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Aortic aneurysm sac pressure measurements after endovascular repair using an implantable remote sensor: initial experience and short-term follow-up

Received: 4 June 2007
Revised: 20 October 2007
Accepted: 23 November 2007
Published online: 20 December 2007
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Abstract The purpose of this single-center study was to report our initial experience with an implantable remote pressure sensor for aneurysm sac pressure measurement in patients post-endovascular aneurysm repair (EVAR) including short-term follow-up. A pressure sensor (EndoSure, Atlanta, GA) was implanted in 12 patients treated with different commercially available aortic endografts for EVAR. Pressure was read pre- and post-EVAR in the operating room. One-month follow-up (30 days \pm 6 days) was performed including sac pressure readings and IV contrast CT scans. Variables were compared using the paired Student's *t* test. An intra-procedure type-I endoleak and a type-III endoleak were successfully treated resulting in decreasing sac pressures.

In all patients, post-EVAR systolic sac pressure decreased by an average of 33% ($P \leq 0.005$) compared to pre-EVAR measurements. One-month follow-up demonstrated a 47% decrease in systolic sac pressure ($P \leq 0.05$). On follow-up CT scans, the average maximum aneurysm diameter pre-EVAR was 6.3 ± 1.6 cm and post-EVAR 6.0 ± 1.7 cm ($P \leq 0.05$). The diameter of the aneurysm sac was larger only in one patient with a type-III endoleak. Remote sac pressure measurement may provide important information in addition to imaging and may help to reduce the number of follow-up CT scans.

Keywords Aortic aneurysm · Stent graft · Pressure sensor

Introduction

Endovascular aneurysm repair (EVAR) with stent grafts is an alternative treatment to conventional open repair in patients with aortic aneurysms [1]. EVAR has been shown to be beneficial in reducing perioperative morbidity and mortality [2]. To date, follow-up results with second-generation and third-generation devices have been excellent [3]. However, complications caused by EVAR have been identified, including endoleak and aneurysm sac expansion. At present, computed tomography (CT), magnetic resonance imaging, or duplex ultrasound scanning is routinely used for follow-up after EVAR for identification of indirect markers of sac pressurization. Recently, measurement of aneurysm sac

pressure is proposed to provide important information in addition to imaging [4, 5]. The APEX (Acute Pressure Measurement to Confirm Aneurysm Sac EXclusion) multicenter trial focused on the intraoperative use of a remote sensor for aneurysm sac pressure measurement [6]. The results indicated that implantation of a remote pressure sensor was safe, and aneurysm sac pressure sensing was feasible. It was found to be a valuable guide in evaluating the completeness of the EVAR procedure. However, further study is needed to prove its efficacy for postoperative surveillance.

The purpose of this single-center study was to report our initial experience with an implantable remote pressure sensor for aneurysm sac pressure measurements pre- and post-EVAR including short-term follow-up.

Methods

Patients

Twelve patients (four women, eight men, average age 72 years, range 61–85 years) underwent EVAR with remote pressure sensor implantation. This study was approved by the Institutional Review Board and was performed according to the Health Insurance Portability and Accountability Act of 1996 (HIPPA). Informed consent was documented for all pressure sensor implantations. A Zenith endoprosthesis (Cook Inc., Bloomington, IN) was used in six patients, an Excluder endoprosthesis (Gore Inc., Flagstaff, AZ) in three patients, a PowerLink system endoprosthesis (Endologix Inc., Irvine, CA) in one patient, and a TAG thoracic endoprosthesis (Gore Inc., Flagstaff, AZ) in two patients.

Device description

The EndoSure wireless pressure measurement system (CardioMEMS, Atlanta, GA) consists of two main components: a sterile sensor pre-packaged in its delivery system and a separate electronics cart. The implantable EndoSure wireless pressure sensor measures $30 \times 5 \times 1.5$ mm (Fig. 1). It is a hermetically sealed circuit encapsulated in fused silica and silicone and is surrounded by a wire basket. This wire basket surrounding the sensor has no electrical functionality, but acts to keep the sensor centered within the sac. Inside the fused silica is a micron scale cavity. Changes to the membrane of this cavity result in changes to the sensors resonant frequency. These changes correlate to



