Limitations of Implantable Pressure Sensors for EVAR

Before this technology can be widely accepted, issues with respect to reimbursement and efficacy must be addressed.

BY GEOFFREY H. WHITE, MD

Scientific knowledge regarding pressure within an abdominal aortic aneurysm (AAA) sac after treatment by endovascular grafting (EVAR) is currently limited, but clinical research and understanding of this technology is increasing.[1-4] Any technological modality that improves our knowledge in this area is a positive advance and should be encouraged, especially if noninvasive monitoring of pressure changes can be reliably achieved on a regular basis in long-term studies. This element promises to be a major attribute of intrasac pressure sensor devices, along with any particular benefits to the individual patient. Remote pressure sensing technology shows great promise, but there is much to be learned before widespread acceptance is advocated.

The current obstacles facing the use of implantable pressure sensors are summarized in Table 1. These negative factors are primarily a reflection of the relative newness of the pressure sensing devices and the current lack of long-term performance data, as well as the existence of a borderline or in-between range of pressures, the significance of which is not yet known. The questions facing interventionists today are: How can these devices be used most effectively and/or most cost effectively? What should be done when a borderline pressure profile is obtained?

TABLE 1. NEGATIVE ASPECTS OF AAA PRESSURE SENSORS

- Cost
- Lack of long-term function studies
- Lack of reimbursement
- May only change management in a small subset of patients
- Suspected pressure compartmentalization in AAA sacs
- Possibility of undetected sudden changes between pressure measurement intervals
- Acute device complications (infection, migration, malposition, etc)
- Possibility of device degradation and/or failure
- Possibility of device/biological interactions
- Not all graft complications are reflected in pressure changes
- May lead to overtreatment of minor problems (eg, type II endoleaks)
- No long-term validation that pressure sensors can confirm continuing effective treatment of AAA

PREDICTIVE POTENTIAL AND LIMITATIONS

There is no doubt that EVAR results in marked reduction of sac pressure in most patients.[4-6] Early clinical trials of two implantable devices have shown that remote AAA sac pressure sensing is feasible and can be performed easily and safely.[7,8] Pressure measurements proved to be accurate, and statistically significant differences in pulse pressures were documented in groups of patients before and after exclusion of aneurysms.[8] However, measurements in the indeterminate range have been documented from patients with both major and minor endoleaks and other disorders. Therefore, it is apparent that there will be problems in interpretation of such readings from pressure sensors in the individual patient and in decision making as to how measurements in each case should be acted upon. In other cases, the real need may be to obtain prior warning of any device events that would warn of pressure changes before the event.[9] It remains to be proven whether the application of pressure sensors will be effective in preventing AAA rupture.

PROCEDURAL COST IMPACT

Implantation of a wireless pressure sensor adds to the cost of an endovascular AAA repair procedure. At present, medical insurance companies are not reimbursing the costs of these devices on the basis that they are considered to be "experimental and investigational, because of inadequate published evidence of their clinical effectiveness."[10]

CLINICAL QUESTIONS REMAIN

Reports to date from both direct pressure measurements[1,2] and wireless pressure transducers have raised new questions.[3,7] Why are sac diastolic pressures higher than systemic diastolic pressures? Why do pulse pressures in the excluded sac change with time? Will all endoleaks result in significantly elevated pressure measurements? If there is no endoleak, why doesn't the pressure drop below recognized safe levels in all instances? How often will suspicious pressure measurements lead to additional imaging studies that may be unnecessary under current guidelines? Will pressure sensors be helpful in the management of patients who have AAA sac enlargement without endoleak (ie, endotension)?

Pressure sensing devices seem to be reliable and accurate at the time of implantation and in the short to intermediate term, but long-term functionality and durability are unproven. It is the late-phase surveillance during which noninvasive monitoring could have the greatest benefit. There is evidence that pressures obtained within an aneurysm sac may be affected by a range of factors, such as distribution and consistency of thrombus, site of retrograde flow from patent lumbar arteries, type of endograft used, and patient position. Nevertheless, in one study, AAA sac shrinkage after endograft implantation was found to correlate with chronic sac pressure measurement, and also that the pressures continued to decrease over time.[11] However, the absence of sac shrinkage does not imply persistent pressurization of the sac, and data linking low pressure in the aneurysm with safety from rupture in the long-term do not yet exist.

Further experience will be required to determine which pressure levels are significant when above the baseline range. There will also need to be correlation of findings from pressure measurement with the measurements of wall stress and 3D morphology of various aneurysms.

