Direct intra-aneurysm sac pressure measurement using tip-pressure sensors: In vivo and in vitro evaluation

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Objective: **Direct intra-aneurysm sac pressure measurement with percutaneous translumbar puncture is a new method for follow-up after endovascular aneurysm repair. The purpose of this study was to evaluate a tip-pressure sensor system for intra-aneurysm pressure measurement in an in vitro aneurysm model and in vivo in patients by studying intraobserver variability.**

Methods: **We used 0.014-inch guide wire–mounted tip-pressure sensors. For the in vitro aneurysm model, saccular aneurysms filled with thrombus were inserted in a left-heart-driven aneurysm model. Pressure was measured simultaneously with guide wire pressure sensors in the lumen of the model and within the aneurysm thrombus. In vivo, intraobserver variability was evaluated with double percutaneous translumbar puncture of the abdominal aortic aneurysm (AAA) with pressure measurement in 15 patients (14 men, 1 woman; median age, 75 years [63-80 years]; median AAA diameter, 55 mm [47-80 mm]) at a median of 32 months (2-100 months) after endovascular aneurysm repair. Mean pressure index was calculated as the percentage of mean intraaneurysm pressure relative to simultaneous mean systemic pressure.**

Results: **In vitro, the difference in pressure between the tip-sensor measurements and the pressure output of the aneurysm model was 2 mm Hg (1-4 mm Hg) when the output varied between 150/50 and 200/100 mm Hg (n = 90). Mean pressure in the lumen of the model and within the aneurysm thrombus differed by 1 mm Hg (−5-15 mm Hg (n = 10). In vivo, intraobserver variability of mean pressure index (Bland-Altman plot) was 0% (−7%-17%; n = 15%).**

Conclusion: **Direct intra-aneurysm sac pressure measurement with tip-pressure sensors mounted on 0.014-inch guide wires is a reliable and reproducible technique for measuring intra-AAA pressure both in vitro and in vivo. (J Vasc Surg 2004;40:711-6.)**

Endovascular aneurysm repair (EVAR) is based on exclusion of the aneurysm sac from blood flow and systemic pressure to decrease tension on the abdominal aortic aneurysm (AAA) wall. The presence of blood flow within the AAA sac but outside the stent graft, that is, endoleak, may be directly identified with imaging methods. On the contrary, intra-aneurysm sac pressure during follow-up after EVAR was until recently evaluated only indirectly. This has included evaluation of AAA size and even the pulsatile wall motion of the aneurysm.[1]

For measurement of intra-aneurysm sac pressure 2 main problems need to be addressed: access to the AAA and use of a pressure sensor that does not lose reliability when measurements are obtained within thrombus.

We have recently developed a method for direct intra-aneurysm sac pressure measurement (DISP) with translumbar access and tip-pressure sensors.[2] DISP shows that expanding aneurysms after EVAR are associated with significantly higher intra-aneurysm sac pressure and greater pulse pressure compared with shrinking aneurysms.[3] Furthermore, DISP exhibited potential for predicting AAA evolution (shrinkage or expansion) in aneurysms that were unchanged in diameter at the time of pressure measurement. DISP therefore has potential for optimizing imaging follow-up after EVAR.

The purpose of this study was to evaluate 0.014-inch guide wire–mounted tip-pressure sensors used for DISP in an in vitro aneurysm model, and in vivo intraobserver variability of DISP.

METHODS

Pressure measurement system

Micromachined wired tip-pressure sensors[4] consisting of a silicon chip (100 × 150 × 1500 μm) with a piezoelectric sensor were mounted on 0.014-inch guide wires (Radi Medical AB). The piezoresistive pressure sensor had a pressure sensitivity of 2.0 μV/V/mm Hg, conferring accuracy better than 2 mm Hg. The system frequency range was 0 to 200 Hz, and resonant frequency was 1 MHz.