Fig. 1 Implantable EndoSure™ wireless aneurysm pressure sensor measuring $30 \times 5 \times 1.5$ mm (CardioMEMS, Atlanta, GA). The sensor contains no batteries or internal power source, but is instead powered by RF energy provided by a proprietary external electronic antenna that is attached to the receiving station (not shown; courtesy of CardioMEMS, Atlanta, GA)

pressure changes. The sensor contains no batteries or internal power source, but is instead powered by radio-frequency energy provided by a proprietary electronic antenna. The sensor is implanted during EVAR procedure. To take a measurement, the antenna is placed on the patient's abdomen to activate the sensor. The antenna transmits radiofrequency energy to the sensor, which charges the circuit inside the sensor. Subsequently, the sensor returns a resonant frequency signal back to the antenna, which is translated by the electronics into a pressure measurement. Finally, a real-time pressure waveform is displayed on a monitor.

Device deployment

The CardioMEMS EndoSure sensor delivery system is low profile with a 14-F inner diameter and 17-F outer diameter. The working length is 35 cm, the overall length is 67 cm, and the tether length is 110 cm. The system is pre-loaded and has a Tuohy-Borst hub and radiopaque band for navigation purposes.

After the endograft delivery system was introduced from the ipsilateral common femoral artery over a super-stiff support wire, another super-stiff support wire was introduced from the contralateral femoral artery. Then the EndoSure sensor delivery sheath was introduced over this super-stiff wire. After the EndoSure sensor was positioned inside the aneurysm sac, the outer sheath was withdrawn over a pusher rod. After deployment in the aneurysm sac, the sheath is removed with the EndoSure sensor retained in the aneurysm sac on its tether. The tether is removed after stent graft deployment and repositioning of the EndoSure sensor in the aneurysm sac. At this point the sensor is free in the aneurysm sac without attachment. On completion of endograft deployment, the EndoSure sensor was confined within the aneurysm sac and isolated from the systemic circulation. At this point, the tether wire was pulled to release the sensor.

Pressure measurements and follow-up

Simultaneous EndoSure and intra-arterial systemic pressures were measured in the operating room. Systemic pressures were measured with a catheter in the radial artery. Pressure readings were obtained pre- and post-EVAR in the operating room including 1-month follow-up. Additional pressure measurements were performed in one patient with type-I endoleak in the operating room. The systolic sac pressure, diastolic sac pressure, and the pulse sac pressure were recorded. In addition, the systolic and diastolic systemic pressures were recorded.

One-month follow-up ($30 \text{ days} \pm 6 \text{ days}$, range 19 to 44 days) was performed including pressure readings at a physician office visit and a CT scan including CT

angiography with IV contrast medium. Additional pressure measurements and CT scan were performed in a patient with a type-III endoleak 2 weeks post-EVAR. The maximum aneurysm diameter was measured on CT scans pre- and post-EVAR. Systemic pressures were obtained with a pressure cuff applied to the upper extremity.

Statistics

Data were entered into a worksheet (Excel 2003, Microsoft, Redmond, WA). Descriptive and summary statistics with mean and standard deviation were calculated, and graphs were created. Continuous variables were compared using the paired Student's *t* test. Significance was assumed at $P \leq 0.05$.

Results

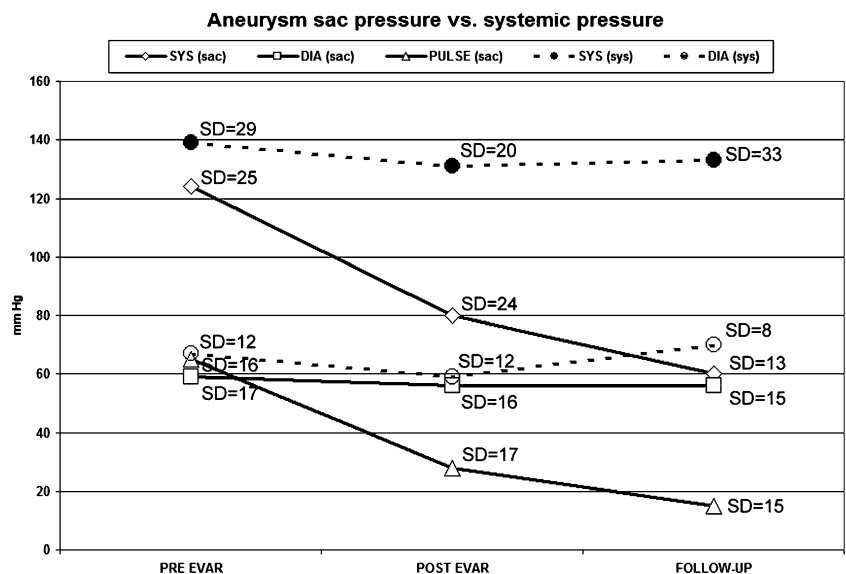
In all patients the aneurysm was successfully excluded at the primary operation, meaning no endoleak was detected on final angiography (Fig. 2). One patient demonstrated a type-I endoleak during the EVAR procedure, which was treated intraoperatively with an extender cuff resulting in further decrease of sac pressure (Fig. 3). On 1-month follow-up, a small type-II endoleak was noted in two patients, but sac pressures did not change in one patient and had decreased in the other patient (Fig. 4). One patient had a type-III endoleak with increasing sac pressure on follow-up, which was successfully treated with a Palmaz stent resulting in decreased sac pressure (Fig. 5).