Will the use of implanted pressure sensors truly relieve physicians of the need to perform regular CT scans for surveillance? Graft migration is one of the major predictors of graft failure;[9,12] pressure sensors may not detect migration until a late stage when the sac becomes re-pressurized, and plain radiographs are notoriously difficult to interpret with respect to lesser degrees of migration. Thus, the recommended combination of pressure monitoring and abdominal x-ray may prove to be insufficient, especially in high-risk subgroups such as patients with difficult aortic anatomy.

Variations in sac pressure transmission due to sac contents and endograft structure have been studied.[6] This study provided evidence that graft material did have effects on aneurysm exclusion and that permeability of some graft fabrics allowed circulating clotting factors and macrophages to enter the sac, with some related changes in pressure profiles. Further knowledge of these influences will help guide interpretation of the results obtained from implanted sensors in different patients.

Finally, there remains doubt that pressures measured at one site within an aneurysm sac would always accurately reflect the pressure profiles elsewhere in the sac.[13,14] Compartmentalization may be a factor, and it is possible that multiple sensors may be required in some situations.[14] Further experience will be required to ultimately prove whether recognition of a pressurized aneurysm sac will change patient outcomes in a significant manner. Until these factors are determined, it seems that pressure sensors may be used as an adjunct to current imaging modalities, rather than as a replacement. ■

Geoffrey H. White, MD, is Head of the Department of Vascular Surgery, and Associate Professor of Surgery, Endovascular Research Unit of the Department of Surgery, Royal Prince Alfred Hospital, at the University of Sydney in Sydney, Australia. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. White may be reached at ghwhite@mail.usyd.edu.au.

1. Sonesson B, Dias N, Malina M, et al. Intra-aneurysm pressure measurements in successfully excluded abdominal aortic aneurysm after endovascular repair. J Vasc Surg. 2003;37:733-738.
2. Dias NV, Ivancev K, Malina M, et al. Direct intra-aneurysm sac pressure measurements using tip-pressure sensors: in vivo and in vitro evaluation. J Vasc Surg. 2004;40:711-716.
3. Milner R, Ruurda JP, Blankensteijn JD. Durability and validity of a remote, miniaturized pressure sensor in an animal model of abdominal aortic aneurysm. J Endovasc Ther. 2004;11:372-377.
4. Chuter T, Ivancev K, Malina M, et al. Aneurysm pressure following endovascular exclusion. Eur J Vasc Endovasc Surg. 1997;13:85-87.
5. Ohki T, Yadav J, Gargiulo N, et al. Preliminary results of an implantable wireless aneurysm pressure sensor in a canine model: will surveillance CT scan following endovascular AAA repair become obsolete? J Endovasc Ther. 2003;10(Suppl I):32.
6. Hynecek RL, Troccola SM, DeRubertis BG, et al. Evaluation of pressure transmission and intra-aneurysmal contents after endovascular repair using the Trivascular Enovus ePTFE stent-graft in a canine model of AAA. (Abstract), Eastern Vascular Society 2006; Vascular Web. Available at: http://evs.vascularweb.org/EVS_Contribution_Pages/Annual_Meeting/Abstracts_Programs/Abstracts/2006. Accessed October 20, 2006.
7. Ellozy SH, Carroccio A, Lookstein RA, et al. First experience in human beings with a permanently implantable intrasac pressure transducer for monitoring endovascular repairs of abdominal aortic aneurysms. J Vasc Surg. 2004;40:405-412.
8. FDA clears EndoSure wireless AAA pressure measurement system. CX Vascular Newsletter. http://www.cxvascular.com/News.
9. Harris PL, Dimitri S. Editorial: predicting failure of endovascular aneurysm repair. Eur J Vasc Endovasc Surg. 1999;17:1-2. Accessed: October 20, 2006.
10. Aetna clinical policy bulletin, September 29, 2006. http://www.aetna.com/cpb/data.
11. Ellozy SH, Carroccio A, Lookstein RA, et al. Abdominal aortic aneurysm sac shrinkage after endovascular aneurysm repair: correlation with chronic sac pressure measurement. J Vasc Surg. 2006;43:2-6.
12. Tonnessen BH, Sternbergh WC, Money SR. Late problems at the proximal aortic neck: migration and dilation. Semin Vasc Surg. 2004;17:288-293.
13. Hinnen JW, Koning OH,Visser MJ, et al. Effect of thrombus on pressure transmission in the abdominal aortic aneurysm. J Vasc Surg. 2005;42:1176-1182.
14. Milner R, Blankensteijn JD. Remote pressure sensing and aneurysm repair monitoring. Endovasc Today. 2003;5:49-50.