Two versions of the pressure guide wires were used. In both the sensor was of the same kind. For systemic pressure measurement a commercially available coronary Pres-

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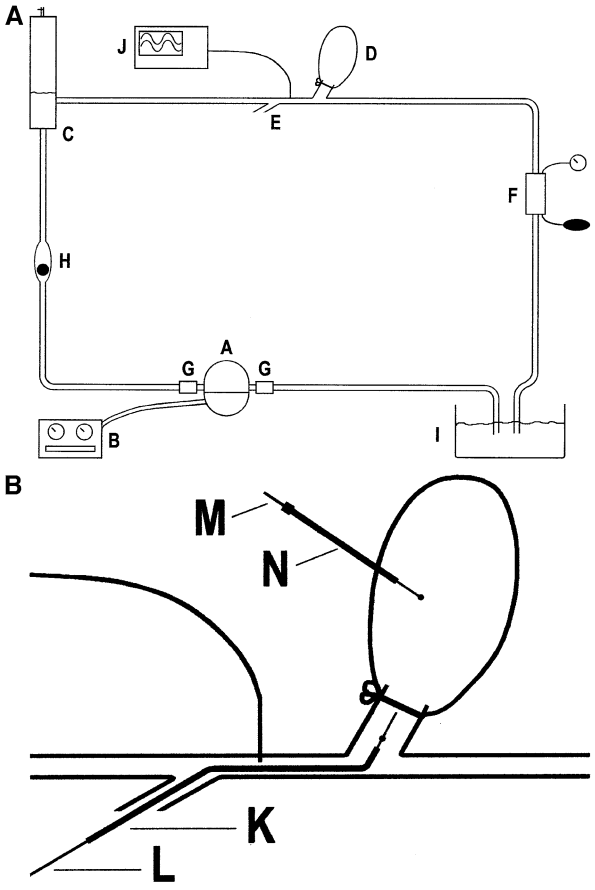

Fig 1. A, Schema of aneurysm model driven by an artificial left-heart. Artificial heart consisted of a 70-mL chamber *(A)*, and was driven by a pneumatic driver *(B)*. Compliance of the model was adjusted with an air chamber *(C)*. Aneurysms made of thoracic pig aorta could be attached to a side port *(D)*. One working side port *(E)* enabled introduction of catheters. A blood pressure cuff around a segment of rubber tubing was available to adjust peripheral resistance *(F)*. System included 3 valves *(G, H)*, an open reservoir *(I)*, and a flow transducer *(J)*. Starch solution was used as perfusate. **B,** Amplification of part of aneurysm model during experiments. Pressure was measured simultaneously in the lumen of the model and within the aneurysm thrombus with tip-pressure sensors mounted on 0.014-inch guide wires. A 4F angiographic catheter *(K)* was introduced through the working side port. This catheter was used for insertion of a long-tipped guide wire *(L)*, placing the sensor in the lumen of the side port to which the aneurysm *(D)* was connected. Pressure within the thrombus of the saccular aneurysm was measured with a short-tipped guide wire *(M)* inserted through a 20-gauge needle *(N)*.

sureWire 4 (Radi Medical AB) with a 3-cm long radiopaque platinum floppy tip was used. In the second version, used for intra-aneurysm sac pressure measurement, the radiopaque tip was shortened to 1 mm to enable precise placement of the sensor within the aneurysm. Both pressure guide wires were connected to an interface, where the measurements were digitally recorded.

Immediately before insertion the sensor was calibrated in saline solution. The calibration was verified each time the sensor was completely withdrawn.

In vitro aneurysm model

Model characteristics. The in vitro aneurysm model (Fig 1, *A*) consisted of an artificial left-heart, a tubing system, and a collecting system. A similar model has been described.[5] The artificial heart was made of a 70-mL chamber with 2 valves, and was driven by a pneumatic heart driver. Heart output could be changed by varying the frequency, diastolic suction, and systolic driving pressures, and systolic-diastolic timing. An air chamber with the possibility of changing the proportion of air to perfusate was used to modulate system compliance. Peripheral arterial resistance could be adjusted with a cuff around a segment of rubber tubing. A working side port was built in to enable introduction of angiographic catheters. Starch solution with bloodlike viscosity was used as perfusate.

Two saccular aneurysms were obtained by closing 1 end of a segment of porcine thoracic aorta with a running polypropylene 5-0 suture (Prolene; Ethicon). Both aneurysms (5-cm long by 2-cm wide) were filled with a single transverse section of human thrombus obtained at AAA open surgery in 2 patients. The thrombus was cut and inserted to completely fill the distal two thirds of the aneurysms. The proximal ends of the aneurysms were connected to a side port of the system with surgical ligatures to achieve seal to the perfusate.