Problems with pressure sensor delivery occurred in one patient when the dilator tip detached from the delivery sheath and had to be retrieved using a snare. The EndoSure delivery system was initially introduced over a 0.035"

Amplatz super stiff guidewire. The guidewire kinked with the system in the common iliac artery, and the system was removed. The guidewire was then exchanged for a stiffer Meyer guidewire (Boston Scientific, Natick, MA). The EndoSure delivery system was inspected and found to be intact. The decision was made to attempt reinsertion over a stiffer guidewire. The EndoSure delivery system could be advanced into the very distal abdominal aorta, but no further. The dilator tip of the device extended into the proximal neck of the aneurysm, but not above. The sheath was retracted leaving the dilator and EndoSure device in place and the pressure sensor deployed into the aneurysm sac. This was easily advanced to the superior lateral aspect of the sac. During attempted removal of the EndoSure delivery sheath the dilator tip detached from the delivery sheath. The remainder of the delivery sheath was removed over the guidewire and a 22-F sheath was introduced. Through this, using different "Amplatz gooseneck snares" (15 and 25 mm; Microvena, WhiteBear Lake, MN), the detached dilator tip was eventually removed. This has remained on the guidewire the entire time of the procedure. During the removal process the fragment was initially withdrawn into the tip of the sheath and then the snare detached from the hypotube on the dilator. It was ultimately determined that a segment of hypotube had been amputated and embedded in the snare.

In another patient the remote pressure sensor was damaged during an attempt to reposition the sensor from a 4-cm-long aneurysm neck into the aneurysm sac. After deployment of the endograft an attempt was made to reposition the EndoSure sensor from the aneurysm neck into the aneurysm sac. At this point, the EndoSure device was damaged. This was confirmed by the inability to obtain a pressure sensing from the device. Previously, after initial deployment of the device, sac pressure was read. The EndoSure pressure sensor was no longer functional. In

Fig. 2 Average aneurysm sac pressures pre- and post-EVAR and on 1-month follow-up compared with systemic blood pressure. Systolic sac pressure is decreased after endovascular aneurysm repair. EVAR, endovascular aneurysm repair; sac, aneurysm sac pressure; sys, systemic blood pressure; SD, standard deviation (mm Hg)



another patient, no pressure reading prior to EVAR could be obtained supposedly due to interference of the radio-frequency signal by an electronic infusion pump.

Intraoperative sac pressure measurements demonstrated a 33% decrease in mean systolic sac pressures ($P < 0.005$) and a 60% decrease in mean pulse sac pressures ($P < 0.001$) post-EVAR. After EVAR, the initial sac systolic mean pressure (80.4 ± 20.9 mmHg) was significantly less than the systemic systolic mean pressure (131.2 ± 25 mmHg) ($P < 0.001$). After EVAR, the initial sac diastolic mean pressure was 56 ± 17.3 mmHg, and the systemic diastolic mean pressure was 59 ± 13 mmHg. Pre-EVAR the average systemic pulse pressure was 72 ± 7 mmHg, and post-EVAR the average systemic pulse pressure was 72 mmHg ± 25 mmHg ($P > 0.05$).

One-month follow-up demonstrated a 47% decrease in mean systolic sac pressure ($P \leq 0.05$) and a 76% decrease in

mean pulse sac pressure ($P < 0.001$). The sac systolic mean pressure (60.6 ± 18.3 mmHg) was significantly less than the systemic systolic mean pressure (132.7 ± 14.6 mmHg) ($P < 0.001$). The sac diastolic pressure was 56 ± 16.8 mmHg, and the systemic diastolic mean pressure was 70.1 ± 8.2 mmHg. On follow-up the average systemic pulse pressure was 61 ± 3.5 mmHg ($P > 0.05$). There was no statistically significant difference between the systolic mean sac pressure post-EVAR and on 1-month follow-up ($P = 0.2$).

