Plaque Excision in 2005 and Beyond: Rebuttal

Rebuttal of "Issues of the Past Have Yet to Be Resolved"

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The following is a rebuttal to the article published by Michael H. Wholey, MD, MBA, "Issues of the Past Have Yet to Be Resolved," which appeared in the August 2005 issue of Endovascular Today, *pp. 40-44. For those readers not familiar with Dr. Wholey's article, please refer to the printed edition or view the article in our online archives at www.evtoday.com.*

We would like to comment on the article entitled "Issues of the Past Have Yet to Be Resolved" by Michael H. Wholey, MD, MBA, et al in the August 2005 issue of *Endovascular Today*. The article was based on his limited experience with the SilverHawk Plaque Excision System (FoxHollow Technologies, Redwood City, CA) of 13 cases during the last 11 months with a follow-up of 11 weeks (range, 4-24 weeks), as well as a discussion of the history of atherectomy devices. The authors raised two issues with the SilverHawk plaque excision device that we would like to address. The first was the potential for embolization while performing plaque excision, and the second was that there is no prospective randomized trial evaluating the SilverHawk device against other modalities.

In the article, Dr. Wholey presented his initial experience with the SilverHawk device and his outcomes and complications. As with any new device or new user, no matter their endovascular experience, there is a learning curve with the use of the device. Most investigators using the SilverHawk device have found that there is a small but a real learning curve of 10 to 15 cases before they become proficient in the use of the device. Dr. Wholey's quoted experience is certainly within this learning curve. With increased experience, most investigators have found that the incidence of adjunctive procedures such as angioplasty and stents dramatically decreases and the primary therapy is plaque excision alone. In February 2005, Dr. Wholey published his experience with embolization during standard angioplasty and stent procedures and found that there was a 100% distal embolization rate associated with both angioplasty and stent interventions.[1] It is not surprising that he reports similar results with SilverHawk, especially because in 10 of the 13 cases he reports he performed adjunctive angioplasty and/or stenting. He also reports making up to four passes with the plaque excision devices before emptying the nose cone, but never comments on the use of the "fuel gauge" to determine if the device is full. Overpacking the storage nose cone can be a potential source of distal embolization. Dr. Wholey's results are further complicated by the fact that the filter device was not removed or inspected after the plaque excision portion of the procedure, but only at the completion of the procedure including the angioplasty/stenting. How do we determine when the embolic event actually occurred? Of interest, the embolic particles, which ranged from 2 mm to 10 mm, are very large, unlike those encountered in coronary and carotid territories. The depth of the debris was not listed but is important. The SilverHawk standard LS cutter cuts to a depth of 0.3 mm. If the particulate matter is different from this it may suggest emboli off the artery from device passage or from adjunctive therapy, not from the failure to capture.

Dr. Wholey and associates actually raise the more global question of whether we should be performing distal embolic protection with all endovascular procedures (or at least those involving angioplasty and/or stenting) rather than for any specific endovascular therapy. Interestingly in the TALON registry, with experienced investigators using the SilverHawk device treating more than 600 patients and more than 1,200 lesions, there was a <1% embolization rate. These figures are markedly different from Dr. Wholey's preliminary data.

In regards to the need for a prospective randomized trial to validate the use of the SilverHawk device in the treatment of lower-extremity ischemia, this is certainly desirable but extremely impractical based on the lack of a gold standard to compare to. The actual gold standard would be a comparison to open surgical bypass with vein, but this trial would be impractical to impossible due to difficulty in con-

vincing patients to agree to randomization between open versus endovascular procedures because of the differences in the invasiveness between the two procedures. Most other nonsurgical modalities have been approved for biliary use only and are used off-label in the arterial circulation. This has not been questioned as a reasonable adaptation of the indication but it does make a prospective, randomized trial difficult because the majority of the commonly used devices are not approved for the arterial system. Therefore, a randomized clinical trial would require randomization to a non–FDA-approved device, which would require a separate IDE for the control device to be randomized against the SilverHawk. Does one then need to get an IDE for all popular stents because no single stent is accepted as the gold standard?

Finally, we would like to address the changes that have been incorporated in the SilverHawk device using the lessons that have been learned from past experience. The need for primary therapy without adjunctive therapy cannot be overemphasized. The trauma associated with angioplasty is significant and has been avoided with the appropriate use of the SilverHawk. There is greater diversity in the size of the current plaque excision devices that allow treatment of vessels from 2 mm to 6.5 mm. This working range is markedly larger than the atherectomy device Dr. Wholey cited in his article, which was designed only for use in the coronary vasculature, and was approved by the FDA 18 years ago. One of the greatest advances with the new SilverHawk device is the ability to treat the popliteal and tibial vessels. This is a region that requires either extensive surgery for a below-the-knee bypass with vein or is associated with a high failure rate with endovascular treatment even with drug-eluting stents.

Clearly, past mistakes need not be repeated. The initial registry data pertaining to the SilverHawk currently suggest benefit in a real world, uniquely difficult territory to treat. Further evaluation is absolutely necessary and must move forward. Embolic events must be further evaluated, and we agree that distal embolic protection may be useful in selected cases, regardless of the therapy used, whether it is angioplasty, stents, or SilverHawk. However, the need for distal protection in all patients is debatable. The ultimate outcome for the patient is limb salvage and generally fewer symptoms. Thus far in the registry and single-center experiences, restenosis appears to be under 20% at 1 year in a similarly high-risk population. Further assessment will be necessary in an open-minded and scientific way, but initial promising clinical data should not be ignored. ■

1. Wholey MH, Toursarkissian B, Postoak D, et al. Early experience in the application of distal protection devices in treatment of peripheral vascular disease of the lower extremities. Catheter Cardiovasc Interv. 2005;64:227-235.