Experiments. A long-tip pressure guide wire was calibrated and introduced through an angiographic catheter into the model lumen. After positioning the sensor in the lumen of the side port to which the saccular aneurysm was connected the readings from the pressure guide wire were compared with the artificial left-heart output (90 measurements).

Thereafter the aneurysm was punctured with a 20-gauge needle (Mediplast; Procurator Medical AB) until the tip reached the mid-portion of the aneurysm (1 cm). A short-tip pressure guide wire was inserted into the aneurysm sac through the needle (Fig 1, *B*). The needle was then withdrawn over the wire to uncover the pressure sensor. Intra-aneurysmal and intraluminal pressure measurements were obtained simultaneously from both guide wire–mounted sensors (10 recordings).

In vivo model—direct intra-aneurysm sac pressure measurement (DISP)

DISP technique. Anatomic suitability for translumbar AAA puncture was evaluated with contrast material–enhanced computed tomography (CT), including delayed scans, performed in the month before DISP. Suitability was defined as an aneurysm large enough to enable safe translumbar introduction of the needle into the AAA sac without entering the peritoneal cavity or creating risk for damage to the stent graft.

The DISP procedure included digital subtraction abdominal aortography. Nonionic iodinated contrast medium (Omnipaque; Nycomed Amersham) was used. In

patients with renal insufficiency (serum creatinine concentration >180 μmol/L) carbon dioxide was also used as contrast medium. Thereafter the multiple-side-hole angiographic catheter used for aortography was exchanged for a hockey-stick catheter. A long-tipped 0.014-inch guide wire–mounted pressure sensor was then passed through this catheter into the main body lumen of the stent graft.

The catheter with the pressure guide wire was secured, and the patient was placed in a prone position. Translumbar puncture of the aneurysm sac was then performed with the patient under local anesthesia (Carbocain; Astra Zeneca AB), with a 20-gauge needle (Mediplast; Procurator Medical AB). The puncture was guided by fluoroscopy with the down-the-barrel technique (Fig 2, *A*). The perpendicular projection was used to evaluate the depth of the puncture (Fig 2, *B*). Radiopaque structures, including the stent graft and surrounding bony structures, were used as landmarks for orientation as determined on the pre-DISP spiral CT scan. On entering the AAA sac aneurysmography was performed by injecting a small amount of iodinated contrast medium, to confirm the needle position and identify any possible endoleaks. Thereafter the needle was further advanced into the AAA sac. A short-tipped pressure guide wire was introduced through the needle until the radiopaque marker located at the guide wire tip reached the needle tip. The needle was then withdrawn 1 to 2 cm over the wire.

Both pressure guide wires were connected to a computerized interface, where the measurements were digitally recorded. The equipment provided on average 10 heart cycles within each recording (Fig 3). Recordings were obtained when the pressure sensor was at mid-distance between the stent graft and the AAA wall.

Sedation with intravenously administered cetobemidon (Ketogan; Pharmacia) and midazolan (Dormicum; Roche) was used when necessary. A relaxed state was always pursued, because intrasac and retroperitoneal pressures were influenced by any strain that increased intra-abdominal pressure, such as the Valsalva maneuver (Fig 4).

For measurements to be considered valid and included in this study a decrease in pressure was required when the pressure sensor was withdrawn from the aneurysm sac into the retroperitoneum (Fig 5). In addition, the drift of the initial calibration had to be 5 mm Hg or less after completion of the measurements.

Mean pressure index (MPI) was calculated as the percentage of mean intra-aneurysmal pressure relative to the simultaneous mean systemic pressure. All aneurysms were punctured twice. After complete removal of the needle from the patient after the first puncture, translumbar puncture of the AAA was repeated. Intra-aneurysm sac pressure was measured after recalibration of the sensor.

Patients. Fifteen patients (14 men, 1 woman), with median age of 75 years (63-80 years), with suitable anatomy for DISP and no evidence of endoleak at CT, digital subtraction angiography, or aneurysmography were included. DISP was performed at a median of 32 months (2-100 months) after EVAR when AAA diameter was 55 mm (47-80 mm). This corresponded to an increase in AAA diameter (≥5 mm) in 5 patients, a decrease in AAA diameter (≥5 mm) in 3 patients, and unchanged AAA diameter in the remaining 7 patients. All patients underwent two translumbar punctures of the AAA sac.

