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Laparo- and thoracoscopic aortic aneurysm neck optimization and treatment of potential endoleaks type IA and II in a porcine model

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HIGHLIGHTS

- Laparo-/thoracoscopic approaches for treating endoleaks can be simulated in a pig model.
- Laparo-/thoracoscopic approaches to optimize a challenging aortic aneurysm neck can be simulated in a pig model.
- Endoscopic aortic surgery is challenging and a learning curve must be expected.
- A pig model with aortic aneurysm can be used as a realistic surgical learning tool before human application.

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ABSTRACT

Background: Endovascular repair of aortic aneurysms has a higher incidence of late complications, and open conversion (OC) associated with high mortality may be required. As alternatives to OCs, we propose minimal invasive laparo-/thoracoscopic approaches, either to control endoleaks after endovascular repair, or to convert non-endovascular treatable cases due to a hostile neck anatomy by inserting a peri-aortic PTFE collar before endovascular repair. Such interventions may reduce complications and the necessity for OCs in the future.
Methods: In twelve pigs, were 10 had infra-/juxtrarenal AAAs, externally placed collars/aneuwraps around the proximal AAA neck and just below the left subclavian artery and division of the aortic side branches were carried out laparo-and thoracoscopically.
Results: For the laparoscopic and thoracoscopic procedures respectively, mean operative time was 143 ± 41 min and 86 ± 51 min and a mean of 2.6 and 2.25 aortic side branches were ligated/divided. For both procedures, the last half in the series were carried out significantly faster ($p < 0.05$) indicating a learning curve. Blood loss was minimal and no procedure related complications were seen.
Conclusion: Using these minimal invasive endoscopic approaches, it seems feasible to externally band aneurysm necks and ligate aortic side branches in a pig model. These procedures could potentially be considered as alternatives to OCs in controlling endoleaks and in improving the safety of endovascular interventions. As endoscopic aortic surgery is challenging a learning curve is expected. Practicing the described procedures using this model, can be used as a learning tool prior to similar interventions on humans.

1. Introduction

Aortic aneurysms are most often asymptomatic but highly lethal with an overall mortality around 80–90% when rupture occurs [1]. Especially abdominal aortic aneurysms (AAA) is a major health problem as it for the age group between 65 and 80 years has a prevalence of about 5–9% in men and 1.3–2.2% in women [2–4], while the prevalence of thoracic aneurysms is estimated to 10.4–16.3 and 7.1–9.1 per 100.000 in men and woman respectively [5,6].

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Traditionally the treatment was an open surgical repair (OSR). However, since the introduction of endovascular aortic aneurysm repair, for the elective management of thoracic and abdominal aortic aneurysms (TEVAR and EVAR), first described over two decades ago by Volodos et al. and Parodi et al. [7–9], the treatment of choice for these conditions has been revolutionized. Retrospective analysis of U.S. cases found that 84.5% treated for AAAs in the period 2003–2007 underwent an endovascular procedure [10]. Similarly, in 2007 22% with thoracic aneurysms underwent an endovascular procedure [11]. Despite the technological advances during the past 20 years, there are still concerns related to the long-term patency of the stent grafts, due to a higher incidence of late complications requiring reinterventions (especially in cases with type 1 endoleaks) after EVAR when compared to OSR (23.4% vs. 13.1%) [12]. Most reinterventions are endovascular, but in some instances an open conversion (OC) may be required. A review by Kouvelos et al. [13] reported an OC rate of 3.7% from 1991 to 2014 and in 62.4% of the cases endoleaks was found to be the indication (42% of these were type 1 and 26.8% were type 2) and the 30-day mortality was 3.2% and 29.2% for elective and nonelective cases respectively.

A hostile neck anatomy (HNA), i.e. an angulated neck >60° and/or a short/wide neck (<15 mm/> 28 mm) increases the risk of late type 1 endoleaks, and remain the most common reason why patients aren't elected for the procedure, although fenestrated grafts have been introduced [14,15].

In this paper, we wish to present possible minimal invasive laparo-/thoracoscopic approaches, as alternatives to OCs. The procedures include externally placed wraps around the proximal AAA neck and just below the left subclavian artery and division of the aortic sidebranches, that may potentially be used to treat late type 1 and 2 endoleaks after EVAR/TEVAR, and/or create a more favorable and stable neck anatomy in cases with short/wide and/or angulated HNA prior to EVAR/TEVAR and hereby increase the proportion of patients that can be safely treated endovascularly.

We wish to assess the feasibility of such procedures using a customized peri-aortic PTFE collar/Aneuwrap in a reproducible porcine model with AAA disease, and assess as to how far this model is comparable to the clinical setting, and whether it can be used as a learning tool in order to practice the described procedures prior to human application.

2. Materials and methods

Twelve female Danish Landrace pigs (Mean weight = 55.1 kg (Range 17 kg)) were used. 2 pigs (Mean weight = 57.5 (Range 5 kg)) had no previous intervention, while 10 pigs (Mean weight = 50.4 kg (Range 11 kg)) who 28 days earlier by means of elastase infusion and balloon dilatation underwent an infra-/juxtrarenal aortic aneurysm inducing procedure resulting in a mean AAA AP-diameter of 16.26 mm ± 0.93 SD (Range 2.9 mm), equivalent to a 57% mean increase as compared with a weight-matched control group [16]. The lumbar arteries were left intact.

