Intra-aneurysm Sac Pressure – The Holy Grail of Endoluminal Grafting of AAA

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Objectives: to relate intra-aneurysm sac pressure during endoluminal AAA repair to early and late endoleak, as well as to the aneurysm size upon follow-up.

Design: prospective clinical investigation.

Methods and patients: in 46 patients who had their AAAs treated by a stent graft (group I), intra-operative pressure measurement was performed (aorto uni-iliac stent grafts: 25 cases, bifurcated stent grafts: 21 cases). In 18 patients with open repair (group II) flow in the inferior mesenteric artery, and the pressure in the aneurysm sac was measured, before and after aortic and iliac cross clamping. Values are given in median with range.

Results: in group I, complete exclusion of AAA (no endoleak on intra-operative control angiogram) resulted in a statistically significant decrease in mean sac pressure from 74 (55–101) to 47 (4–104) mmHg. Pulse pressure reduced from 67 (34–103) to 8 (0–74) mmHg. In 11 patients a proximal type I endoleak was sealed by balloon modeling, after which the mean sac pressure reduced from 63 (14–91) to 52 (4–74) mmHg (n.s. versus patients with primary seal). Intra-operative pressure did not correlate with change in AAA diameter during twelve months follow-up. In group II, cross clamping of the proximal aorta significantly reduced mean sac pressure to 32 (21–55) mmHg, and the pulse pressure to 0 (0–13) mmHg (p < 0.05). Subsequent cross clamping of the iliac arteries did not significantly change the pressures.

Conclusions: measurement of intra-aneurysm sac pressure can help to detect and treat endoleaks during endoluminal grafting. However, the intra-operative sac pressure did not predict the fate of aneurysm during follow up. Compared to open repair of AAA, the sac pressure after endoluminal grafting remains significantly higher, in relation to pulse pressure.

Key Words: Aneurysm sac pressure; Stent graft; Open surgery.

Introduction

Minimally invasive endovascular repair of the abdominal aortic aneurysm (AAA) is now widely practised.1,2 The primary aim is decompression of the aneurysm sac and reduction in wall tension. The “Achilles’ heel” of the endovascular therapy of AAA is endoleak.3,4

It is hypothesised that some aneurysms grow after placement of stent graft, despite the absence of endoleak, due to endotension.5,6 Importantly, endoleak and endotension can lead to rupture.7–10

The aim of the study was to investigate relationship between intra-operative intra-aneurysm sac pressure measurement and early and late endoleaks. Secondly, we wish to determine if the intra-operative aneurysm sac pressure measurement can predict aneurysm expansion (Study group I). Finally, we wished to compare intra- and post-operative aneurysm sac pressure in patients undergoing conventional and endovascular repair.

Methods and Patients

Endoluminal grafting

The present work represents the analysis of prospectively collected data in two study groups. Between August 1995 and October 2000, 294 patients with AAA were treated. Of these 121 received a stent graft, of which 46 underwent pressure measurement (Study group I). The median age was 75 years (range: 62–85), and the median size of the AAA was 55 mm (range: 42–90 mm). In 25 patients an aorto uni-iliac stent graft was implanted in conjunction with a femoro-femoral bypass and a contra-lateral common iliac artery occlusion. Twenty-one patients received bifurcated stent graft. The implanted aorto uni-iliac stent grafts were ZenithTM (n = 16), VanguardTM (n = 4), and EndologixTM (n = 1).
A straight uncompressible angiographic catheter was positioned with its proximal end above the visceral arteries. After deployment of the stent graft this catheter was connected to a pressure transducer and equilibrated. During withdrawal of the catheter the pressure was consecutively measured in the aorta proximal to the stent graft, within the aneurysm sac and distal to the stent graft (Figs 1a, 1b).

Aneurysm sac pressure was compared with invasive radial artery pressure.

When a proximal or distal localised type I or type III endoleak (i.e. disconnection on modular systems) was detected on angiography, this was corrected by balloon modelling of the respective part of the stent graft, followed by repeated measurement of the aneurysm sac pressure. Complete AAA exclusion was defined as the absence of contrast medium in the aneurysm sac at post-deployment angiography. No patient left the operating theatre with a type I or III endoleak. The final measurement of the aneurysm sac pressure thus was used as reference value for the post-operative course.

