Fixation of Infrarenal Aortic Stent-grafts Using Laparoscopic Banding – An Experimental Study in Pigs

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Purpose: to test whether a laparoscopically-placed external band around the infrarenal aorta could stop vessel dilatation and prevent stent-graft detachment from the aortic wall.

Methods: in 13 growing pigs Gianturco-based stent-grafts were placed in the infrarenal aorta. In eight pigs, an external PTFE band (1 cm width) was placed laparoscopically around the infrarenal aorta. The remaining five pigs served as controls. Angiographic aortic diameters were measured: (1) at the most distal renal artery; (2) 1.5 cm further distally; (3) at the middle of the stent-graft; and (4) below the stent-graft, 1 cm above the aortic bifurcation.

Results: at a median follow-up of 16 weeks the pigs in the control group (n = 5) and in the banded group (n = 7) increased their weight from 24 kg to 107 kg and 23 to 83 kg, respectively. In the control group, aortic dimensions increased by approximately 40% at all levels. In the banded group, aortic dimensions were unchanged at levels 2 and 3, but increased significantly at levels 1 and 4 (i.e. above and below the stent-graft). In the control group all stent-grafts detached causing a proximal perigraft leakage. No detachment or proximal perigraft leak was observed in the banded group.

Conclusion: a laparoscopically placed external band around the infrarenal aorta of growing pigs seems to counteract the vessel dilatation and thereby provides a stable fixation of self-expandable stent-grafts.

Key Words: Stent-grafts; Aneurysm; Laparoscopy; Endoleak; Migration.

Introduction

Endovascular aneurysm repair (EVAR) of abdominal aortic aneurysms (AAA) is a new promising method with encouraging initial results.1–5 However, concerns have been raised about the long-term durability regarding the proximal and distal fixation of the stent-grafts. Dilatation of the infrarenal neck over time might lead to a distal stent-graft migration. If the stent-graft migration exceeds the length of the aneurysm neck then an endoleak may develop with a re-exposure of the AAA to systemic pressure and impending risk of rupture as a consequence. It has previously been shown that a dilatation of the infrarenal neck occurs after EVAR6–8 as well as after open aneurysm repair.9–11 In one report, the frequency of stent-graft migration was reported to be as high as 45% and in half of the patients this was attributed to aortic neck dilatation.12

The purpose of the present study was to test whether an external band placed around the infrarenal aorta could: (1) stop vessel dilatation and (2) prevent stent-graft detachment from the aortic wall and thereby preclude perigraft leakage and/or migration.

Material and Methods

A total number of 13 young (12 weeks old) pigs of both sexes were sedated using ketamine (Ketalar®, Parke-Davies, Morris Plains, NJ, U.S.A.). After anaesthesia induction using Pentothal® (Abbott, North Chicago, Illinois, U.S.A.) the animals were intubated and ventilated by a Siemens-Elema respirator (model 900, Siemens-Elema, Stockholm, Sweden) using a mixture of 30% oxygen and 70% N₂O. Anaesthesia was maintained throughout the experiment with a continuous iv infusion of midozalam (Dormicum®, Roche, Basel, Switzerland) and ketamine (Ketalar®). A continuous infusion of Ringer solution of approximately 1000 ml was given during the experiment. Each pig received a prophylactic single dose of bensylpenicillin procaine (Streptocillin vet®, Boehringer Ingelheim, Agrovet A/S Hellerup, Denmark).
The pigs were divided into two groups: (1) a banded group which received an endovascular stent-graft and a laparoscopically placed external band around the infrarenal aorta (n = 8) and (2) a control group which received an endovascular stent-graft alone, without any placement of an external band (n = 5).

The procedure was started with laparoscopy in the banded group. The pig was placed on its right side. Pneumoperitoneum was induced by insufflation of carbon dioxide through a 10 mm port after a small mini-laparotomy to the left of the umbilicus. Through the port a 30° endoscope (Storz, Tuttingen, Germany) was placed and connected to a monitor. Three additional 5–10 mm ports were placed on the right and left side of the abdomen to allow bowel retraction and disinsection. The infrarenal aorta caudal to the left renal vein was exposed circumferentially for a 20 mm distance using blunt dissection and electrosurgical scissors. The lowest renal artery was identified and marked with titanium clips in order to facilitate identification during stent-graft deployment. A pre-stretched 50 × 10 mm Gore-Tex (W.L. Gore, Flagstaff, Arizona, U.S.A.) band was placed around the aorta for subsequent fixation. Ports were left in place and pneumoperitoneum was relieved. The pig was placed on its back. The laparoscopic procedure took about 1 h.