On CT angiography, the average maximum aneurysm diameter was 6.3 ± 1.6 cm pre-EVAR and 6.0 ± 1.7 cm post-EVAR ($P \leq 0.05$). The diameter of the aneurysm sac was larger in one patient with a type-III endoleak (previously 5.6 cm, on follow-up 5.8 cm). In the other patients the size of the aneurysm sac was either smaller or unchanged after EVAR.

Fig. 3 An 80-year-old woman with an enlarging abdominal aortic aneurysm: **a** Intraoperatively only a slight decrease of pressures was observed and angiography demonstrated a proximal type-I endoleak. Initially after proximal deployment of an extender cuff the endoleak has sealed and the systolic sac pressure was reduced by approximately 50%. EVAR, endovascular aneurysm repair; sac, aneurysm sac pressure (mmHg); sys, systemic blood pressure (mmHg). **b** Intraoperative pressure measurement in the aneurysm sac prior to endovascular aneurysm repair. **c** Intraoperative pressure measurement in the aneurysm sac post-endovascular aneurysm repair. The sac pressure had reduced although aortic angiography demonstrated a proximal type-I endoleak. **d** Intraoperative pressure measurement in the aneurysm sac post-endovascular aneurysm repair resulting in further sac pressure reduction. **e** Three-dimensional reconstruction of a CTA pre-endovascular repair. The maximum diameter of the aneurysm is 5.2 cm. There is ectasia of the common iliac arteries. **f** Three-dimensional reconstruction of a CTA post-endovascular aneurysm repair demonstrating the remote pressure sensor within the aneurysm sac (arrow)

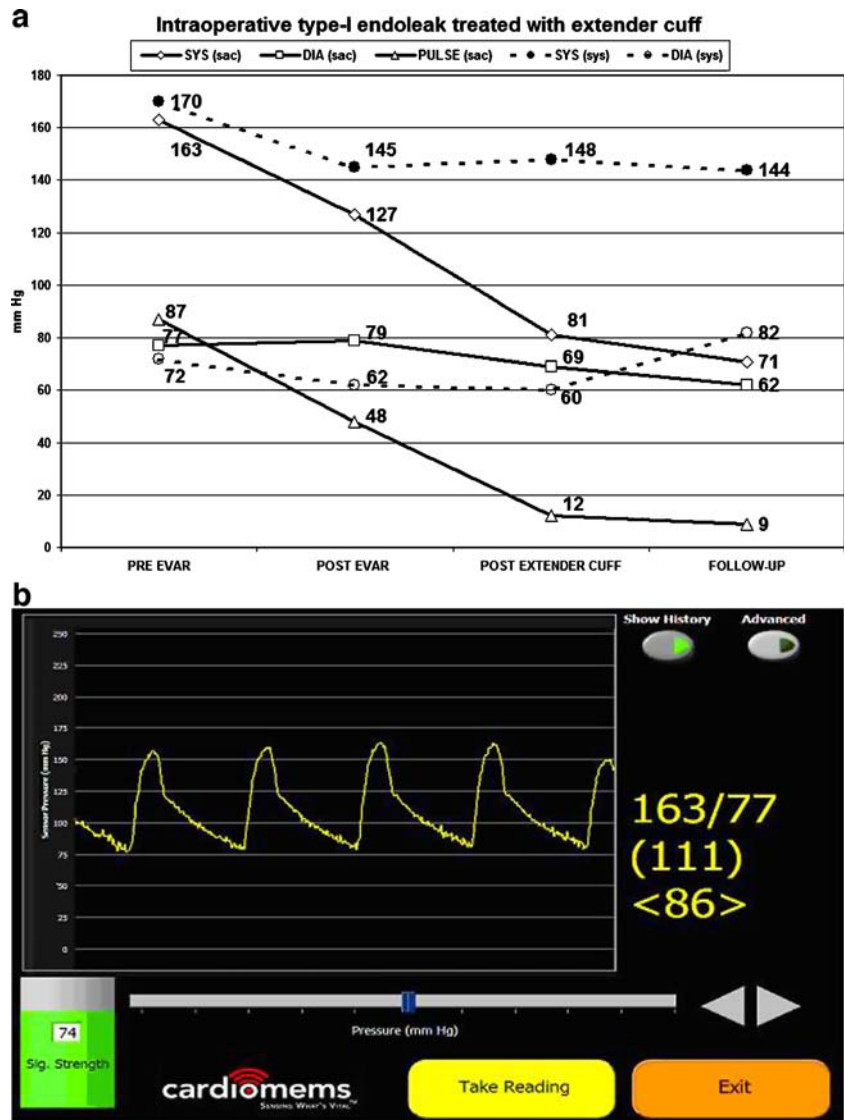


Fig. 3 (continued)