During the postoperative follow-up (median: 464, range 34–1292 days) CT scans were carried out at 1, 3, 6 months and then 6 monthly. Special attention was paid to endoleaks and maximum aneurysm diameter, defined as the shortest diameter at the widest portion of the AAA. To reduce intra- and inter-observer variability, measurements were repeated three times, and the mean was used for analysis. An increase or decrease of 3 mm was considered significant.11,12

**Open repair**

Study group II comprised a consecutive series of 18 patients (12 males, 6 females) undergoing elective trans-peritoneal repair of infrarenal AAA between October 2000 and March 2001. These aneurysms were not suitable for endoluminal grafting because of a short proximal neck. The median age in this group was 67 years (range: 47–81 years), and the median aneurysm diameter 65 mm (range: 50–82 mm). After complete preparation of the infrarenal aorta, the origin of the IMA and the iliac vessels, a flow-probe was placed on the IMA. The flow measurements, based on the ultrasound-transit-time method, were performed using the MediStim Flowmeter (MediStim AS; Norway).13,14 To ensure optimal coupling between the ultrasound probe and the vessel, the diameter of the probe was adapted to the vessel diameter. The acoustic coupling was optimised by addition of sterile sodium chloride solution or sterile ultrasound gel between the probe and the vessel.

A catheter was placed through the aneurysm wall into the flowing lumen of the aneurysm to measure

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**Fig. 1.** Position of stent graft and straight angiographic catheter during pressure measurement in the aneurysm sac (IAP) (Study group I – endoluminal grafting). (a) Bifurcated stent graft; (b) aorto uni-iliac stent graft.
sac pressure (Fig. 2). Afterwards a standardised ventral aortotomy was performed and the number of back-bleeding lumbar arteries was counted and registered.

Statistics

The data collection was put into a standardized data mask (FileMaker Pro 5 and MS Excel 2000), statistical evaluation was done by descriptive statistics: median with range (min-max). Comparative statistics were performed for the non-parametric data with the Wilcoxon test within groups or the Mann–Whitney U-test between groups. \( p < 0.05 \) was considered to be significant. Correlations of variables were analysed by the statistical method of Pearson’s factor of correlation. All evaluations were performed using the statistical package SPSS for MS-WINDOWS, release 10.0 (SPSS, Inc., Chicago, Illinois, U.S.A.).

Results

Pressure measurements

Study group I (endoluminal grafting)

Pressure measurements performed during the stent graft placement showed a highly significant reduction of the mean as well as pulse pressure in the aneurysm sac pressure compared to the systemic pressure (Table 1).

There were no significant differences in the radial pressure parameters between the patient groups receiving aorto uni-iliac stent grafts or bifurcated stent grafts. But after deployment of the stent graft there were significantly higher intra-aneurysm sac pressures in the bifurcated group than in the aorto uni-iliac group (mean pressure: 56 (43–104) mmHg versus 31 (4–72) mmHg) (\( p < 0.001 \) (Table 1).

Within the stent graft groups there was a significant drop in all pressure parameters (\( p < 0.001 \), with the exception for the diastolic pressure in the bifurcated group, which was unaffected.

In 11 patients a proximal type I endoleak was verified by intra-operative post-deployment angiography, in seven cases with an aorto uni-iliac and in four cases with a bifurcated stent graft. In these patients an aneurysm sac mean pressure of 63 (14–91) mmHg was measured. After sealing the leakage by balloon modelling of the proximal part of the stent grafts, these endoleaks disappeared in all cases, resulting in an aneurysm sac mean pressure fall to 52 (4–74) mmHg in median (\( p < 0.05 \)). Patients with aorto uni-iliac stent grafts showed a median pressure gradient of 14 mmHg when compared to pre-sealing (\( p < 0.05 \)), whereas in patients with bifurcated stent grafts (\( n = 4 \)) the pressure gradient was numerically smaller (11 mmHg), and not statistically different to the pre-sealing value (Table 2).

