Endotension as a Result of Pressure Transmission through the Graft following Endovascular Aneurysm Repair—An In vitro Study

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Background: Endovascular aneurysm repair (EVAR) significantly reduces, but does not abolish aneurysm sac pressure, possibly because of trans-fabric transmission.

Objective: To investigate how blood pressure is transmitted through different types of grafts into the aneurysm sac.

Design: Experimental study, in vitro.

Methods: A latex aneurysm was inserted into an in vitro circulation model. The systemic mean pressure (SPmean) was varied from 50 to 120 mmHg. The grafts used for aneurysm exclusion were: thin wall polyethylene (PE), thick wall polyethylene (PE), and thin wall ePTFE. Mean aneurysm sac pressure (ASPmean) was measured, as was pulse pressure (ASPpulse).

Results: At an SPmean of 70 mmHg, the ASPmean was 34 ± 0.8 mmHg (polyethylene knitted, thick wall), 30 ± 1.0 mmHg (polyethylene woven, thin wall), and 17 ± 0.6 mmHg (thin wall ePTFE). The ASPmean increased with SPmean, the relationship depending on the graft material. Stiffer grafts were associated with lower ASPmean and ASPpulse (p < 0.001).

Conclusions: The relationship between aneurysm sac mean pressure and systemic pressure (SP) depends on the graft material. These data highlight the need for further studies regarding endotension.

Key Words: Endovascular aneurysm repair; In vitro study; Endotension.

Introduction

The aim of abdominal aortic aneurysm (AAA) repair is prevent rupture. Unlike conventional repair and endovascular aneurysm repair (EVAR) the sac can remain pressurised despite the apparent absence of endoleak.¹⁻⁵ Such aetiology of such 'endotension' and its relationship rupture remains ill-defined.⁶,⁷ The present study was designed to investigate whether, and to what extent, pressure is transmitted through different types of grafts into the aneurysm sac.

Methods

An in vitro circulation model containing an adjustable pulsatile pump (Rollerpumpe, Stöckert Instrumente GmbH, Munich, Germany), silicone tubing, different latex fusiform aneurysms (25 cm by 4 cm widest part by 1.8 [neck]), a cuff device to alter peripheral resistance, a wind-kessel, and a collecting system was constructed (Fig. 1).

At the widest part of the aneurysm, a 4 mm in diameter hole (Diamond-Edge Disposable Aortic Punch, Genzyme Cooperation, Fall River; MA, USA) and a 4 mm latex-glued side port connected it to a pressure measurement catheter. The aneurysm model was connected to the silicone tubing system inside a closed chamber of polyvinylchloride.

Pressure measurements were performed via catheters (16 G). The catheter for measuring the systemic pressure (SP) parameters was introduced through a side-port of the tubing proximal to the aneurysm. The systemic and intra-sac pressures were measured simultaneously (Medi-Stim AS, Oslo, Norway). After exclusion of the aneurysm sac, intra-aneurysm sac pressure (ASP) and SP parameters were recorded: systolic pressure (ASPsyst/SPsyst), diastolic pressure (ASPdist/SPdist), and mean pressure (ASPmean/SPmean). The pulse pressure was calculated as the difference between the systolic and the diastolic pressure (ASPpulse/SPpulse). The proportion between
The pressure inside the aneurysm sac and the systemic pressure were expressed as pressure ratio ASP/SP.

The aneurysms were excluded with three different types of grafts: (1) a thin-wall expanded polytetrafluoroethylene (PTFE) tube graft (Gore-Tex, Flagstaff, Ariz., USA), (2) a 16 mm knitted thick-wall polyethylene tube graft (Hemashield; Meadox Medical, Oakland, NJ, USA), (3) a 16 mm woven thin-wall polyethylene tube graft (Cooley very soft; Meadox Medical, Oakland, NJ, USA).

The grafts were glued to disposable tube connectors and fixed in the aneurysmal neck at the proximal and distal ends. In order to avoid leakage through the prosthesis in the absence of a normal clotting mechanism, the prostheses were sealed with a thin layer of latex. Thus, the prostheses were made impervious to the perfusate.

The perfusate consisted of saline solution; other perfusates with plasma-like viscosity were not used, as viscosity does not play a major role in this experimental set-up.

For the flow measurements we used the ultrasound transit time method, which allowed measuring the flow inside the circulation system with a particle-free solution.8,9

Model characteristics

In the system, we varied the mean systemic pressure from 50 to 120 mmHg by changing the peripheral resistance with the cuffs applied around the tubing. Pulse pressure was equilibrated to 40 mmHg. The stroke volume of the pulsatile pump was manipulated to allow flow variation through the aneurysm or graft from 1.0 to 2.5 L/min. The pressure curve was made comparable to that of a middle-sized animal (like dogs) or human being.

