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EDITORS' INTRODUCTION

Trans-Atlantic Debate: Are Intra-sac Pressure Measurements Useful Following Endovascular Repair of Abdominal Aortic Aneurysms?☆

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Few would argue with the need for long term follow up following endovascular repair of abdominal aortic aneurysms. A small risk of reintervention persists and the challenge remains to identify those patients that will require additional procedures to prevent subsequent complications. The ideal follow up regimen remains elusive. Up until this point, most regimens have consisted of radiologic imaging, with either CT scans or ultrasonography to identify continued aneurysm perfusion (endoleaks) and document sac dynamics, either shrinkage, growth or stability. However, aneurysm sac growth or shrinkage serves only as a surrogate measurement for pressurisation and although its uniformly believed that attachment site endoleaks require treatment, it remains controversial as to how to determine which Type II endoleaks pressurise an aneurysm sufficiently to require therapy.

In response to these difficulties several manufacturers have developed pressure sensors that can be implanted at the time of the initial repair. They've been shown capable of measuring intra-sac pressures that have appropriately responded to reinterventions for endoleaks. However, are they the answer we're looking for? Are they ready for widespread use? Do they offer a reliable and consistent measure of intra-sac pressure that can be trusted to determine the need, or lack of need, for further therapy? Our debaters will try to convince us one way or another.

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Part One: For the Motion. Serial Sac Pressure Measurements can Determine Which Type II Endoleaks can be Treated CME

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Introduction

Repair of abdominal aortic aneurysms (AAA) was revolutionized by the introduction of endovascular aneurysm repair (EVAR) by Dr. Juan Parodi.[1] The devices utilized to treat aortic aneurysms have improved significantly since his initial report in 1991. Therefore, the incidence of device-related endoleaks (type I and III) occurs less frequently in this 3rd decade of EVAR as compared to when devices first received FDA approval. On the other hand, type II endoleaks remain controversial. The branch vessel filling of the sac (e.g. inferior mesenteric artery and lumbar arteries) leads to variability in the behavior of the residual aneurysm sac.

Pressure sensing technology (CardioMEMS, Inc., Atlanta, GA) has been proven efficacious in the acute exclusion of aneurysms with an endograft.[2] Long-term surveillance with pressure sensors is still being evaluated. I hope to demonstrate to you that I am correct about the utility of pressure sensors to determine therapy for type II endoleaks as opposed to Professor Cao's opinion that there is no benefit for pressure sensing in relationship to type II endoleaks.

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Endoleaks and Pressure Sensors

As mentioned above, pressure sensors have been shown to be effective in determining the acute exclusion of an aneurysm treated with an endograft. There is more evidence in the literature that sensors are effective for longer-term surveillance as well.[3,4] These two studies show the efficacy of sensors in surveillance after EVAR and TEVAR in relation to both type I and type III endoleaks. Both studies show that, in general, the measured pressure is reduced as the residual aneurysm sac shrinks except when a type I or III endoleak is present. Hoppe and colleagues[3] reported only two type II endoleaks in their series of patients treated for abdominal aortic aneurysms. Both of these leaks were associated with a low residual sac pulse pressure. Parsa and colleagues[4] followed 7 patients with type II endoleaks after TEVAR. Once again, the residual sac pulse pressure was low and the aneurysm sacs were not enlarging.

Ellozy and colleagues presented their experience at Mt. Sinai in New York with a pressure-sensing technology that is not being utilized currently (Remon Medical Technologies, Caesarea, Israel).[5] This technology is based on ultrasound rather then radiofrequency (CardioMEMS), but serves an identical purpose of sac pressure monitoring. Their experience was small, overall, but a few patients had type II endoleaks. The pressure was elevated in two patients with type II endoleaks. These two patients did not have sac expansion. Several others had type II endoleaks with either low residual sac pressure or a resolved endoleak on follow-up imaging.

Personal Experience

We placed almost 70 remote pressure sensors (CardioMEMS) in patients at Emory University Hospital undergoing endovascular abdominal aortic aneurysm repair over a two-year period of time. In addition, we were one of the eleven sites in the APEX trial. Most patients had low residual pulse pressure in the sac that correlated well with exclusion, both in the short term and on follow-up surveillance. Several type I endoleaks were treated intra-operatively. And, two type III endoleaks were detected on follow-up surveillance and treated with cuff placement for iliac limb modular disconnections. Both patients had expanding aneurysm sacs and elevated pulse pressures. One type III endoleak was seen at 6-month follow-up. The second was noted on two-year evaluation. Both patients have been problem-free since their secondary intervention with cuff placement. The residual pulse pressure was very low in both with shrinking aneurysm sacs.

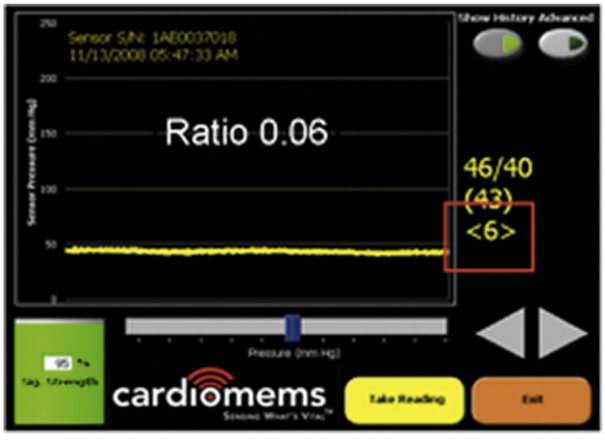

Figure 1 Sac pressure tracing from a patient with a type II endoleak and a shrinking aneurysm sac. The residual pulse pressure is 6 mm Hg with a ratio of 0.06 (sac pulse pressure/systemic pulse pressure).

