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ORIGINAL RESEARCH

Preliminary Assessment of Intra-Aneurysm Sac Pressure During Endovascular Aneurysm Repair as an Early Prognostic Factor of Aneurysm Enlargement

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Purpose: Numerous cases of abdominal aortic aneurysm (AAA) enlargement, and even rupture, despite endovascular aneurysm repair (EVAR), have been documented. This has been linked to increased aneurysm sac pressure (ASP). We decided to conduct further research with the aim to identify correlations between ASP during EVAR and subsequent aneurysm enlargement.

Patients and Methods: This experimental prospective study included 30 patients undergoing EVAR of infrarenal AAAs. Invasive ASP measurements were done using a thin pressure wire. Aortic pressure (AP) was measured using a catheter placed over the wire. Systolic pressure index (SPI), diastolic pressure index (DPI), mean pressure index (MPI), and pulse pressure index (PPI) were calculated both for ASP and AP. The results of follow-up computed tomography angiography (CTA) at 3 months were compared with baseline CTA findings.

Results: During EVAR, a significant reduction was observed for SPI (from 98% to 61%), DPI (from 100% to 87%), MPI (from 99% to 74%), and PPI (from 97% to 34%). There were no significant correlations of pressure indices with an aneurysm diameter, cross-sectional area, velocity, thrombus shape and size, number of patent lumbar arteries, length and diameter of aneurysm neck, diameter of the inferior mesenteric artery, as well as diameter and angle of common iliac arteries. On the other hand, aneurysm neck angulation was significantly inversely correlated with reduced PPI. After combining CTA findings with pressure measurements, we identified a positive correlation between PPI and aneurysm enlargement (ratio of the cross-sectional area at the widest spot at baseline and at 3 months after EVAR).

Conclusion: The study showed that ASP can be successfully measured during EVAR and can facilitate the assessment of treatment efficacy. In particular, PPI can serve as a prognostic factor of aneurysm enlargement and can help identify high-risk patients who remain prior monitoring.

Keywords: abdominal aortic aneurysm, aneurysm sac pressure, endovascular surgery, endoleak

Introduction

Endovascular aneurysm repair (EVAR) is a common modern technique for the treatment of abdominal aortic aneurysm (AAA). It involves implantation of a bifurcated stentgraft to create a new lumen for blood flow within the abdominal aorta and common iliac arteries. In some cases, unibody grafts are used instead of bifurcated ones, especially when one-sided common iliac artery is occluded or other technical issues make it impossible to implant contralateral iliac graft. As a result of EVAR, the pulsatile blood pressure no longer affects the aneurysm sac.

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Despite stentgraft implantation, numerous cases of aneurysm enlargement, and even rupture, after EVAR have been documented. The failure is usually linked to endoleak (EL), that is, blood leakage into the aneurysm sack. Depending on ethology there are 5 types of EL: type I the leak at the end of prosthesis: proximal end (Ia), distal end (Ib) or the leak at the iliac occluder (Ic); type II is the leak from aneurysm's branches: single (IIa) or multiple branches (IIb); type III is the leak connected with the defect of stentgraft: the leak between modules of prosthesis (IIIa) or the defect in the material of prosthesis (IIIb); type IV is the leak through fabric microporosity of stentgraft; type V (also called endotension), is an aneurysm enlargement with no visible leakage on computed tomography angiography (CTA).[1,2] EL occurs in 17% to 26% of patients undergoing EVAR,[3–6] especially in cases with aneurysm growth and rupture.[7] The EUROSTAR registry including 6000 patients after EVAR reported an EL frequency of 22%. Interestingly, the registry also showed that 5.3% of AAAs with no visible EL were still growing. At 4 years, the risk of aneurysm rupture increased abruptly from <1% to 7.5%–13.6%.[7] It was shown that those cases were linked to increased aneurysm sac pressure (ASP).[8,9]

Our previous research confirmed the efficacy and safety of ASP measurement by pressure wire during EVAR. While we generally observed a significant reduction in ASP during the procedure, there were some patients with only a small decrease or even no changes in ASP.[10] Therefore, we decided to conduct further research with follow-up CTA at 3 months. The aim of the study was to identify correlations between ASP during EVAR and subsequent aneurysm enlargement.