Fig. 2. Intra-operative experimental setup (Study group II – open repair).

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The post-sealing pressure parameters were not statistically significant different to those where there was a primarily sealed upper stent.

Study group II (open repair)
After cross clamping of the proximal aorta a highly significant decrease of all pressure parameters in the aneurysm sac were observed. After additional cross clamping of the iliac arteries, the lower pressure parameters compared to the systemic pressure were consistent (Table 3).

The IMA was occluded in nine patients, whereas in the other nine patients there was an orthograde perfusion of the IMA detectable (Table 4), a median flow of 30 ml/min (range: 10–122 ml/min) was registered. After cross clamping of the proximal neck, two patients showed an unchanged orthograde flow, in two cases the flow stopped, and in the remaining five patients a conversion of the flow to a retrograde perfusion of the IMA was observed. These changes in flow direction were altered by additional cross clamping of the iliac arteries in two cases, in one case orthograde perfusion reappeared, and in the second case a retrograde perfusion of the IMA was registered.

There were in median two retrogradely perfused lumbar arteries with a range from 1 to 6 arteries per patient when opening the aneurysm sac. The aneurysm sac pressure measured following complete exclusion of the aneurysm sac by aortic and iliac cross clamping did not correlate to the number of back bleeding lumbar arteries ($r = -0.062$, $p = 0.774$). Furthermore, the aneurysm sac pressure at the time of complete exclusion of the aneurysm sac was not significantly different in case of perfused or occluded IMA ($p > 0.05$).
Alterations of the aneurysm diameter during follow-up

The number of patients followed for more than 12 months was so small, that statistical analysis is performed only up to 12 months. During the first twelve months of follow up, 14 of the 46 study patients (Study group I) (24%) were affected by an endoleak. In two cases with aorto uni-iliac stent grafts a contralateral occluder-associated type I endoleak were found during follow up (3rd and 6th month CT examination), in all other cases they were classified as type II endoleak. The prevalence of postoperative endoleak at the different times of follow up (1, 3, 6, 12 months) lied at 22% (9/41), 16% (7/45), 11% (5/46) and 10% (3/31) respectively.

In cases of no evident endoleak on CT imaging, a significant reduction (p < 0.05) of the pre-interventional median aneurysm diameter (56 [43–90] mm) could be seen by 2.5 (−12 to +11) mm after 3 months, 5.0 (−18.0 to +7) mm after 6 months, and 9 (−18 to +2) mm after 12 months. On the other hand, in the case of endoleak no change in the median aneurysm diameter (55 [42–75] mm) was found (Table 5).

Without endoleak there was a relevant increase (≥3 mm) of the aneurysm diameter in individual patients in 6% (5/91) of the follow up examinations, in 35% (32/91) a stability (−2 to +2 mm) was seen, and in 59% (54/91) a diameter reduction (≥–3 mm) was present.

On the other hand in the presence of an endoleak, a relevant decrease of the maximum aneurysm diameter (≥3 mm) was found in 5 of 18 follow up examinations, no change in 8/18, and in 5/18 a relevant increase of the diameter was observed.

A relevant decrease of the aneurysm diameter in spite of an endoleak was seen in one case with occluder-associated type I endoleak and in four cases with type II endoleak (lumbar arteries).

The development of the aneurysm diameter in the postoperative follow up did not correlate to any of the intra-operatively measured pressure parameters (systolic, diastolic, mean or pulse pressure) (p > 0.05).

Further analysis documented, that there was no difference in aneurysm sac pressure at operation between those patients who subsequently developed type II endoleak and those that did not (mmHg [median with range]: pulse pressure: 10 (0–30) versus 8 (0–74); mean pressure: 50 (19–73) versus 46 (4–104) (p > 0.05).

