Physician Training and Outcomes With the Zenith Fenestrated Graft

Appropriate physician training and selective application of this technology are critical in achieving the best possible outcomes for a complex patient population.

BY LUIS A. SANCHEZ, MD, FACS

The use of endovascular grafts for the treatment of infrarenal aneurysms was initially approved in the US in 1999. At that time, extensive physician training (2-day courses), live case observation, and physician proctoring by experienced users were required as part of the rollout process. Inexperienced physicians learned appropriate patient selection as well as basic and critical endovascular techniques for the safe and effective use of these early endovascular devices. To date, eight devices have been approved in the US for endovascular aneurysm repair (EVAR). Physician training for each one of these devices has been simplified as the expertise of endovascular specialists has increased, and many of these devices have similar technical requirements and deployment techniques.

BACKGROUND

The Zenith Fenestrated graft (Cook Medical, Bloomington, IN) was approved in the US in April 2012. This graft is the first fenestrated graft approved in the US, and its application is significantly different from currently available EVAR devices. These devices are custom-made based on the specific anatomy of the patient and require careful patient selection and detailed device planning by the treating physician. Additionally, the technical endovascular skills necessary for the safe and effective performance of these procedures (ie, fenestrated EVAR [FEVAR]) is significantly more extensive than for standard EVAR. Appropriate physician training and selective application of the technology will be critical in achieving the best possible outcomes for a complex patient population. A rigorous training program for physicians with extensive expertise in EVAR and other complex endovascular procedures was started in June 2012.

TRAINING SESSIONS

The in-depth, 2-day training sessions for the physicians include multiplanar reconstructions for planning the Zenith Fenestrated graft procedure, detailed graft planning and sizing, extensive review of the device and its deployment, a taped case observation, discussions on tips and tricks for successful FEVAR, and hands-on deployment of the fenestrated devices under fluoroscopy. A small group of physicians (five to eight) is being trained in every course to achieve one-on-one training in the critical aspects of image evaluation, case selection, and device planning, which are essential for the successful application of this advanced technology. Additionally, every trained physician will be proctored for a minimum of two cases (usually two to five cases) by an experienced endovascular specialist with expertise in performing FEVAR.

To evaluate the postapproval FEVAR results, as well as the training program, a ZFEN Post-Approval Study and ZFEN Training Registry are being conducted. The ZFEN Post-Approval Study will enroll 21 new patients who will be followed for 5 years (data from these patients will be combined with those from the patients in the initial ZFEN study). The patients in this postapproval study will come from centers that did not participate in the initial study and that have completed the commercial training program.

To further assess the success of the training program, the ZFEN Training Registry will include 82 patients. No more than two patients will be entered at any one site, providing for at least 41 participating sites in the registry. The aim of the registry is to assess whether the commercial training program is adequate to enable physicians who did not enroll patients in the initial study to achieve operative results comparable to those achieved by experienced users based on technical success. The ZFEN Training Registry will only collect procedural data. The primary endpoint is technical

success, which is defined as successful completion of the procedure with endograft patency, preservation of all vessels targeted by a fenestration, and no type I or type III endoleaks at completion of the procedure. Importantly, as the training program and its results are being evaluated, the endovascular expertise of the physicians trained over time and their commitment to this advanced technology will advance the training program. The training programs will have to evolve over time to accommodate the knowledge base of the physicians being trained to ultimately achieve the best possible results.

RESULTS

To date, 17 training sessions have been conducted since June 2012. During those sessions, 114 physicians from 76 facilities were trained. Of this group of physicians, 24 of them have successfully completed both the workshop and the required proctored cases. Additionally, our institution has been involved in data collection of early postapproval experience with FEVAR from selected sites that have either completed the commercial training program or have access to the device due to prior experience with it. Early clinical data have been collected on 57 consecutive patients treated with the commercial Zenith Fenestrated graft at seven US institutions from June 2012 to December 2012. Seventy-four percent of the patients were from five original trial sites, whereas 26% of the patients were from two postapproval trained sites. The technical success rate was 100%, and only one patient had a kinked renal stent that was successfully restented. In this group, the 30-day outcomes of FEVAR for juxtarenal aneurysms compares well with the results of the US fenestrated trial.

CONCLUSION

In summary, the training and early outcomes of FEVAR with commercially available devices will be carefully scrutinized over the next few years. The results of the ZFEN Post-Approval Study and the Training Program Registry will be very helpful in assessing the treatment results of FEVAR and improving the training programs available for current and future fenestrated and branched devices. ■

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