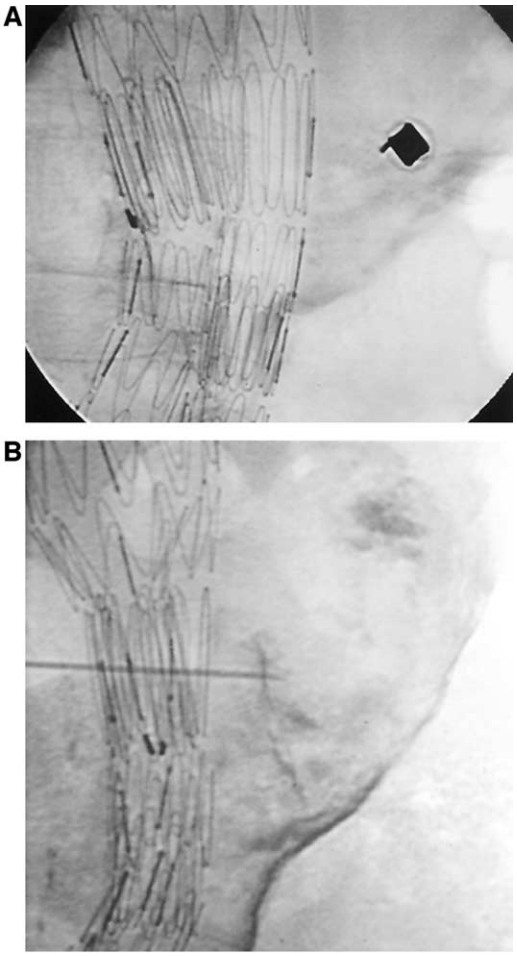

Fig 2. Translumbar puncture of the abdominal aortic aneurysm sac for direct intraaneurysm sac pressure measurement in vivo under fluoroscopic guidance. **A,** Down-the-barrel technique was used, with the stent graft and surrounding bony structures as landmarks. **B,** Perpendicular projection was used to evaluate depth of the puncture.

All patients received antibiotic prophylaxis with isoxacillin (Ekvacillin; Astra Zeneca AB), or klindamycin if allergic to penicillin (Dalacin; Pharmacia). Anticoagulation was achieved routinely with 3000 to 5000 intra-arterial units of heparin (Leo Pharma), depending on body weight.

Statistical analysis

Normal distribution was not assumed. Values are presented as median, and 5th and 95th percentiles in parenthesis when not stated otherwise. The Wilcoxon signed rank test was used for paired comparisons. Variability was evaluated with the Bland-Altman plot.[6] Results were considered significant at $P < .05$. Exact P values are presented.

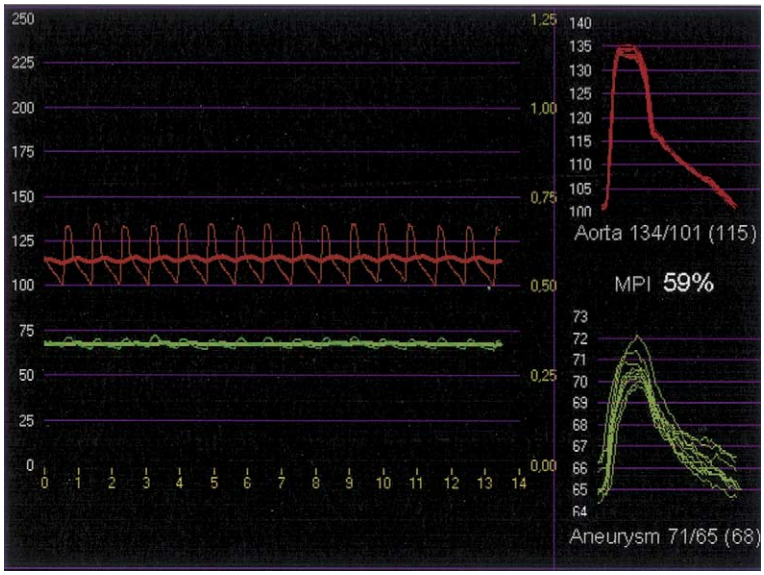

Fig 3. Example of recording of direct intraaneurysm sac pressure measurement. Intraaneurysm *(green curve)* and systemic pressures *(red curve)* were recorded simultaneously. After each recording the system used 10 consecutive heart cycles to calculate mean values of systolic/diastolic (mean) pressures (on right side of image). Mean pressure index *(MPI)* is calculated as percentage of intraaneurysm sac pressure relative to systemic pressure.