Materials and Methods

Study Design

This experimental prospective study was based on the analysis of intraoperative measurements and CTA findings. Invasive ASP measurements were performed during EVAR of infrarenal AAAs. Follow-up CTA was done at 3 months (which is our standard practice for EVAR patients), and the findings were compared with those obtained at baseline.

Population

The study included 30 patients (6 women and 24 men) at a mean age of 71.69 ±6.92 years (range, 58–86 years). Patients with an asymptomatic AAA who were referred for EVAR were considered eligible for the study. Morphology of AAAs was infrarenal, fusiform with dimensions as follows: aneurysm length 83.13 ± 27.50 mm, aneurysm diameter 58.51 ± 12.30 mm, volume of thrombus 54.02 ± 23.50%, neck length 4.04 ± 1.70 mm, neck diameter 2.48 ± 0.39 mm, neck angulation 36.02 ± 14.60 degree, IMA diameter 1.82 ± 1.53mm, amount of lumbar arteries >2.5 mm: 2.61 ± 1.58. All cases were in the Instructions For Use (IFU) of EVAR, including aneurysm neck length of at least 20 mm.

Endovascular Aneurysm Repair

Standard EVAR[11] was performed in a hybrid operating room. The whole procedure was carried out under local anaesthesia in the inguinal region. Bilateral femoral artery access was performed using a pre-close technique. The main bifurcated body of the abdominal stentgraft was deployed, positioned, and expanded under angiographic guidance, just below the origin of the lower renal artery. Next, the iliac parts of the stentgraft were deployed and expanded. Final angiography was performed to confirm proper graft implantation and detect possible EL.

Pressure Measurement

A 0.014-inch wire (COMET II Pressure Guidewire, Boston Scientific) was used for ASP measurements, as described previously.[10] A 6F Judkins right catheter was inserted by left radial access and introduced proximally to the aneurysm. The pressure wire was advanced through the catheter into the aneurysm sac at the beginning of the EVAR procedure to monitor the ASP. Aortic pressure (AP) was measured using a catheter placed over the wire. Pressure measurements were done at each stage of the EVAR: before stentgraft deployment, after deployment, and, finally, after ballooning of the stentgraft parts. Systolic, diastolic, mean, and pulse pressures were recorded for both ASP and AP. When the EVAR was completed, the wire and the catheter were removed.

Statistical Analysis

To obtain unified results, we used the following pressure indices for both ASP and AP: systolic pressure index (SPI), diastolic pressure index (DPI), mean pressure index (MPI), and pulse pressure index (PPI). The normality of data distribution was assessed by the Shapiro–Wilk test. The Student's *t*-test was used for a comparison between the obtained coefficients. The Wilcoxon test was applied for a non-parametric analysis. The analysis of variance and correlation tests were also performed. The significance level was set at a P value of less than 0.05. The Statistica 13.3 software (StatSoft, Poland) was used for analysis.

Ethics

The approval of the Bioethics Committee of Medical University in Wroclaw was obtained (KB-51/2019). All procedures performed in studies involving human participants were in accordance with the ethical standards of the Committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent was obtained from all individual participants included in the study.

Consent for publication was obtained for every individual person's data included in the study.

Results

All patients underwent EVAR without any intraoperative complications. We implanted variable models of bifurcated stentgrafts: Cook (9 cases), Jotec (3 cases), Gore (7 cases), Medtronic (3 cases), Terumo (8 cases). The only significant correlation was on PPI, with the best results for Gore and Terumo (Figure 1), however it was not connected with EL presence or results after 3-months.

During EVAR, all pressure indices decreased significantly: SPI from 98% to 61%, DPI from 100% to 87%, MPI from 99% to 74%, and PPI from 97% to 34%.

