteristics, there was more tibial involvement in the diabetic cohort than the general group, which is consistent with the pattern of disease that we see in diabetics. But otherwise, not a whole lot of difference; the amount of calcification, lesion length, percentage of chronic total occlusions were similar in the diabetic cohort compared to the entire group. So not really any notable differences there. The baseline level of impairment in terms of Rutherford was worse in the diabetic cohort.

Procedurally, utilizing different laser platforms in different sizes in the smaller vessels, but consistent with the instructions for use, there were similar rates of major adverse events or very, very low and notably for this platform, essentially no embolization seen on core lab analysis in the diabetic subgroup and less than 2% in the overall population, attesting to the safety of this platform generally as well as in the specific diabetic cohort that we're evaluating. As we sort of looked at the outcomes over time, there was a higher rate of amputation in the diabetic cohort, but remarkably lower than we might anticipate in this group of individuals, with major amputations seen in 1 year at about 3.5% and after 24 months at 5%.

Obviously, the non-diabetics and claudicants and other such amputations were less common. So that was the only notable difference, but what was striking is that while there was a higher rate of amputation representing comorbidities, recurrent disease, and other conditions associated with the diabetic group, the rate of target vessel revascularization was actually higher in the global group than it was in the diabetic cohort. This speaks to the durability of this intervention, even in diabetic patients who don't necessarily always have the level of glycemic control that we would like to see. If you look at the patient-reported outcomes, walking impairment questionnaire, as well as other measures such as Rutherford, which are out to 24 months, which is fairly novel to see these patients out to this period of time, we found that there were gains, of course, at the time of intervention, and those gains would generally sustain. And the diabetics, particularly in terms of the walking impairment questionnaire as well as Rutherford scores, they were lower in the overall population, both the baseline and follow-up, but the increment of improvement from intervention to post-

intervention as well as follow-up out to 24 months were the same, essentially parallel. So it's a global population, there were dramatic improvements with only mild declines that were approximately 5% per year, and that was the same in the diabetics. So overall very, very durable interventions in these groups.

In conclusion, what this analysis supports is that the utilization of this particular technology, predominantly in tibial pathology and a diabetic population of individuals with a limb threat, has very, very favorable results, technology at very high technical success rate, comparable measures of plaque reduction associated with this, comparable measures of overall luminal gain after adjunctive angioplasty, very, very low complication rates and durability, and very low amputation rates compared to historical controls. ■

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