The right external iliac artery was exposed through an incision in the groin; 7500 IU of heparin (Lövens, Ballerup, Denmark) was given i.v. The vessel was punctured and a 0.35 mm guidewire (Amplatz Stiff, Boston Scientific, Watertown, U.S.A.) was inserted with the tip placed in the descending thoracic aorta under fluoroscopy. A 15 mm longitudinal incision was made in the external iliac artery and a 14F introducer sheath (Cook Europe Inc., Copenhagen, Denmark) was inserted over the wire. An angiography was performed through the introducer for visualisation of the renal arteries and the abdominal aorta. Under fluoroscopic guidance a stent-graft was deployed immediately below the lowest renal artery. A balloon (8 × 40 mm, Cordis, Roden, The Netherlands) dilation was then performed of the stent-graft to ensure an adequate expansion. The position of the graft and an absence of stent-graft-related leak were documented with an angiogram. Self-expandable stent-grafts were constructed from polyester graft, 8 mm in diameter (Cooley Verisoft, Meadox/Boston Scientific Corp, Oakland, NJ, U.S.A.), the crimping of which had been removed by ironing, and then sutured using 6-0 Gore-tex to four self-expandable Gianturco Z-stents (Cook Europe Inc., Copenhagen, Denmark) with a total length of 55 mm. The proximal Gianturco Z-stent had six sets of 10 mm long caudally oriented hooks and cranially oriented barbs to improve proximal fixation.

After deployment of the stent-graft the procedure was continued with a second laparoscopy. The Gore-Tex band was tightened firmly around the aorta using two titanium clips together with two sutures (Ethibond, Ethicon, Johnson & Johnson, U.S.A.). A completion angiography was performed and the diameter of the aorta was measured at four levels: (1) at the most distal renal artery; (2) at the band or 15 mm below the most distal renal artery; (3) at mid-stent-graft; and (4) at 10 mm above the aortic bifurcation, i.e. below the stent-graft. Calibration was made to allow for compensation of the magnification error. Ideally, these measurements should have been performed in a procedure-blinded fashion. However, since the clip on the band was radiologically opaque, it was not possible to do it in this way. The measurements were always done without knowledge of the diameters in the initial angiogram, which is why we think the measurements were robust.

The longitudinal incision in the external iliac artery was closed with a patch (Gore-Tex). The skin wound was closed in a standard fashion. The anaesthesia was terminated and the pigs were taken to the animal ward.

In five pigs (control group) stent-grafts were deployed as already described though without laparoscopic placement of an external band around the aorta. After a median of 16 weeks the pigs were anaesthetised again and the left common femoral artery was exposed. A 12F introducer sheath was inserted and an angiogram of the infrarenal aorta was repeated. In some of the pigs the follow-up angiography was performed through an introducer placed in the suprarenal aorta before the animals were sacrificed and the aortic specimen containing the stent-graft was removed. Diameter measurements of the infrarenal aorta were repeated at the same four levels and in the same way as performed at the initial angiography. The pigs were then euthanased.

All pigs survived the main study. However, a pilot series of five pigs was used to master the technique of inserting large introducer sheaths (14F) required for the stent-graft deployment through the small external iliac artery in the pig. Due to arterial damage resulting in subsequent arterial thrombosis these animals had to be sacrificed after developing severe hind leg ischaemia. Placing the arteriotomy more proximally and closing it using a patch solved this problem. Another animal (banded group) had to be sacrificed due to incidental deployment of the stent-graft across the renal arteries.
Table 1. Weight data in pigs with banded aorta compared to controls. Values are given in medians and interquartile ranges.