Absolute pressure values are described as systolic/diastolic (mean) in millimeters of mercury. Statistical analysis was performed with SPSS version 11.5.1.

The study was approved by the institutional ethics committee, and all patients gave informed consent before the procedure.

RESULTS

In vitro aneurysm model

Tip-pressure sensor comparison with pressure output of model. Median variability of mean pressure (n = 90) between readings obtained with the guide wire–mounted pressure sensor and the pressure output of the model was 2 mm Hg (1-4 mm Hg).

Simultaneous intra-aneurysm and luminal pressure measurements. Two saccular aneurysms were used for the experiments. Median intra-aneurysm sac and intra-luminal pressures were, respectively, 136 (92-151)/78 (50-92) (100 (65-111)) mm Hg and 138 (113-151)/78 (54-89) (100 (77-112)) mm Hg (systolic/diastolic (mean)). Median variability of simultaneous mean pressure measured in the lumen of the flow model and within the thrombus of the saccular aneurysm (10 measurements with 10 systolic-diastolic cycles each) was 1 mm Hg (−5- 15; Fig 6).

In vivo intraobserver variability of DISP

Unsuitable anatomy limited the performance of DISP in fewer than 10% of patients who had undergone EVAR at least 1 year previously. Twenty percent of patients with suitable anatomy required right-sided translumbar puncture through the inferior vena cava. This was not associated with complications.

Fifteen patients were included in the study; translumbar puncture of the AAA was successful in all cases. The procedure was not associated with local complications such as damage to the stent graft or infection. Measurements were valid for all patients included in the study.

Intraaneurysm sac pressure (n = 15) during the first puncture was 46 (13-120)/43 (10-105) (44 (11-112)) mm Hg, (systolic/diastolic (mean)) and during the second puncture was 48 (14-119)/43 (12-105) (45 (13-111)) mm Hg, (systolic/diastolic (mean)). Simultaneous systemic pressure registered during the first puncture was 143 (91-242)/74 (54-133) (100 (70-175)) mm Hg and during the second puncture was 143 (91-271)/76 (55-114) (102 (69-198)) mm Hg. Median MPI was 46% (8%-98%) during the first puncture, and 49% (13%-98%) during the second puncture ($P = .975$). MPI variability between the 2 punctures was 0% (−7-17; Fig 7).

DISCUSSION

DISP with tip-pressure sensors mounted on 0.014-inch guide wires is a reliable and reproducible technique for measuring pressure within aneurysm sac thrombus, both in vitro and in vivo.

The use of in vitro aneurysm models to test pressure sensors has the advantage of controlling circulatory conditions. Starch with the same viscosity as blood was chosen as perfusate, because in previous in vitro studies no difference was found in pressure transmission between this perfusate and blood, independent of the pressure measuring system used (Hinnen et al, unpublished data).

Tip-pressure sensors are considered the gold standard for pressure measurement. The location of the sensor at the

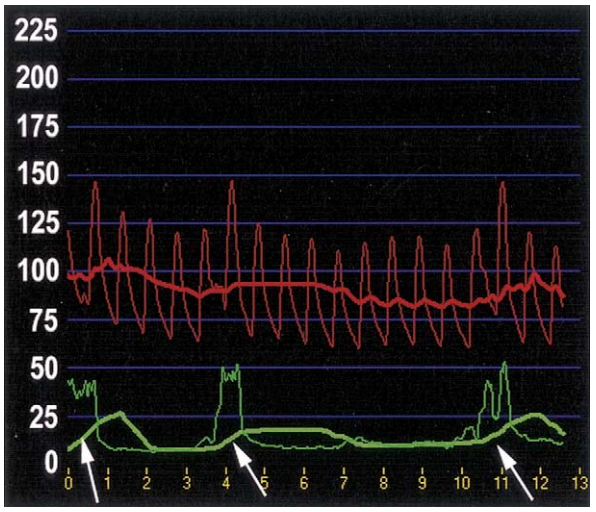

Fig 4. Effects of straining on retroperitoneal pressure. *Red curve,* Systemic recording; *green curve,* translumbar recording. *Horizontal ("nonpulsatile") lines*, Mean pressure. Retroperitoneal pressure increases during short peaks of intraabdominal pressure *(arrows)*.