The experiments

The experiments were performed in the absence of endoleaks. When disconnected, and when the aneurysm model was lying on the vessel bench, filling the aneurysm sac with perfusate did not result in a decrease of fluid level in the aneurysm side-port. Secondly, when the aneurysm model was connected to the tubing system, there was no increasing fluid level in the aneurysm side-port at a systemic mean pressure (SP\textsubscript{mean}) of 120 mmHg, indicating the absence of endoleaks.

Following these equilibration manoeuvres, each experiment was repeated six times.

At the beginning of each experiment, the mean pressure in the systemic circulation was equilibrated to 50 mmHg with an intact pulsatile circulation.

By increasing the SP\textsubscript{mean} by 10 mmHg steps, circulation was stopped when a mean pressure level of 120 mmHg was reached. At each level, the ASP parameters were recorded following a period of equilibration.

Statistical analysis

Continuous variables are expressed as the mean ± SD. Repeated measurements analysis of variance were used to test the means derived from the pressure measurements. The graphics are shown as box-and-whisker-plots. A P value less than 0.05 was considered statistically significant.

The experiment was conceived, planned, and evaluated by the first author (M.G.) and was performed in the Vascular Experimental Laboratory at the Medical Centre of the University of Cologne under the direction of Dr Brunkwall and Dr Gawenda, who designed the model according to the initial plan. Mr Jaschke and Mr Winter performed the experiments and collected the data, and Dr Gawenda and Dr Wassmer independently analysed the data and made statistical analyses. All five authors reviewed the results and discussed the conclusions.

Results

At a SP\textsubscript{mean} of 70 mmHg, the aneurysm sac mean pressure was 34 ± 0.8 mmHg (polyethylene knitted, thick wall), 30 ± 1.0 mmHg (polyethylene woven, thin wall), and 17 ± 0.6 mmHg (thin wall ePTFE). The aneurysm sac mean pressure increased with inclining systemic pressure (Fig. 2). The pressure transmission through the graft was related to the type of graft.
material, where ePTFE led to a lesser aneurysm sac mean pressure compared with thin wall polyethylene. The highest mean pressure was demonstrated when using knitted thick wall polyethylene ($p < 0.005$) (Fig. 2). The registered pressure ratio changed by increasing $SP_{mean}$ and was correlated to the used graft material (Table 1).

Transmission of pulsatile pressure to the aneurysm sac through the inserted graft was also detectable. In case of a low compliance, as for the ePTFE graft, the pulse pressure inside the aneurysm sac was very low. In contrast, the more compliant grafts resulted in relevant pulsatile sac pressure ($p < 0.05$) (Fig. 3).

### Discussion

EVAR aims at the complete exclusion of the aneurysm sac. Thereby, the systemic aortic blood pressure and the tension should be eliminated from the weakened aneurysm wall. Measuring the aneurysm sac pressure as well as the fate of the aneurysm in patients undergoing EVAR contrasted this theory.

In 1997, Chuter and co-workers published at first, that a relevant aneurysm sac pressure persisted following EVAR. Subsequently placing an aorto-uni-iliac stent graft, made of woven thin wall polyethylene, resulted in a pressure ratio of 0.5 between the excluded aneurysm sac and the systemic circulation.$^{10}$

Interestingly, when a bifurcated stent graft with knitted polyethylene was used including a technically successful aneurysm exclusion without evidence of endoleak, the elevated aneurysm sac pressures were even higher (ratio aneurysm sac mean pressure/$SP_{mean} = 0.75$).$^{11}$

Several sources for the measured pressure within the aneurysm sac could be speculated upon: (1) a pressure transmission through back-bleeding lumbar arteries and/or an open IMA, (2) a pressure transmission through the back-bleeding hypogastric artery in case of aorto-uni-iliac stent graft where one common iliac artery is open, (3) a pressure transmission through the graft material of the implanted stent grafts (‘diaphragm effect’).

The first potential explanation is less likely to contribute to a pulsatile aneurysm sac pressure, while during open aneurysm repair, following aortic and iliac cross clamping, the detectable aneurysm sac mean pressure was $39 \pm 15 \text{mmHg}$ (ratio 0.44) without a relevant pulsatility ($1 \pm 2 \text{mmHg}$). Moreover, the aneurysm sac pressure showed neither a correlation to

### Table 1. Pressure ratio according to systemic mean pressure and used graft material.

<table>
<thead>
<tr>
<th>$SP_{mean}$ (mmHg)*</th>
<th>ePTFE</th>
<th>Polyethylene woven, thin wall</th>
<th>Polyethylene knitted, thick wall</th>
</tr>
</thead>
<tbody>
<tr>
<td>50</td>
<td>0.27</td>
<td>0.37</td>
<td>0.42</td>
</tr>
<tr>
<td>120</td>
<td>0.21</td>
<td>0.46</td>
<td>0.57</td>
</tr>
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*$SP_{mean}$: systemic mean pressure (mmHg).
the collateral perfusion via open IMA nor to the number of perfused lumbar arteries.\textsuperscript{11}