<table>
<thead>
<tr>
<th>Follow-up (weeks)</th>
<th>Banded aorta (Stent-graft + external band, n=7)</th>
<th>Controls (Stent-graft without external band, n=5)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight 0 weeks (kg)</td>
<td>23 (21–24)</td>
<td>24 (22–28)</td>
<td>0.291</td>
</tr>
<tr>
<td>Weight 16 weeks (kg)</td>
<td>83 (76–89)</td>
<td>107 (100–114)</td>
<td>0.007</td>
</tr>
</tbody>
</table>

Table 2. Aortic dimensions in pigs with banded aorta compared to controls. Values are given in medians and interquartile ranges.

<table>
<thead>
<tr>
<th>Level 1</th>
<th>Number of pigs</th>
<th>Aortic diameter (mm)</th>
<th>Banded aorta (Stent-graft + external band, n=7)</th>
<th>Controls (Stent-graft without external band, n=5)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 weeks</td>
<td>9 (9–10)</td>
<td>10 (10–10)</td>
<td>0.256</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16 weeks</td>
<td>12 (12–13)</td>
<td>13 (12–14)</td>
<td>0.417</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 2</td>
<td>Number of pigs</td>
<td>Aortic diameter (mm)</td>
<td>Banded aorta (Stent-graft + external band, n=7)</td>
<td>Controls (Stent-graft without external band, n=5)</td>
<td>p-value</td>
</tr>
<tr>
<td>0 weeks</td>
<td>7 (7–8)</td>
<td>8 (8–8)</td>
<td>0.685</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16 weeks</td>
<td>8 (8–8)</td>
<td>11 (11–14)</td>
<td>0.004</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 3</td>
<td>Number of pigs</td>
<td>Aortic diameter (mm)</td>
<td>Banded aorta (Stent-graft + external band, n=7)</td>
<td>Controls (Stent-graft without external band, n=5)</td>
<td>p-value</td>
</tr>
<tr>
<td>0 weeks</td>
<td>8 (8–8)</td>
<td>8 (8–8)</td>
<td>0.685</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16 weeks</td>
<td>8 (8–8)</td>
<td>12 (11–14)</td>
<td>0.004</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 4</td>
<td>Number of pigs</td>
<td>Aortic diameter (mm)</td>
<td>Banded aorta (Stent-graft + external band, n=7)</td>
<td>Controls (Stent-graft without external band, n=5)</td>
<td>p-value</td>
</tr>
<tr>
<td>0 weeks</td>
<td>8 (8–8)</td>
<td>10 (8–10)</td>
<td>0.256</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16 weeks</td>
<td>14 (12–17)</td>
<td>16 (15–16)</td>
<td>0.345</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The study was approved by the Animal Ethics Committee of Lund University and the animals were cared for according to the European Convention for Laboratory Animal Care.

Statistics

The results are expressed as medians and interquartile ranges. Mann–Whitney U-test was used for comparison between groups. Wilcoxon signed rank test was used for paired data.

Results

Twelve of the 13 pigs were available for follow-up (FU). One pig in the banded group was excluded because of suprarenal deployment of the stent-graft. Repeated angiography was performed after a median of 16 weeks. The growth expressed as weight changes of the animals is compiled in Table 1. Aortic dimensions in the banded and control groups at 0 and 16 weeks are compiled in Table 2.

There was no difference between the banded group (n=7) and the controls (n=5) with regard to initial (0 week) aortic diameters at all four measurement levels. At 16 week FU, the animals in the control group had larger aortic diameters at level 2 (+38%, p=0.004) and level 3 (+50%, p=0.004) compared to the animals in the banded group. The aortic dimensions above and below the stent-graft (level 1 and level 4) showed no difference between the two groups (controls and banded). However, there was an increase due to the growth of the animals and their aortas of approximately +30% at level 1 and approximately 60% at level 4.

All the stent-grafts in the control group (n=5) had detached from the aortic wall and there was a perigraft leak seen either along one or both sides of the stent-graft (Figs 1 and 2). One of the stent-grafts had also occluded. Even though all stent-grafts had detached, not one showed distal migration. The mean increase of the aortic dimensions at all four levels of measurement in the control group, including the distance from the renal arteries to the aortic bifurcation, was approximately 40% (level 1 = 30%, level 2 = 38%, level 3 = 50% and level 4 = 60%).

