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doi: 10.1016/j.ejvs.2010.11.009

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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Authors concluded for the need of a definite "learning curve" associated with refining the technique for insertion of the implants, interrogation of the sensor, and operation of the electronics. Although some of these problems have been resolved with training and improvements in the systems by manufacturers, the available data supporting today the efficacy of these devices are provided from very few populations.

Key Message: Despite the efforts in providing reliable data with intra-sac pressure measurements techniques, only limited numbers and sporadic information have been achieved.

Long-Term Efficacy of Pressure Monitoring Systems in Preventing Aneurysm Rupture

Although some long-term studies are in progress, follow-up data from clinical trials analyzing implantable devices (Impressure and CardioMEMS EndoSure) have just approached 2 years, while most safety, efficacy and accuracy published data refer to end-procedural time or 30-month assessment. The APEX trial provided data at the end of the procedure and at 30 days.[6] Hoppe et al. showed one-month follow-up data (follow-up ranging 19—44 days).[5] Ellozy et al. reported results using the Impressure Transducer with a mean of 11 months.[3] Only sporadic information is provided in the long term. Specifically, the APEX study reported on a single patient who underwent successful endovascular aortic repair with low sac pressure (sac/systolic pressure ratio = 0.31) and then experienced an increase in sac pressure ratio to 0.57 during follow-up at12-month[6,7] A subsequent CT scan showed sac enlargement and a type II endoleak that was repaired successfully. In another study, two Type II endoleaks were detected: sac pressure was unchanged in one and decreased in the other;[5] in addition, a single patient with a type III endoleak on CT had increasing sac pressure.[5] Although some Authors suggested that implantable pressure devices may remain functional and safe,[3] no one has advocated follow-up limited to pressure information.

Key message: Long-term information of intra-sac pressure measurements is based only on anecdotal cases from clinical trials and cannot provide a definitive clinical direction.

Indication for Treatment

In clinical trials implanted pressure sensors were able to detect Type I, Type III as well as Type II endoleaks, but a definitive proof of efficacy is lacking. Specifically, the clinical relevance in detecting Type II endoleak is not yet clarified since these endoleaks were found to be associated with different sac pressure. Elevated and diminished sac pressures in the presence of endoleak strongly rely on specific configurations of in- and out-flow channels through aortic collateral branches and cannot predict their clinical relevance.[3,6,7] For instance, in the small clinical trial of Ellozy,[3] a lumbar endoleak thrombosed at 6 months but left an elevated intra-sac pressure while in the APEX trial, 4 patients showed a less than 30% reduction in sac pressure but without any evidence of endoleak at angiography.[6] Unfortunately, there were no data on the aneurysm diameter in these cases to support the hypothesis of endotension as sealed endoleak transmitting systemic pressure to the excluded aneurysm sac.

There is also little information on endotension and intra-sac pressure. Dias et al.[8] recently reported data on invasive trans-catheter pressure monitoring in patients without endoleak and with unchanged aneurysm diameter more than 1 year after endovascular aortic repair (EVAR).[8] Authors suggested that the presence of intra-sac fluid was associated with lower intra-sac pressurisation and thus better prognosis. Nevertheless, only 5 aneurysms with intra-sac fluid were analysed: after 36 months, one shrank, three remained unchanged while one expanded. No strong message on how to manage endotension according to intra-sac pressure measurement can be supported by this sporadic information.

Key message: The clinical relevance of type II endoleak as well as endotension need to be further evaluated in future studies over a longer time period and correlated with aneurysm sac growth, diameter and other adverse events besides intra-sac pressure.

Safety

A major drawback of direct percutaneous intra-sac pressure measurement approach is its invasive nature. Translumbar puncture of the sac can be safely accomplished only in patients without special anatomical configurations (e.g. obesity, sac large enough to be accessed, etc.) increasing the risk of the procedure (viscera or stent integrity preservation).[8] Although the introduction of implantable pressure sensor has supplanted most of these risks, information on long-term complications of wireless implanted devices (e.g. radiofrequency exposure, foreign body reaction, displacement, infection, etc.) is lacking.