We examined the calculated indices in relation to the anatomical features of AAAs. The correlations are presented in Table 1. There were no significant correlations between the pressure indices and aneurysm diameter, cross sectional-area, velocity, thrombus shape and size, number of patent lumbar arteries, neck length, neck diameter, diameter of inferior

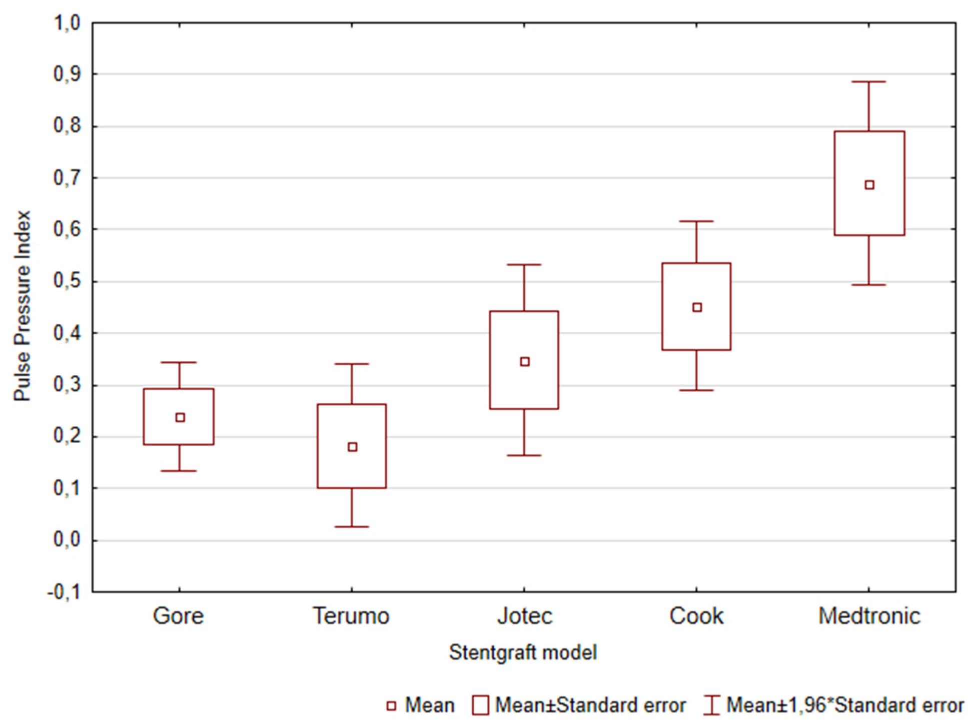

Figure 1 PPI results after EVAR for different types of implanted stentgrafts models.

Table 1 Correlations Between Anatomical Features of Abdominal Aortic Aneurysm and Pressure Indices After Endovascular Aneurysm Repair

Parameter	SPI	DPI	MPI	PPI
Cross-sectional area of the aneurysm	0.11	0.26	0.21	−0.11
Cross-sectional area of lumen	−0.07	0.04	0.01	−0.24
Cross-sectional area of thrombus	0.21	0.32	0.28	0.07
Ratio of thrombus to aneurysm area	0.19	0.31	0.25	0.15
Thrombus shape	0.30	0.34	0.32	0.29
Aneurysm length	−0.18	0.07	−0.05	−0.34
Aneurysm neck length	−0.13	−0.2	−0.17	−0.11
Aneurysm neck diameter	−0.12	−0.27	−0.19	−0.05
Aneurysm neck angle	−0.34	−0.2	−0.27	−0.46[a]
Aneurysm velocity	0.00	0.14	0.09	−0.20
Right common iliac artery diameter	0.25	0.05	0.18	0.23
Left common iliac artery diameter	0.10	0.06	0.10	0.06
Angle between common iliac arteries	0.05	0.00	0.00	0.16
Inferior mesentheric artery diameter	−0.12	−0.28	−0.19	−0.02
Number of wide lumbar arteries (>2.5 mm)	0.06	−0.01	0.04	0.03

Notes: [a]Statistically significant (P <0.05).
Abbreviations: DPI, diastolic pressure index; MPI, mean pressure index; PPI, pulse pressure index; SPI, systolic pressure index.

mesenteric artery, as well as diameter and angle of common iliac arteries. On the other hand, there was a significant inverse correlation between aneurysm neck angulation and a reduction in PPI. Directly after stentgraft implantation, EL was revealed in 7 of 30 cases: 6 type II EL and 1 type I (this case required an adjuvant procedure). There was no significant correlation between EL and pressure indices.