2.1. Anesthesia and positioning

Anesthesia was induced by intramuscular injection (mg/kg BW) of 1.25 mg tiletamine, 1.25 mg zolazepam, 0.25 mg butorphanol, 1.25 mg ketamine and 1.25 mg xylazine. With the pigs in the sedated supine position a transabdominal ultrasound scan of the infrarenal aorta in the systolic state was performed in both the transverse and longitudinal plane to measure the preoperative external AAA AP-diameter.

After intubation using a right-sided Ch. 39 Carlens double-lumen endotracheal tube, with the longer tube placed in the right main bronchus and access to an ear vein had been established, the pigs were positioned in a full right flank position equivalent to a left kidney position at an angle of approximately 95° and mechanically ventilated with oxygen 4 L/min and atm. air (1:1, v/v). Anesthesia was extended by continuous intravenous infusion of 10 mg propofol and 25 μg fentanyl per kg BW/h throughout the operation.

2.2. Laparoscopic procedure

Approximately 6–8 cm lateral to the umbilicus on the left side Veress needle was introduced to establish pneumoperitoneum whereafter the Veress needle was converted to a 12 mm laparoscopic trocar for insertion of a 30° laparoscope. Two additional 12 mm working trocars were placed pararectally in the left hypogastric and epigastric region respectively at a distance of approximately 10 cm to the camera port. If needed a 5 mm assisting port would be placed laterally in the left flank just ventral to the anterior axillary line.

A left retrocolic prerenal transperitoneal approach as described by Coggia et al. [17] to the infrarenal aorta was performed by displacing the viscera by reflecting the left colon and small bowel medially across the midline and opening the retroperitoneum to provide an adequate visualization of the retroperitoneal space.

Using the Harmonic Ace, the aneurysmatic aorta was dissected circumferentially from the moderate to severe surrounding fibrosis from the lowest renal artery to the trifurcation. The infrarenal aortic side branches (Fig. 2A) that could result in potential endoleaks type 2 i.e. the lumbars and the inferior mesenteric artery were ligated with non-absorbable polymeric hem-o-lock clips and divided.

To create a stable and cylindrical proximal 20 mm in length and 12 mm wide aneurysm neck, simulating a suitable landing site neck for EVAR and preventing a type 1A endoleak, an external aortic wrap (Aneuwrap) as described by Kudo et al. [18] was made with slight modifications (Fig. 1). After insertion of the wrap through the 12 mm port it was by the use of laparoscopic graspers from the left side with the PTFE sheet ventrally placed posteriorly to the aorta just inferiorly to the lowest renal artery with the buckle ends to the left. Each of the two straps were maneuvered into their corresponding buckle ends (Fig. 2B–C) and tightened until the entire circumference of the aorta was covered by the PTFE sheet resulting in the desired cylindrical 20 mm long x 12 mm wide aneurysm neck (Fig. 2D).

2.3. Thoracoscopic procedure

With the pigs in the right lateral position a 3 cm incision inferior to the inferior angle of the left scapulae was made, corresponding to the posterior axillary line, and in the 6th or 7th intercostal space the first 12 mm trocar was inserted and a 30° endoscope was initially inserted. After deflation of the left lung by blocking its ventilation another 5 mm trocar was introduced about 3 cm ventral to the anterior axillary line in the 7th or 8th intercostal space where an endoscopic retractor was introduced to hold the deflated lung ventrally exposing the mediastinum and its underlying structures (Fig. 3A). Finally, two 12 mm trocars were introduced in the 9th or 10th intercostal space in the midaxillary line and in the 5th or 6th intercostal space in the anterior axillary line, whereafter the endoscope was placed in the midaxillary port.

The mediastinum was opened and the descending aorta was exposed and dissected circumferentially from the left subclavian artery and about 10–12 cm distally (Fig. 3B). The thoracic aortic side branches that could result in potential endoleaks type 2 i.e. the bronchial, mediastinal, oesophageal branches and the posterior intercostals were coagulated or ligated with non-absorbable polymeric hem-o-lock clips and divided (Fig. 3E).