The option of pressure transmission via the collateral flow of the hypogastric artery was disproved by the findings of Treharne and co-workers. They used aorto-uni-iliac stent grafts made of ePTFE, and reported a median aneurysm sac pressure of 53 (50–65) (inter-quartile range) mmHg in case of an open contralateral common iliac artery. Following the occlusion of the contralateral common iliac artery the median aneurysm sac pressure was 55 (51–65) mmHg. Moreover, no pulse pressure was found in the aneurysm sac.\textsuperscript{12}

The present paper for the first time demonstrates, that the levels of aneurysm sac mean pressure, as well as the aneurysm sac pulse pressure, were the results of pressure transmission through the graft material. Using considerably stiffer and less compliant graft types, the recorded levels of aneurysm sac mean pressures were depressed. In addition, the transmission of pulsatile pressure through the graft material was correlated to the different graft materials used. Pulsatility declined in case of increasing stiffness of the graft material used.

Beside these new findings, other investigators reported that the closed chamber of the aneurysm sac following EVAR is not free of pressure.\textsuperscript{2,5,10,12,14–17}

In an experimental set-up with artificial circulation in a model of rubber tubing aneurysm (maximum aneurysm diameter of 70 mm) excluded by knitted polyethylene tube graft, Schurink and co-workers measured an aneurysm sac pressure of 0 mmHg in the absence of endoleak.\textsuperscript{15} This result contrasted to all others, even to our own. In our experimental set up, an aneurysm sac pressure of zero was only found in case of an existing aneurysm side branch without outflow resistance.

Parodi and co-workers who also created a fusiform latex aneurysm model with a maximum transverse diameter of 60 mm, excluded the aneurysm with an expanded PTFE tube graft, resulting in a pressure ratio (aneurysm sac mean/systemic circulation mean pressure) of 0.35 at a SP\textsubscript{mean} of 108.4 ± 20.6 mmHg.\textsuperscript{18}

Several animal models have also been used to evaluate the aneurysm sac pressurization. Sanchez and co-workers created a fusiform arterial aneurysm (3 × 3 cm) by balloon dilatation of an 8 mm PTFE prosthetic graft, sewn in as an interposition graft of the infrarenal aorta of mongrel dogs. They eliminated the aneurysm by placement of a low porosity ePTFE endovascular graft and recorded a mean aneurysm sac pressure (ASP\textsubscript{mean}) of 13 ± 9 mmHg compared to 92 mmHg systemically. The mean pressure after high-porosity tantalum-Dacron coknit endovascular graft (TD-EG) with fenestrations of approximately 1 mm in width and 1.5 mm in length was not significantly lower than the systemic pressures obtained with the forelimb sphygmomanometer. The mean intra-aneurysmal pulse pressure after exclusion with the low-porosity PTFE-EG immediately decreased and stayed stable at a low state, whereas the placement of the high-porosity TD-EG did not significantly decrease the pulse pressure.\textsuperscript{16}

In another experimental set-up by the same group of investigators, an experimental fusiform aneurysm was produced by means of focal balloon dilatation of an 8 mm PTFE graft with a 30 mm modified prostate balloon resulting in a final aneurysm diameter of 23 mm. Following implantation in dogs the aneurysms were excluded by endovascular grafts constructed by means of dilated PTFE grafts and balloon expandable Palmaz stent. Pressure measurement in the aneurysms, excluded by endovascular grafts without endoleak, demonstrated a mean systolic pressure ratio of 0.34 ± 0.16, the mean of the aneurysmal pulse pressure was 12 ± 11 mmHg. Other pressure parameters were not reported.\textsuperscript{3}

In another dog model, using a patch of small intestine to create an aneurysm, uncrimped Dacron grafts (Cooley Very Soft) were sutured to Gianturco Z stents at both ends to exclude the aneurysm, verified by a completion angiography. Following this, the aorta to aneurysm sac pressure differences varied between 15 and 75 mmHg, with a mean pressure difference of 51 mmHg, whereas systemic pressure parameters were not mentioned.\textsuperscript{15}

In a third animal model aneurysms were created by fascial patch angioplasty of the infrarenal aorta. Following insertion of an endovascular polyethylene graft, the systolic pressure was lower in the aneurysm sac (82.9 ± 20.20 [mean ± SD] mmHg) than in the adjacent aorta (113.4 ± 25.9 mmHg; P = 0.002). The effects on diastolic pressure and mean pressure were less pronounced.\textsuperscript{14}

These published results of pressure measurement are very contentious, and a comparison between the in vitro measurements, the animal experimental set-ups and the findings during human EVAR is difficult. Nevertheless, the pressurization of the aneurysm sac following EVAR seems to be a reality, but the clinical relevance is not clear.

Despite the technical correct placement of the stent graft, creating a closed chamber without evidence of EL, several investigators reported an aneurysm enlargement through follow-up.\textsuperscript{11,18,19} The term ‘endotension’ was defined as possible explanation to this phenomenon.\textsuperscript{6,7} At an international conference of 27 selected participants, held to resolve controversies and
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References


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