Only 20 of the 30 patients completed the 3-month follow-up. The results of CTA at baseline and at 3 months are compared in Table 2. The EL was present in 8 cases. It was slightly type 2 EL. There was no correlation between EL and other anatomical features like aneurysm size.

The aneurysm lumen was significantly reduced due to thrombus formation, while the overall aneurysm size was not changed or even enlarged in some cases (Figure 2). However, after combining CTA findings with pressure

Table 2 Anatomical Features of Abdominal Aortic Aneurysm at Baseline and at 3 Months After Endovascular Aneurysm Repair

Parameter	At Baseline	At 3 Months	P value
Cross-sectional area of the aneurysm, cm^2	99.41±49.49	95.07±50.97	0.0662
Cross-sectional area of the lumen, cm^2	41.56±24.95	22.31±7.67	0.0016[a]
Cross-sectional area of thrombus, cm^2	57.84±38.37	72.76±47.74	0.0221[a]
Aneurysm length, mm	82.68±28.26	81.90±26.24	0.7456
Aneurysm velocity, cm^3	1202.13±1083.13	1135.18±1076.82	0.1075

Notes: Data are presented as mean ± standard deviation; [a]Statistically significant (P <0.05).

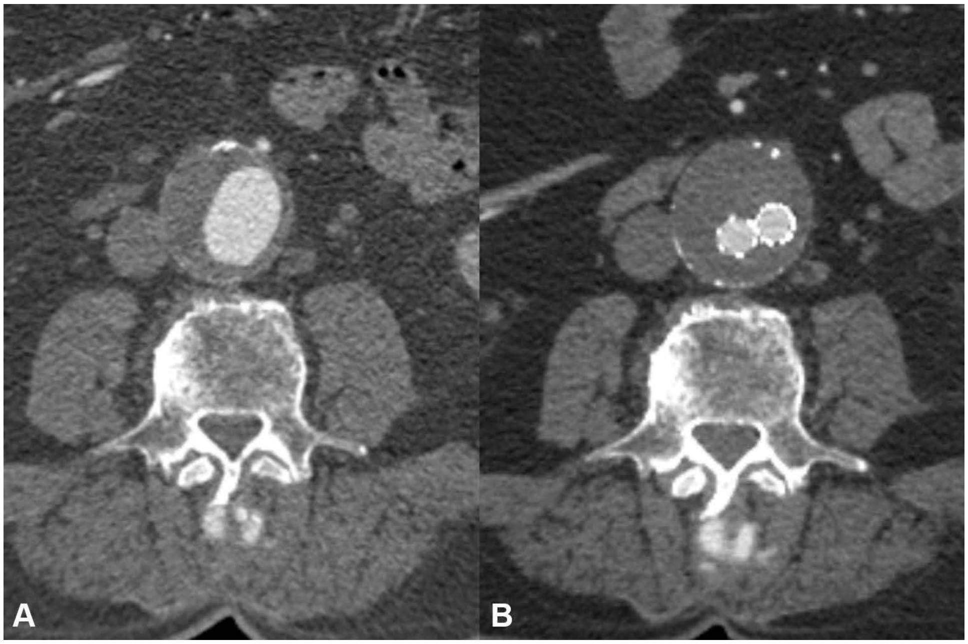

Figure 2 CTA scans showing abdominal aortic aneurysm before treatment (**A**) and after three months (**B**). An aneurysm sac enlargement is visible despite there was no EL.

measurements, we observed a positive correlation between PPI and aneurysm enlargement (the ratio of the cross-sectional area at the widest spot at baseline and at 3 months after EVAR). The correlation is shown in Figure 3.