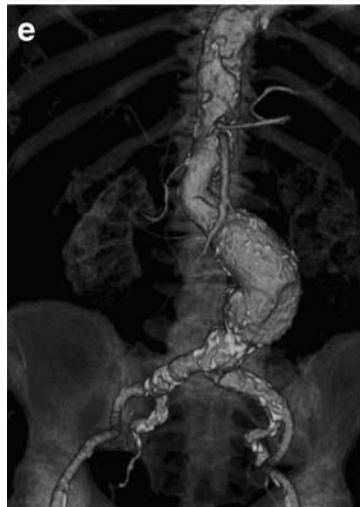
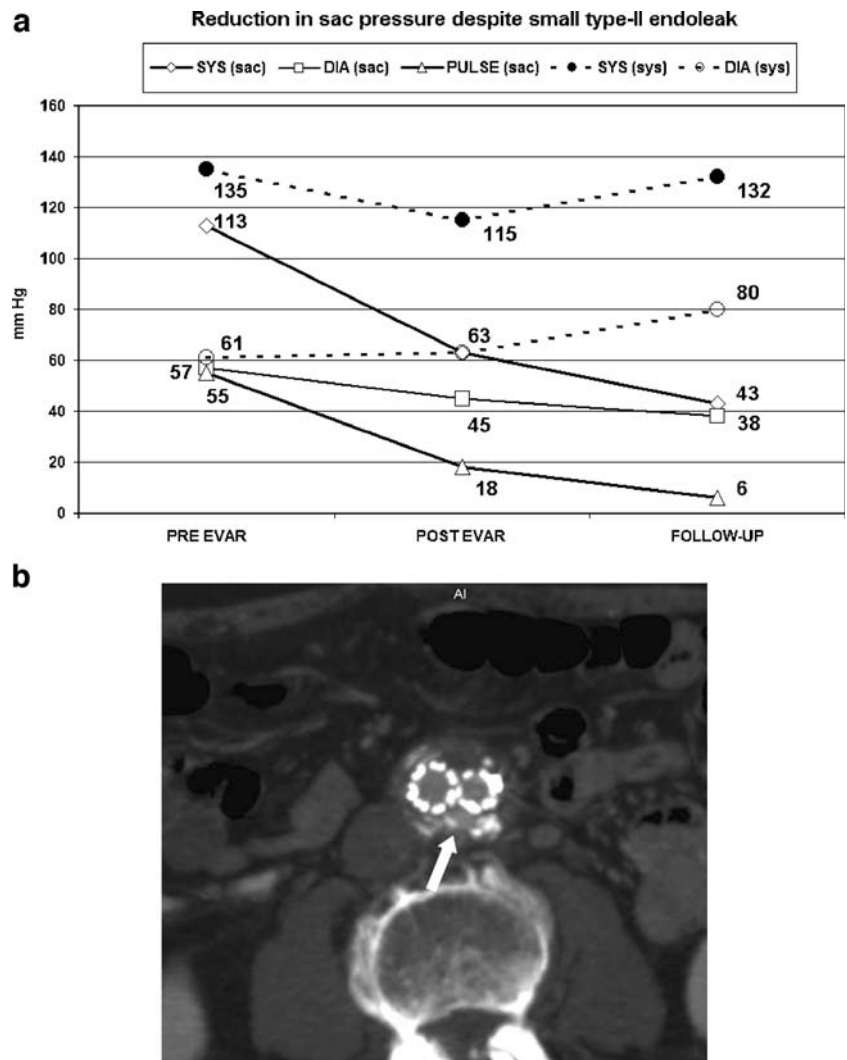