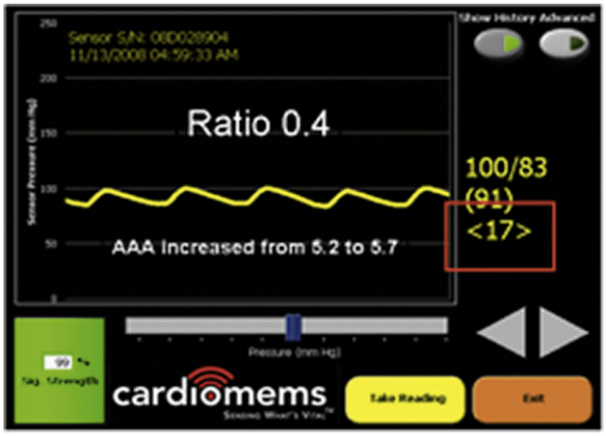

Figure 2 Sac pressure tracing from a patient with an elevated pressure and expanding aneurysm sac. The sac has grown from 5.2 to 5.7 cm with a ratio of 0.4.

Consistent with the published literature, our experience with type II endoleaks has been limited. I have two examples that will help explain the potential of pressure-sensing for the detection of type II endoleaks. The first patient had a low residual pulse pressure and a shrinking aneurysm sac (Fig. 1). The second patient has an elevated pulse pressure and an expanding aneurysm sac (Fig. 2). This patient was diagnosed with an intra-cranial malignancy just prior to his planned secondary intervention. Therefore, his procedure was cancelled. He has not had follow-up since that time.

Treatment of Type II Endoleaks

So, does pressure-sensing determine which type II endoleaks need to be treated? I think the answer is "yes" and "no" with the current literature support. An elevated pressure in association with an expanding aneurysm sac needs to be treated. A low residual pulse pressure with a stable or shrinking sac does not need treatment. The grey zone is more difficult to determine.

There is not an absolute number or residual pulse pressure that can be utilized to make a decision to treat a type II endoleak. I hope that as experience grows with pressure sensors in the literature that type II treatment will be better described. It would be ideal to treat an aneurysm based on residual pulse pressure prior to aneurysm sac expansion and the risk of rupture.

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Part Two: Against the Motion. Measuring Intra-sac Pressure Measurements is of No Benefit to the Patient CME

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The goal of any treatment of aortic aneurysm is to prevent rupture. From an endovascular standpoint this purpose is achieved by eliminating flow in the aneurysm sac. Failure to completely exclude the aneurysm from systemic circulation (e.g. endoleak, endotension) results in continued pressurisation and persisting risk of expansion/rupture. Measurement of sac pressure provides a physiological assessment of success. After the first experiences showing feasibility and reliability of direct percutaneous translumbar intra-sac pressure measurement with catheters[1,2] the development of minimally invasive implantable telemetric pressure sensors was increasingly advocated in the last decade as an easy and convenient method for surveillance after endovascular aneurysm repair. To date, three different types of pressure sensors (all implantable at the time of the endovascular procedure and not containing any internal energy source battery) using different technologies of transmitting the pressure from inside the body to an external antenna have been investigated. The Impressure AAA Sac Pressure Sensor (Remon Medical Technologies, Caesarea, Israel) is ultrasound-based (ultrasounds activate the sensor and communicate with the external device). The CardioMEMS EndoSure Wireless AAA Pressure Sensor (CardioMems, Atlanta, GA, USA), the only pressure sensor with FDA approval, is radiofrequency-based and consists in a resonant circuit. The TPS Telemetric Pressure Sensor (Helmhotz Institute for Biomedical Engineering and the Institute of Materials in Electrical Engineering, RWTH, Aachen, Germany), tested only in in-vitro models, is based on a completely digital microchip which transfers digital data to an external monitoring station. In addition, a new, non-electronic technology, called "Acoustic pressure-sensing", is currently under development by the Commonwealth Scientific and Industrial Research Organization in Australia.

Even though monitoring the pressure within the aneurysm sac with a catheter or an implantable sensor could be an appealing mean to predict the risk of aneurysm rupture, whether this physiologic monitor may obviate to the necessity of further surveillance investigations after endovascular aortic repair is debatable. Today there are notable limitations to both direct trans-catheter and sensor pressure device usage.

Clinical Relevance

Pressure monitoring has been investigated in vitro, in animal models and in small clinical trials. Nevertheless, since clinical trials have not yet evaluated a sufficient number of patients over the long term, i.e. several years, it is not clear how current protocols of surveillance after endovascular repair might be changed without failing to detect relevant adverse events such graft migration. Ellozy et al., from an IDE study with Impressure AAA Sac Pressure Transducer reported that mean pressure was significantly lower in patients with sac shrinkage at 6 months and at final follow-up. However, pressure could be obtained only in 15 of the 21 patients implanted.[3] In 2008, two case series, both using the EndoSure radiofrequency device, were published.[4,5] The first[4] reported only on intraoperative use in a series of 19 patients. Although statistically significant correlation coefficients were found in all the comparisons between pressure sensors and catheter measurements, values largely ranged, from 0.50 to 0.96. The second case series reported on postoperative monitoring for endoleaks using the CardioMEMS EndoSure sensor in 12 patients with 30 day follow-up.[5] Delivery of the sensor was complicated in 7% with no obtainable pressure reading.[5] In the APEX study (Acute Pressure measurement to confirm aneurysm sac Exclusion) the initial sensor pressure measurements matched with the angiographic catheter pressure measurements of type I and III endoleak. However, of 90 enrolled patients results were not reported in 14 due to "protocol violations, typically a missed measurement".[6]

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