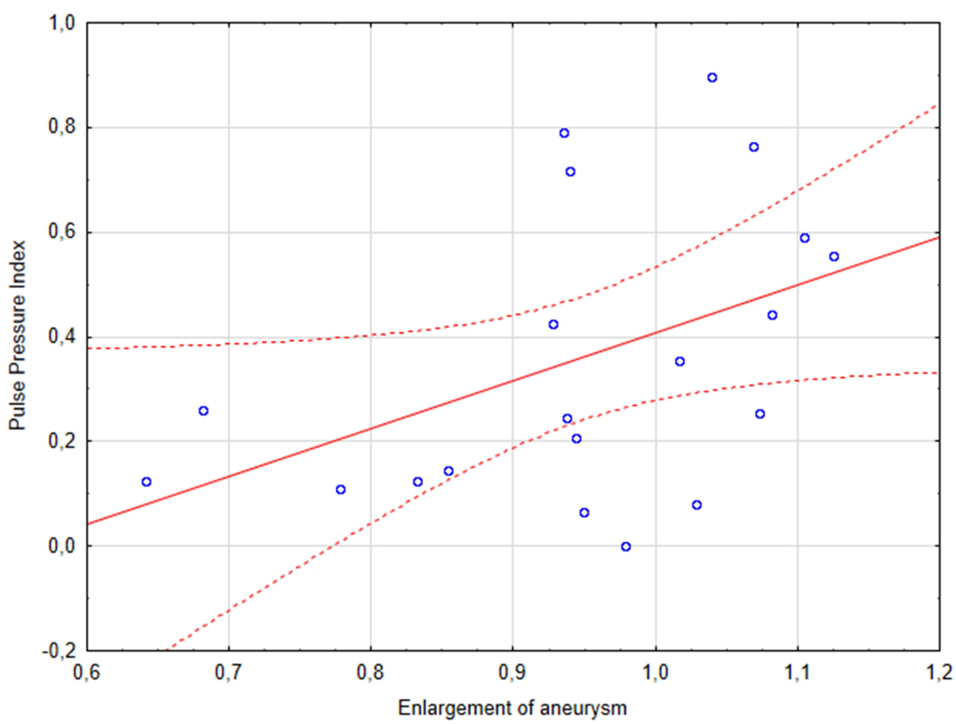

Figure 3 Correlation between pulse pressure index and aneurysm enlargement (ratio of the cross-sectional area at the widest spot at baseline and at 3 months; 1.0 indicates the same size at 3 months). The equation of the slope: PPI = −0.51 + 0.91 *Enlargement of aneurysm. Correlation coefficient 0.44; P<0.05.

Discussion

One of the first studies reporting ASP measurement in 8 patients after EVAR was published in 1997 by Chuter et al.[12] Pressure measurements were performed through a catheter adjacent to the stentgraft implanted in the aneurysm using a simple aorto-uniiliac method. A significant reduction in ASP was noted.

Numerous investigators showed that some patients had elevated ASP despite treatment, even when there was no visible EL. Baum et al measured ASP in 27 patients after EVAR. EL was present in 17 patients; however, of the 10 patients without a visible EL, 4 patients were shown to have equal ASP and AP.[13] This may suggest that type V EL or endotension is associated with aneurysm enlargement and a high risk of rupture. Dias et al assessed ASP in 37 patients after EVAR. They reported a median MPI of 19% in shrinking AAAs, of 30% in unchanged AAAs, and of 59% in expanding aneurysms without EL.[8,9] Therefore, it is clear that ASP is significantly correlated with aneurysm enlargement.