Applicability

Morphological (patient anatomy) and operators constraints strongly affect the applicability of pressure measurements. Direct intra-sac pressure measurements are invasive procedures that can be safely performed only in selected centers with appropriate experience on suitable patients morphologies. Implantable intra-sac pressure sensors require appropriate trained operators and centers available to afford the training and the cost of such devices.

Key message: There are reasons to believe that today, but also in the future, pressure measurement will never become a standard routine practice, because such approach is neither for all comers nor for all practitioners.

Setting the Standard Threshold

In most series it has been accepted a decrease of 30% or more as a critical value to assess decrease in sac pressurisation. Nevertheless, a definitive pressure threshold for subsequent intervention needs to be defined by further

studies. Indeed, the 30% reduction cut-off has been applied to different measurements. For the wireless devices experiences, Ohki et al. (APEX study)[6] used a 30% or more reduction in "pulse pressure from the initial pressure" to define a sealed sac and a less than 30% reduction in pulse pressure to indicate a type I or type III endoleak. This allowed a sensitivity and specificity of the sensor for detection of type I and III endoleaks of 0.80 and of 0.93, respectively compared with completion angiography. However, data accuracy refers to results detected at the time of the procedure and not longer in the time. Dias et al. reported on 18 direct percutaneous intra-sac pressure readings after EVAR and calculated the "mean pressure index (MPI) — the percentage of mean intra-aneurysm pressure relative to the simultaneous mean intra-aortic pressure".[1,8] Median MPI was 26% in 5 patients with shrinking sacs, 28% in 10 patients with unchanged sac and 63% in 3 patients with expanding aneurysms.[8] Authors also suggested that pulse pressure had a greater influence than MPI on diameter change.[8]

Key Message: The sensitivity/specificity of pressure measurements, including appropriate threshold pressures, is still unclear.

Accuracy in Measurement/Malfunctioning

Each specific model of pressure-sensor measurement presents specific drawbacks that hopefully might be resolved by new models in the future. There is no clear advantage of one versus another. Direct trans-lumbar percutaneous approach is invasive, while all the investigated implantable pressure sensors either have to be fixed to the outer surface of the endograft (specifically the ultrasound-based Impressure)[3,9] leading to an upsizing of the introducer sheath or have to be deployed through their own catheter system (e.g. the EndoSure).[5,6] To prevent the upsizing, in vitro and animal studies have been carried out with flexible and foldable wireless passive pressure sensors but the downside of this approach was a significant baseline drift of the pressure measurements, which needs to be improved in the future.[10] Radiofrequency-based sensors (EndoSure) have the advantage to consist in simple resonant circuits and not to require to be fixed on the graft. Nevertheless, although the relatively simple structure is robust, this does not provide any error correction for interferences from other external radiofrequency fields. This interference is more pronounced in the thoracic aneurysm endovascular repair (TEVAR) populations owing to monitoring adjuncts such as transesophageal echocardiography and neurological monitoring.[11] Parsa et al. in a series of 43 TEVAR showed that the presence of multiple radiofrequency energy emitting devices in the operating room allowed proper measurement obtainable in only 47% of patients.[11]

Malpositioning of the sensor may lead to incorrect pressure measurements. The Impressure sensor should be attached to the main body of the endograft in a way that the sensor will measure the pressure inside the excluded aneurysm sac without being pushed against either the aneurysm wall or the iliac limbs. Positioning the sensor between the two limbs of the graft has resulted in less reliable pressure measurements (compression artifacts) and should be avoided.[3] Parsa et al. reported a significant rate of malpositioned EndoSure sensors during TEVAR: 22% with first generation decreasing to a not negligible 10% with last generation devices.[11] Moreover, proper positioning of pressure sensor to detect reliable measurements may be difficult in saccular aneurysms. Finally, the orientation of the pressure sensor and the distance of the sensor in relation to the source of pressure can also influence measurements.