Fig. 4 A 64-year-old man with progressively enlarging infrarenal aortic aneurysm. The patient is at high risk for open surgical repair and underwent endovascular repair with placement of a remote pressure sensor (EndoSure, CardioMEMS, Inc.) within the aneurysm sac for follow-up. **a** Despite a small type-II endoleak, there was reduction of sac pressures on 1-month follow-up. EVAR, endovascular aneurysm repair; sac, aneurysm sac pressure; sys, systemic blood pressure. **b** Axial CTA demonstrates a small type-II endoleak at the level of the aortic bifurcation (arrow)



Discussion

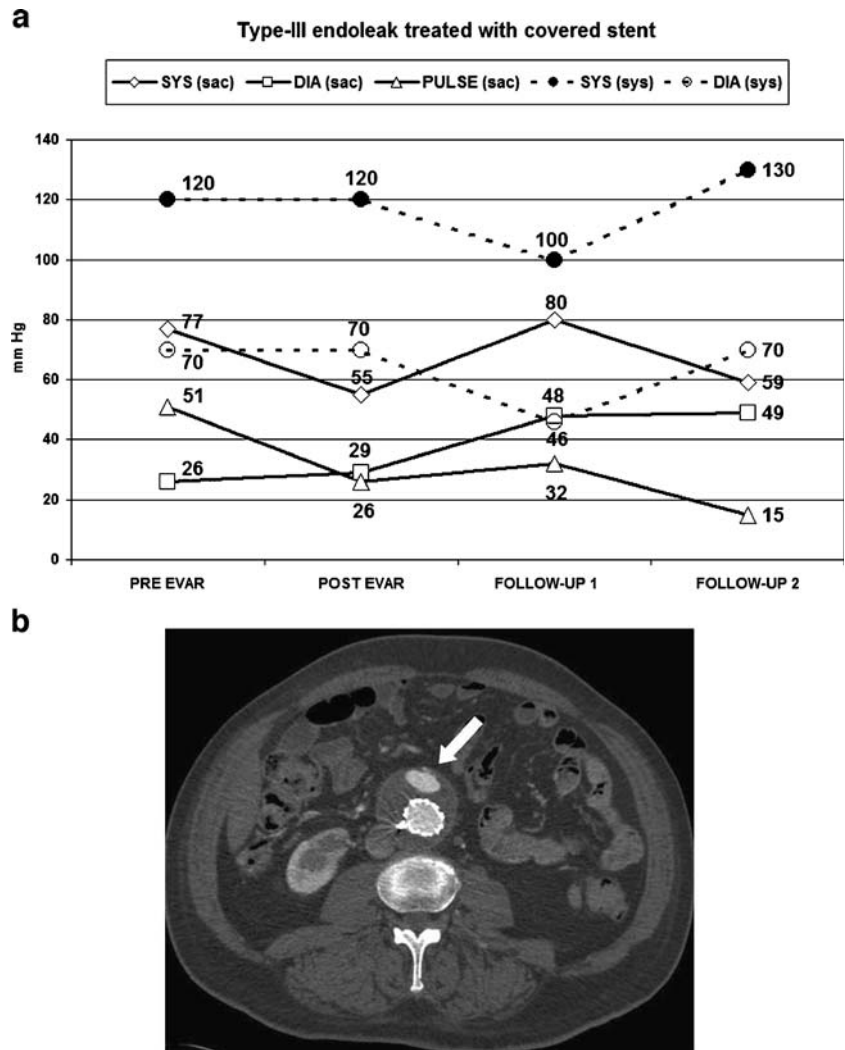
In the present study, monitoring of aortic aneurysm sac pressures with an implantable remote pressure sensor was feasible in patients pre- and post-EVAR using different types of commercially available endografts. After successful EVAR, a significant decrease in sac pressure was observed, and the average systolic sac pressure was significantly lower than the systemic systolic pressure. Furthermore, intraoperative treatment of a type-I endoleak resulted in decreased sac pressure.

Aortic sac pressures after EVAR are subject to multiple factors. Patient-related factors include patent side branches, thrombus composition, and aneurysm configuration [7–9]. Graft-related issues are porosity, compliance, and pulsatility [10]. A previous animal study with pressure transducers in the aneurysm sac demonstrated that sac pressures are significantly reduced by EVAR [7, 10]. Of interest, the quantity of graft porosity correlated with the grade of sac pressure reduction. Another group reports a relationship of

pressure transmission to the aneurysm wall and the composition of aneurysm sac contents [8]. Their results indicate that pressure transmission was reduced by homogenous thrombus compared with unclotted blood.