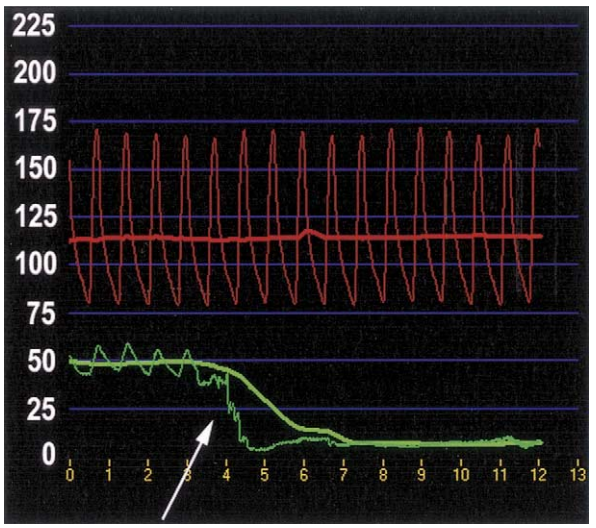

Fig 5. Direct intraaneurysm sac pressure measurement recording during withdrawal of sensor into retroperitoneum. *Red curve,* Systemic pressure register; *green curve,* intraaneurysm sac pressure register. Pressure reduction *(arrow)* occurred on withdrawal of sensor from aneurysm sac (59/43 mm Hg; mean, 49 mm Hg) into retroperitoneum (6 mm Hg). *Horizontal ("nonpulsatile") lines*, Mean pressures.

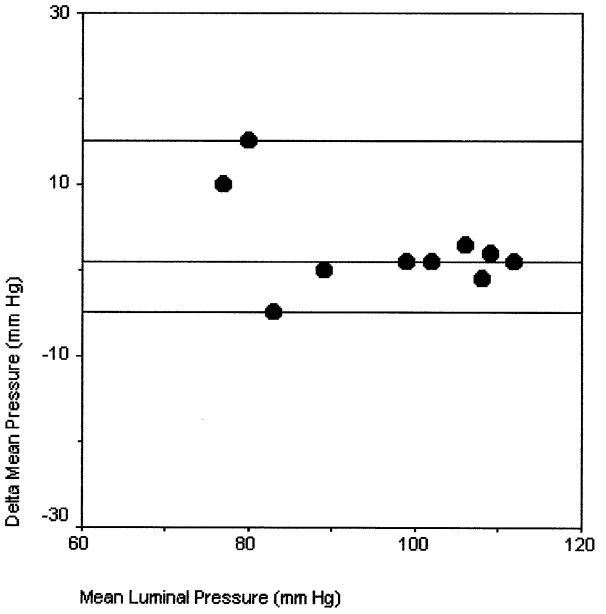

Fig 6. Variability between in vitro mean pressures in lumen of aneurysm model and within aneurysm thrombus (Bland-Altman plot). Delta mean pressure (y-axis) represents difference between mean luminal and intraaneurysm pressures. *Horizontal lines*, Median (1 mm Hg) and 5th and 95th percentiles (−5-15 mm Hg).