In the banded group (n=7), the aortic dimensions at the stent-graft position, levels 2 and 3, were unchanged during the 16 weeks of FU. No proximal perigraft leak was detected at completion angiography. The stent-grafts showed no signs of distal migration. In one pig the left renal artery had occluded, probably due to an incidental coverage by the stent-graft which was deployed too close to it.

There was no migration of the stent-grafts in the control group either. However, the aortas had become elongated with the growth of these animals, resulting in an increased distance between the renal arteries and the aortic bifurcation. Therefore accurate assessment with regard to a possible minute migration within milimetre precision was difficult.

The removed aortic specimen in the banded group (n=7) showed a macroscopic incorporation of the external band within the aortic wall with quite an extensive fibrosis. The stent-graft appeared also to be firmly attached to the banded segment of the aorta. In the control group (n=5) some of the hooks and barbs of the stent-graft had penetrated the entire aortic wall and there was a slight fibrosis.

Discussion

Growing pigs were selected for the present study in order to provoke a stent-graft detachment from the dilating aortic wall, a phenomenon that may occur also in patients treated with endoluminal stent-grafts.
A large and rapid increase in aortic diameter was desired. From a previous study it is known that the infrarenal aorta measures approximately 8 mm in diameter in pigs weighing 19–25 kg. The self-expandable, Gianturco-stent-based stent-grafts, which we elected to deploy, also had an 8 mm diameter. The lack of oversizing of the stent-graft relative to the aortic diameter was intentional, i.e. to allow for an early detection of any further increase of the aortic diameter. In the beginning the weight of the pigs was equal in both groups. However, at 16 weeks FU the pigs in the control group were significantly heavier.

The laparoscopically placed external band around the infrarenal aorta continued to dilate over time, the environment was equal for all animals and thus could not explain this discrepancy, which may be caused by the experimentally induced stenosis of the aorta in the banded group.

We elected an intraperitoneal approach for placement of the band since the aorta is easy to visualise in pigs using this approach. In man, the alternative retroperitoneal approach may be used instead, as it has already been described and applied on a wide scale for nephrectomies.

Another method for fixation of the stent-graft could have been to suture and/or place clips through the aortic wall. However, this might be difficult to achieve around the full circumference of the aorta. In addition, there are technical problems associated with penetration of the aortic wall in order to reach the stent-grafts.

The laparoscopically placed external band around the infrarenal aorta was shown in the present study to counteract dilatation of the aorta and thereby contributed to a firm fixation of an endoluminal stent-graft. This in turn precluded a proximal perigraft leak. In contrast, when no laparoscopic banding was used the infrarenal aorta continued to dilate over time,
causing stent-graft detachment from the aortic wall with a resulting proximal perigraft leak.

There was a progressive dilatation of the aorta above and below the stent-graft in both the banded and in the control groups. In addition, in the control group there was also a dilatation of the portion of the aorta covered by the stent-graft (Table 2). The overall aortic dilatation during the 16 weeks of progressive growth was approximately 40%. In contrast, the diameters of the aorta along the stent-graft in the banded group remained essentially constant during the growth period. However, there was a substantial dilatation of the part of the aorta between the stent-graft and the aortic bifurcation. Nevertheless, no distal perigraft leak could be detected. Under similar circumstances transmission of systemic blood pressure with or without a visible leak would have been the expected finding in patients. Such a discrepancy may be explained by the fact that these were healthy aortas exposed to stent-grafts, as opposed to the diseased vessel walls in AAA patients treated with tubular stent-grafts.

Another interesting observation was that no migration was seen in spite of the obvious stent-graft detachment in the control group. The stent-grafts were equipped with extra-long hooks and barbs, which probably anchored well through the full thickness of the aortic wall. However, the lack of migration did not prevent the appearance of a perigraft leak taking place through the gap between the dilated aorta and the stent-graft with limited diameter. If the pigs had been observed for a longer period of time, migration most likely would have occurred.

The important question is whether these results are applicable in patients with AAA and, if so, which of these patients would be candidates for external banding of the aneurysm neck. Maybe the additive technique of laparoscopic banding would allow us to treat short and wide necks, especially in surgical high-risk patients, which at present are not considered suitable for EVAR. Further, in patients who already have a stent-graft where follow-up shows a threatening dilatation of the proximal neck could be treated with a laparoscopically placed band.

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Fixation of Infrarenal Aortic Stent-grafts

References


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