Parsa et al summarized the causes of endotension, including pressure transmission through a thrombus or endograft fabric, the presence of microleak or ultrafiltration, and possible hyperfibrinolysis, infection and anticoagulation. The literature has highlighted that endotension is in fact the type II or III EL below the sensitivity limits of current imaging modalities.[14] Either way, an ASP measurement can detect EL, whatever its cause, so the diagnosis and proper treatment may be initiated.[8,15]

In contrast to investigators who assessed ASP a few months after treatment, we performed perioperative measurements. Thanks to advances in endovascular techniques, pressure measurements can be done with greater precision and with much less invasive tools, typically using thin-pressure wires for fractional flow reserve measurement in coronary arteries. A thin pressure wire was also used by Milnerowicz et al to assess the pressure in the renal arteries after chimney EVAR.[16]

Although our results differed from those reported by Dias et al, we also showed a significant correlation between ASP and aneurysm enlargement. Sonesson et al measured ASP in 10 patients who showed a reduction in the AAA diameter of at least 6 mm within a year after EVAR. They showed a significant drop in pressure, with a complete reduction in pulse pressure (PPI = 0%).[15] In our study, pulse pressure showed the most significant correlation with aneurysm enlargement; therefore, we hypothesize that it could be used to assess the efficacy of EVAR. Furthermore, we believe that the method described herein could facilitate the identification of patients at risk of aneurysm enlargement. Such patients could remain prior monitoring.

We found a significant inverse correlation between aneurysm neck angulation and a reduction in PPI. While most recent studies generally demonstrate angulation as a significant risk of EL, there are some works that describe it as a much more complicated relation.[17,18] Xenos et al performed a parametric study of AAA CTA results. They found that growing neck angulation reduced the peak fluid pressure in the aneurysm sac. This led to a reduced wall shear stress. While the peak von Mises stress initially increased as a result of the angulation, after exceeding 20 degrees a decrease in the peak stress was observed. At the same time, a substantial decrease in the mean von Mises stress was observed too.[19]

Silveira et al proposed a method that involves regular monitoring of ASP. They implanted a wireless sensor into the aneurysm sac during EVAR in a group of 25 patients. They confirmed that this type of measurement is reliable and effective. They also showed that MPI decreases over time along with thrombus maturation.[20] However, long-term results of this study are lacking. In our opinion, such a detector, perhaps integrated in stentgraft construction, would be a valuable and innovative device to collect long-term real-time ASP data after EVAR.

It should be mentioned, that evolution of EVAR took place to improve sealing accuracy. First, stentgrafts were covered with polytetrafluoroethylene (PTFE) or polyester fabric. In the course of further progress, stentgrafts include a second layer of low permeability PTFE to decrease the risk of type IV EL.[14] The next invention was polimer (polyethylene Glycol) coverage. Over time, polymer has been used in two techniques: the first one uses the polymer-filled endobags, the so-called Endovascular Aneurysm Sealing (EVAS) with Nellix stentgraft, while the second uses the O-ring polymer-based proximal neck sealing device, the so-called Ovation stentgraft. However, further studies showed therapeutic failure after Nelix implantation at a surprising and alarming rate of 33.2%. The most common failure mechanism was the stentgraft migration associated with type IA EL and sac expansion. On the other hand, Ovation stentgraft offers a customized sealing of the aneurysm, which remains stable over the years without influencing neck dilatation. The possibility of using polymer characteristics to create a customized sealing of the aneurysm has been a great revolution in EVAR procedures.[21]

Our study has several limitations. First, the study group was relatively small. Second, not all patients completed follow-up and underwent control CTA. Third, ASP was measured only once during EVAR, so long-term data are lacking.

Conclusion

Our study confirmed that ASP can be successfully measured during EVAR and might be used in the assessment of treatment efficacy. In particular, PPI was significantly correlated with subsequent aneurysm enlargement. Therefore, it might serve as a prognostic factor and help identify high-risk patients, who remain prior monitoring.

Abbreviations

AAA, abdominal aorta aneurysm; AP, aortic pressure; ASP, aneurysm sack pressure; CTA, computed tomography angiography; DPI, diastolic pressure index; EL, endoleak; EVAR, endovascular aneurysm repair; IFU, instructions for use; MPI, mean pressure index; PPI, pulse pressure index; SPI, systolic pressure index.

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Disclosure

The authors report no conflicts of interest in this work.

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