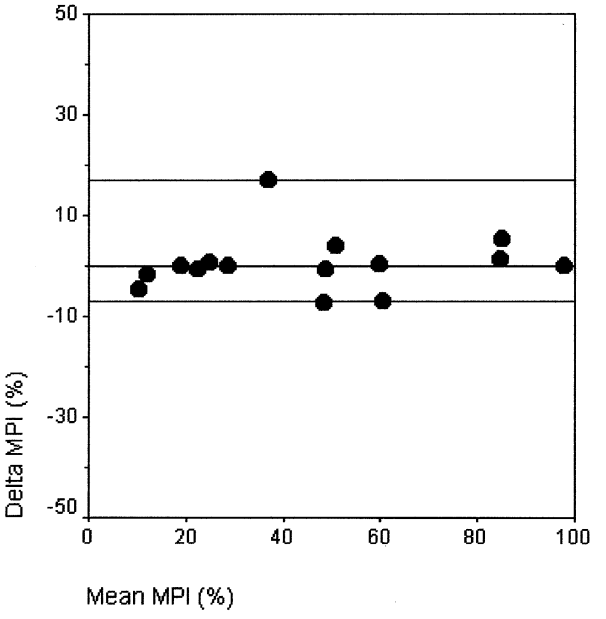

Fig 7. In vivo intraobserver variability of direct intraaneurysm sac pressure measurement with 2 repeated punctures in 15 patients (Bland-Altman plot). Delta mean pressure index *(MPI)* is difference between MPIs measured in first and second punctures. *Horizontal lines,* Median (0%) and 5th and 95th percentiles (−7%-17%).

tip of the guide wire prevents the problems involved in signal transmission when the sensor is centrally located. Signal damping from air bubbles and occlusion of the measuring catheter from thrombus are no longer possible, because the sensor is located in a silicon membrane at the tip of the guide wire. The dependency of fluid-filled systems on the length and diameter of the measuring catheter is also averted. Shortening the tip of the guide wire used for intrasac measurements enabled precise positioning of the sensor within the thrombus. The system used in this study

yielded high agreement for pressure measurement compared with the aneurysm model output (median variability, 2 mm Hg). This capacity was maintained when pressure was measured within thrombus.

All of our patients tolerated well the translumbar puncture of the aneurysm, which in some instances was through the inferior vena cava. This is in accordance with the low rate of complications with other types of percutaneous retroperitoneal access, such as translumbar aortography.[7] Local complications such as damage to the stent graft or infection did not occur either. A contributing factor to the safety of translumbar puncture was the small dimensions of the guide wire and needle.

There are inherent limitations and problems to DISP that require special consideration. Intraabdominal pressure variation, such as during the Valsalva maneuver, affects AAA sac and retroperitoneal pressure (Fig 4). To obtain a similar baseline measurement in all patients it is important that the patients be as relaxed as possible. Muscular tension caused by discomfort in the prone position could alter intra-abdominal pressure and thereby condition intra-aneurysm sac pressure unpredictably. Unpredictable loss of sensor calibration during measurement was also verified in an early series in fewer than 6% of punctures (unpublished data). This was not a problem in the present group of patients. However, control of the drift from the initial zero was always performed each time the guide wire was removed from the patient.

DISP revealed low intraobserver variability between repeated punctures, with good agreement of MPIs (Fig 7). This reinforces the capacity of DISP for measuring AAA sac pressure, and thereby the previously reported associations of low pressure with shrinking AAA diameter and higher pressure with expanding diameter.[3] In addition, this also suggests that pressure did not change significantly in the middle of the AAA in the absence of endoleak. However, this and thereby the validity of intra-aneurysm sac pressure measurements are questioned in a recent report.[8] In that study, pressure was found to have a varying distribution, which was related to the histologic density of thrombus. Nevertheless, the nonuniformity of thrombus structure from untreated aneurysms had already been reported. With increasing distance to the aortic lumen the fibrin organization is progressively lost, and this is associated with a decrease in mechanical strength.[9,10] In addition, the luminal distance also appears to be related to the permeability and density of the canalicular organization of the thrombus.[11] After EVAR the close relation between the aortic lumen and thrombus is lost. This does not allow direct extrapolation of the results obtained while using thrombus from untreated aneurysms to the situation after the stent graft is in place.

Our current policy toward DISP in clinical practice, in the face of high intra-aneurysm sac pressure after EVAR, is to look for possible causes of aneurysm repressurization. In cases of unchanged AAA diameter at DISP, imaging follow-up is intensified. If the aneurysm has already expanded a repeat intervention, either endovascular or conversion to open repair, is considered. With low intra-aneurysm sac pressure a conservative imaging follow-up protocol is continued.[3]

In conclusion, DISP seems to be a reliable and reproducible way to measure intra-aneurysm sac pressure. This reinforces the potential of DISP as a useful adjunct to imaging follow-up after EVAR. Moreover, DISP can be used to validate other methods of intra-aneurysm pressure measurement, such as implantable devices and fluid-based systems.

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