Sac pressure measurements have been previously described [11]. Chuter et al. positioned catheters alongside aorto-uniiliac stent grafts and report a substantial decrease in sac pressure in comparison with radial artery pressure [4]. However, no follow-up measurements were performed, and the possible creation of an attachment site endoleak may be a limitation of this method. Baum et al. report aneurysm sac pressure measurements by direct translumbar puncture and positioning of a 5-F catheter within the aneurysm sac [5]. This method enables direct pressure measurement and also allows for possible endoleak angiography and assessment of embolization results. Sonesson et al. used a guide-wire-mounted pressure sensor for percutaneous translumbar aneurysm sac pressure measurement and found pressure reduction in the aneurysm sac after successful EVAR [12]. This technique provided

Fig. 5 A 76-year-old man with an enlarging infrarenal abdominal aortic aneurysm (maximum diameter 5.5 cm) at high risk for surgical repair. **a** Intraoperatively, a decrease of pressures was observed post-endovascular repair. On a CT scan at 2 weeks (follow-up 1), a type-III endoleak was found with increasing diameter of the aneurysm sac to 5.7 cm and increased sac pressure. Treatment of the endoleak with a covered Palmaz stent resulted in stabilization of the size of the aneurysm sac and a decrease of sac pressure on 1-month follow-up (follow-up 2). EVAR, endovascular aneurysm repair; sac, aneurysm sac pressure (mmHg); sys, systemic blood pressure (mmHg). **b** Axial CTA after 2 weeks demonstrates a type-III endoleak (arrow). The remote pressure sensor indicated increased sac pressure



hemodynamic information within the sac in addition to imaging and may aid in the guidance of possible secondary interventions.

Mozes et al. describe the use of noninvasive vibrometry in an in vitro setting for monitoring of aneurysm sac pressure [13]. In this new concept, radiation pressure was generated by a modulated ultrasound beam. This was used to induce surface vibration at a distance, and the velocity of the resulting surface waves depends on the tensile stress of the vibrated surface. It was feasible to detect a change in tensile stress and calculate the pressure through the vibrated surface by measuring the change in wave velocity. The authors conclude that vibrometry may be used clinically in the future to predict the risk of aneurysm rupture.

Ellozy et al. report their clinical experience with a permanently implantable, ultrasound-activated remote pressure transducer to measure sac pressure following EVAR [14]. As in our study, patients with complete exclusion of the aneurysm had a significant difference in systemic and sac systolic pressures initially ($P < 0.001$) and

at 1-month follow-up ($P < 0.001$). Aneurysm exclusion resulted in a decrease of sac pressure over a time period of several months. Furthermore, successful endoleak treatment resulted in reduction of sac pressure. The transducers were hand-sewn to the outside of the stent graft and repackaged in the delivery sheath. This device can be implanted at the time of EVAR and used for long-term surveillance. While this device uses ultrasound to activate the sensor, we used the CardioMEMS sensor, which is powered by radiofrequency energy. This sensor is deployed using a low-profile delivery system. The sheath is removed after deployment with a tether retaining the sensor in the aneurysm sac. The tether is eventually removed after stent graft deployment and final positioning of the sensor in the aneurysm sac.

The CardioMEMS remote pressure sensor was previously used in a canine model for measurement of intra-aneurysmal pressure generated by type-II endoleaks reporting significant pressurization of the aneurysm sac, which was accurately measured through the thrombus [15].

The authors concluded that, despite the pressure sensor being used in animals and not in humans, their results indicate that the wireless implantable pressure sensor is a promising emerging technology to provide aneurysm sac pressure measurements that will potentially better characterize and diagnose endoleaks after endovascular exclusion.

Endoleak is defined as persistent perfusion of the aneurysmal sac post EVAR [16]. In type-I endoleaks, flow originates from ineffective endograft seal at fixation zones. A type-III endoleak is defined as flow resulting from structural endograft failure. A remote pressure sensor demonstrated successful endoleak detection in vitro [17]. The APEX multicenter trial evaluated the use of the CardioMEMS remote pressure sensor for assessment of intraoperative EVAR success in terms of evaluation of sac pressure and possible endoleak in comparison with catheter pressure measurements angiography in 76 patients [6]. In more than 90% of cases there was agreement between the sensor measurement and angiography regarding the presence or absence of an intraoperative type-I or -III endoleak. The overall sensitivity and specificity were 94% and 80%, respectively. In this study, an endoleak was classified as a pressure reduction of less than 30% after EVAR. The authors conclude remote pressure sensor measurements are a valuable guide in evaluating the completeness of the EVAR procedure. However, follow-up studies will be needed to prove its efficacy for postoperative surveillance.