Key message: malposition, orientation and external interference can significantly alter the reliability of measurements with current available pressure sensor devices.

"Compartmentalisation" (Thrombus Effect) of the Aneurysm

Previous works have demonstrated that pressure measurements in the setting of documented endoleaks may exhibit a lack of uniformity throughout the aneurysm sac with consistently higher pressures measured in the endoleak channels if compared with the surrounding aneurysm thrombus. Even though the effect of thrombus in dampening pressure measurements is supposed to be small (ranging 5%—15%) and does not change the reliability of the pressure systems, a lack of uniformity in thrombus structure may influence the transmission of pressure.[12] Within an aneurysm sac, pressure is transmitted through the clot following both the hydrostatic fluid pressure and the direct contact with the thrombus.[7] When the sensor is placed within a closed system, these 2 pressures are almost equal ($\pm$10%) because the thrombus has enough porosity to allow fluid to move around, and fluid is an excellent vehicle to transmit pressure. Therefore, the sensor will detect the sac pressure accurately, provided that the sac is filled with fluid or clot as when it is surrounded by acute clot immediately after successful endovascular graft deployment. However, usually thrombus consistence significantly changes over the time becoming mostly organised and fibrous with increased hampering effect on pressure transmission. Long-term data to disprove or corroborate such "attenuation effect" of old thrombus on pressure sensor measurements are lacking.

All the pressure-sensing technologies are currently limited to sampling a restricted surface area of the stent-graft and the clinical correspondence of the measured changes is still uncertain. In the presence of extensive aneurysms that may involve multiple segments of the aorta (e.g. thoracic aneurysms) or situations where clear compartmentalisation and unequal pressure distribution exist, more than one sensor may be needed to increase the sensitivity in detecting endoleaks. However, not every aneurysm sac provides enough space to accommodate more than one pressure sensor and the question will have to be addressed in future studies with improved technologies.

Key message: In evaluating reliability of the results from intra-sac pressure measurements especially in the

long-term, the potential effects of compartmentalisation and the interference of thrombus within the sac should be considered.

Costs

Yet, a final consideration is financial: although the service is today provided at no charge, each implant sensor costs approximately $3.500,00 which approaches that of some endovascular components. Longer operative time and additional training should be also considered when doing an economic evaluation.[11]

Conclusions

Lifelong surveillance is necessary after endovascular aortic repair. The effectiveness of measuring intra-sac pressure in the management of patients after endovascular aneurysm repair is still challenged by a number of unanswered questions, regarding safety (invasive direct puncture, long-term complications of wireless implanted devices) efficacy, accuracy ("sac compartmentalisation") and applicability.

Several factors determine aneurysm sac pressure after endovascular repair, including "graft-related" factors such as endoleak, graft porosity and graft compliance, and "anatomical-related" factors such patency of aneurysm collateral branches, aneurysm morphology and the characteristic of aneurysm thrombus. It is still debatable whether the effect of all these factors can be summarised in a single point pressure value and how reliable the clinical relevance of this single measurement in common clinical practice might be, also because of the inconsistent clinical evidence to support these hypotheses.

Thus, at least in current practice, until these important questions are addressed, invasive intra-sac pressure measurements cannot supplant serial imaging for the above stated reasons and are to be considered investigational in the management of patients having endovascular aneurysm repair. However, physiologic measurements may serve as a useful diagnostic adjunct that permits expectant management when low sac pressure is found in addition to low flow type II endoleak after endovascular repair.

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doi: 10.1016/j.ejvs.2010.11.010

EDITORS' COMMENT

Are Intra-sac Pressure Measurements Useful Following Endovascular Repair of Abdominal Aortic Aneurysms?

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DOI of original article: 10.1016/j.ejvs.2010.11.009, 10.1016/j.ejvs.2010.11.010

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