Discussion

In agreement with previous animal and clinical studies, we found that aneurysm exclusion by means of an aorto uni-iliac stent graft results in a significant reduction in aneurysm sac pressure even though there is collateral flow via the hypogastric arteries.15–19

However, with bifurcated stent grafts the aneurysm sac was discernable, demonstrated a pulse pressure despite the absence of endoleak. Presumably, the pulsatile pressure is transmitted through the stent graft or through invisible collaterals arteries or through thrombus.20–22 The most likely explanation is a pressure transmission through stent-graft-material as there was no pulse-pressure recorded when only the IMA or the lumbal arteries filled the sac in open aneurysm surgery. Furthermore, intra-sac-pulse-pressure was not correlated with either IMA flow or the number of lumbar arteries. The most plausible explanation for the pulse-pressure during endoluminal grafting is the transmission of the pulsatile pressure through the stent grafts. It is noteworthy to mention the period behaviour of the pressure, when the aneurysm sac was a closed chamber constructed either by exclusion through a bifurcated stent-graft or by proximal and distal clamping in open surgery. In both cases, the pressure was higher than when the iliac arteries will open. These results from the open repair group do partly help to explain the higher pressure received in the bifurcated endoluminal graft-group. Presently the numbers are too small to draw meaningful comparisons between the different materials or types of graft used with respect to the sac pressure.

Table 5. Changes in aneurysm diameter during follow up (in mm) (Study group I – endoluminal grafting) (median with range).

<table>
<thead>
<tr>
<th>Endoleak</th>
<th>Aneurysm diameter pre-interventional</th>
<th>Relative changes during follow up at</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td>1 month</td>
</tr>
<tr>
<td>No</td>
<td>56 (43–90)</td>
<td>0 (−4 to +5)</td>
</tr>
<tr>
<td>Yes</td>
<td>55 (42–75)</td>
<td>0 (−3 to +4)</td>
</tr>
</tbody>
</table>

1 p < 0.05.
2 n.s.
3 p = 0.001
4 p < 0.0001; by Wilcoxon test.

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Open aneurysm repair demonstrated a pressure reduction to a level of 30–40 mmHg during aortic and iliac cross clamping and this was not related to open lumbar arteries or IMA flow. Nevertheless, after exclusion of the aneurysm sac, orthograde as well as a retrograde perfusion of the IMA was found. The different flow patterns may be helpful in deciding if pre-operative coiling of the IMA and/or lumbar arteries are needed prior to endoluminal grafting.

In a quarter of the patients treated by endoluminal stent graft, the aneurysm sac is not eliminated from the blood circulation.23–26 There is then a continued risk of expansion and rupture.27–31

However, the fate of individual aneurysms is difficult to predict. In 6% of the follow up investigations, where patients had no proof of an endoleak on CT scan, there was a relevant (>3 mm) increase in diameter of the aneurysm. If a type II endoleak is being sealed by occluding collateral vessels it has been shown, that the aneurysm diameter thereafter decreases in size.27 Additionally, in the present study it was found, that one-quarter of the patients showed a decrease of the maximum aneurysm diameter in spite of an untreated type II endoleak.

Other non-mechanical factors (collagenase, metalloproteases, hygroma), may be equally important.53

The present study showed that the intra-operative measurement of aneurysm sac-pressure parameters did not correlate to the fate of the aneurysms diameter during follow-up. It is unknown what happens with the aneurysms sac-pressure when a lumbar artery closes, although reports exist on the presence of aneurysms sac-pressure before coiling of leaks by sub-selective catheterisation, but there are no reports on aneurysm-sac pressure after coiling.34,35

Until it becomes possible to monitor aneurysms sac-pressure throughout follow-up by non-invasive methods, surveillance of the stents graft repair of AAA including CT-scans or duplex at certain times schedules seem wanted.

In summary intra-operative aneurysm sac pressure did not correlate to the fate of aneurysm diameter during follow-up.

### Table 6. Categories of “endotension”.5,6,23

<table>
<thead>
<tr>
<th>Endotension</th>
<th>Definition</th>
<th>Possible causes</th>
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<tbody>
<tr>
<td>Grade I</td>
<td>High pressure, high flow</td>
<td>Type I (graft-related) endoleak</td>
</tr>
<tr>
<td>Grade II</td>
<td>High pressure, low flow</td>
<td>Type II (side branch) endoleak</td>
</tr>
<tr>
<td>Grade III</td>
<td>High pressure, no flow</td>
<td>Sealed endoleak; pressure transmission through graft</td>
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### References


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