Short-term follow-up data were acquired in our study. A small type-II endoleak was noted in two patients, but sac pressures were stable in one patient and had even decreased in the other patient and were left untreated. Another patient had a type-III endoleak, which was diagnosed on both follow-up CT and increased sac pressures. This was treated with a covered Palmaz stent resulting in a decrease of sac pressure. In one patient a proximal type-I endoleak was found after EVAR that was treated intraoperatively with an extender cuff resulting in a further decrease of sac pressure.

While immediate intervention is considered to treat type-I and type-III endoleaks, management of type-II endoleaks originating from branches feeding the aneurysm sac in a retrograde fashion seems to be more conservative because of a high rate of spontaneous thrombosis [18]. If a type-II endoleak has not thrombosed by 12 months post-EVAR, it is defined as a persistent endoleak that needs close monitoring because of an increased risk of sac enlargement and rupture [19]. Occasionally, an endoleak may not be detectable with current imaging methods, particularly if the flow is very low. In this situation sac pressure measurement may be beneficial. Hypothetically, sac pressure measurement may even replace follow-up imaging after EVAR in the future. This may help to minimize the number of follow-up CT scans, which may cause radiation- and contrast-related hazards for the patient.

There is speculation about remaining positive sac pressure post successful EVAR. One assumption to explain the mechanism is pressure transmission to the aneurysm

sac around the ends of the graft [20]. Another explanation is possible pressurization of the aneurysm sac via small collateral vessels. Wain et al. propose pressurization in the excluded aneurysm sac resulting from pressure transmission through the thrombus that may significantly correlate with no demonstrable endoleak causing endotension [21].

The term “endotension” is used when the aneurysm sac does not decrease in size after EVAR, or even increases in diameter or the aneurysm remains pulsatile on physical examination without a demonstrable endoleak on imaging [22]. The underlying cause for endotension still needs to be clarified and remains the subject of discussion. Furthermore, endotension may indicate that the aneurysm is still at high risk for rupture and that secondary intervention should be considered. In case endovascular tension is suspected, sac pressure measurements may assist in guidance of further therapeutic management such as conservative treatment or additional interventional or surgical procedures.

On follow-up CT angiography, the maximum aneurysm diameter on average was significantly smaller than pre-EVAR. In one patient with a type-III endoleak, the diameter of the aneurysm sac was slightly larger than pre-EVAR, and the sac pressures had increased. In two patients with type-II endoleaks on follow-up, aneurysm diameters were stable. In all other patients the size of the aneurysm sac was either smaller or stable post-EVAR. However, the number of patients in our study is limited, and further study with a larger cohort is needed to perform a significant correlation analysis.

In our study, pre-EVAR measurements of the sac pressure could not be obtained in one patient. While the reason for this was uncertain at first, further pressure measurements post-EVAR were possible after a medical infusion pump had been turned off by the anesthesiologist. This suggests that this medical device must have interfered in some way with the frequency of the EndoSure device. To the best of our knowledge, there is no other report of this kind using remote pressure sensors in the literature, and further investigation is needed.

There are several limitations of this study. Due to the limited number of patients, complications that occur at a low rate could have been missed. For example, four different types of stent grafts were used in our patients, further decreasing the potential sensitivity of the study for adverse events. In our study, difficulties with device delivery occurred in two patients. However, the company is currently working on an improved delivery system. Furthermore, no simultaneous sac pressure measurements with a method other than the EndoSure device were performed. Lastly, the longest duration of follow-up in this series was 1-month, and results for extended durations cannot be determined from this study.

In conclusion, measurement of aneurysm sac pressure was feasible using a remote pressure sensor. Following successful EVAR, a significant decrease in sac pressure and a considerably lower systolic sac pressure compared with the systemic systolic pressure were found. On short-term

follow-up, an increase of systolic sac pressure occurred in a patient with type-III endoleak confirmed by CT scan that was reversed after interventional treatment. For patients with a type-II endoleak, long-term follow-up of sac pressures is needed. Remote sac pressure measurement

may provide important information in addition to imaging. In the future, its utilization may even help to reduce the number of follow-up CT scans, which may decrease the risk for radiation and contrast medium-related complications for the patient.

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