In order to simulate the creation of a suitable and stable

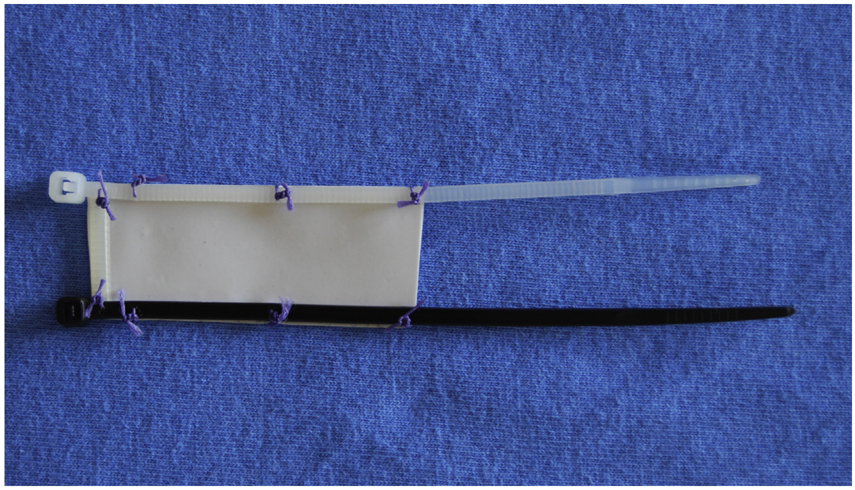

Fig. 1. The modified aneuwrap. Two nylon cable-tie straps (100 mm × 2.5 mm) one black and one clear in order to facilitate later identification of corresponding ends were sewn to a 20 mm × 38 mm wide cut-up sheet of polytetrafluoroethylene (PTFE) vascular prosthetic bypass material. The length of the PTFE sheet was calculated using the equation: Length = Desired neck diameter x π. At the buckle end a 15 mm × 2.5 mm nylon strap was placed connecting the two strips hindering twisting of the strips and securing the Aneuwrap's 20 mm length when placed around the aneurysm neck.

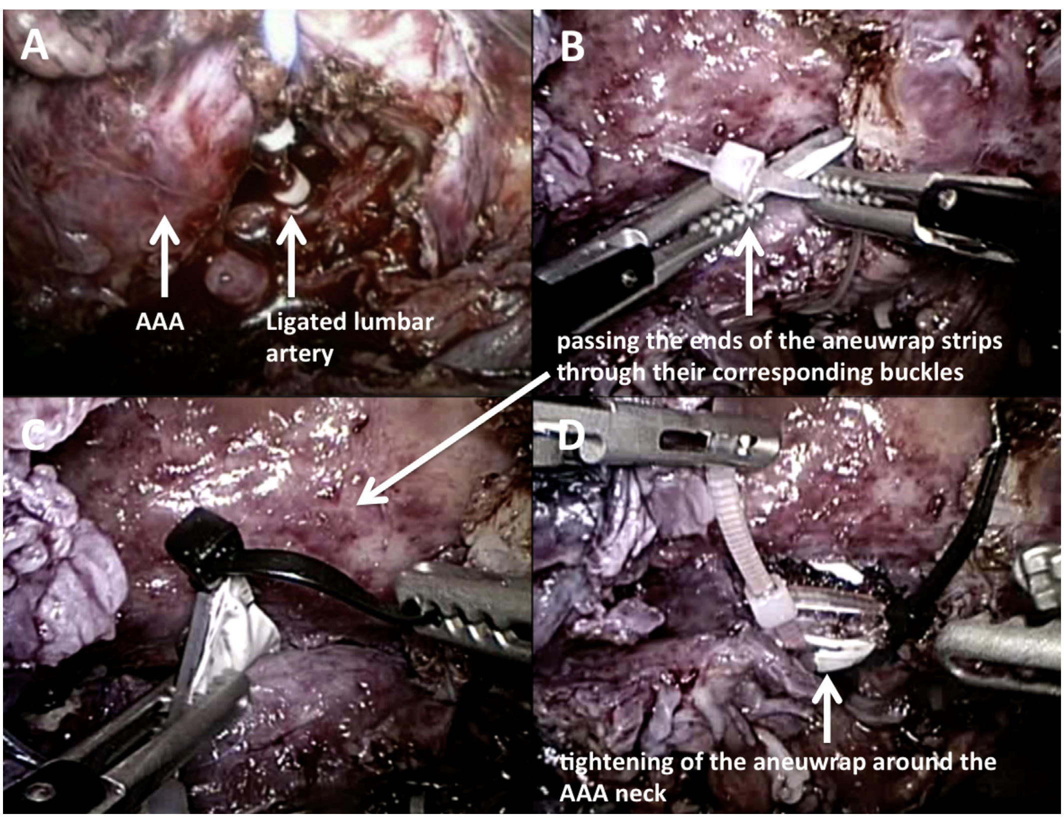

Fig. 2. Abdominal procedure. A. Surgical exposure and isolation from the surrounding fibrosis of the aneurysm and ligation/division of its lumbars. B–D. Locking and tightening of the aneuwrap around the AAA neck.

cylindrical 20 mm long x 12 mm wide landing site neck for TEVAR preventing a type 1A endoleak, a modified Aneuwrap as described above was introduced. The wrap was with the use of graspers placed posteriorly to the aorta just inferiorly to the LSA with the buckle ends to the right whereafter it was locked and tightened around the aorta (Fig. 3C–D,F and Video 1). After a few minutes of observation, the pigs were euthanized with a lethal overdose of intravenous phenobarbital.

Supplementary data related to this article can be found online at http://dx.doi.org/10.1016/j.amsu.2015.11.002.

2.4. Statistical methods

To statistically evaluate whether a learning curve is achieved, i.e. whether the last half of the operations were performed faster than the first half, the Student's t-test was used to evaluate the difference in mean operative time between these two groups for both the laparoscopic and thoracoscopic procedures. Supplemental

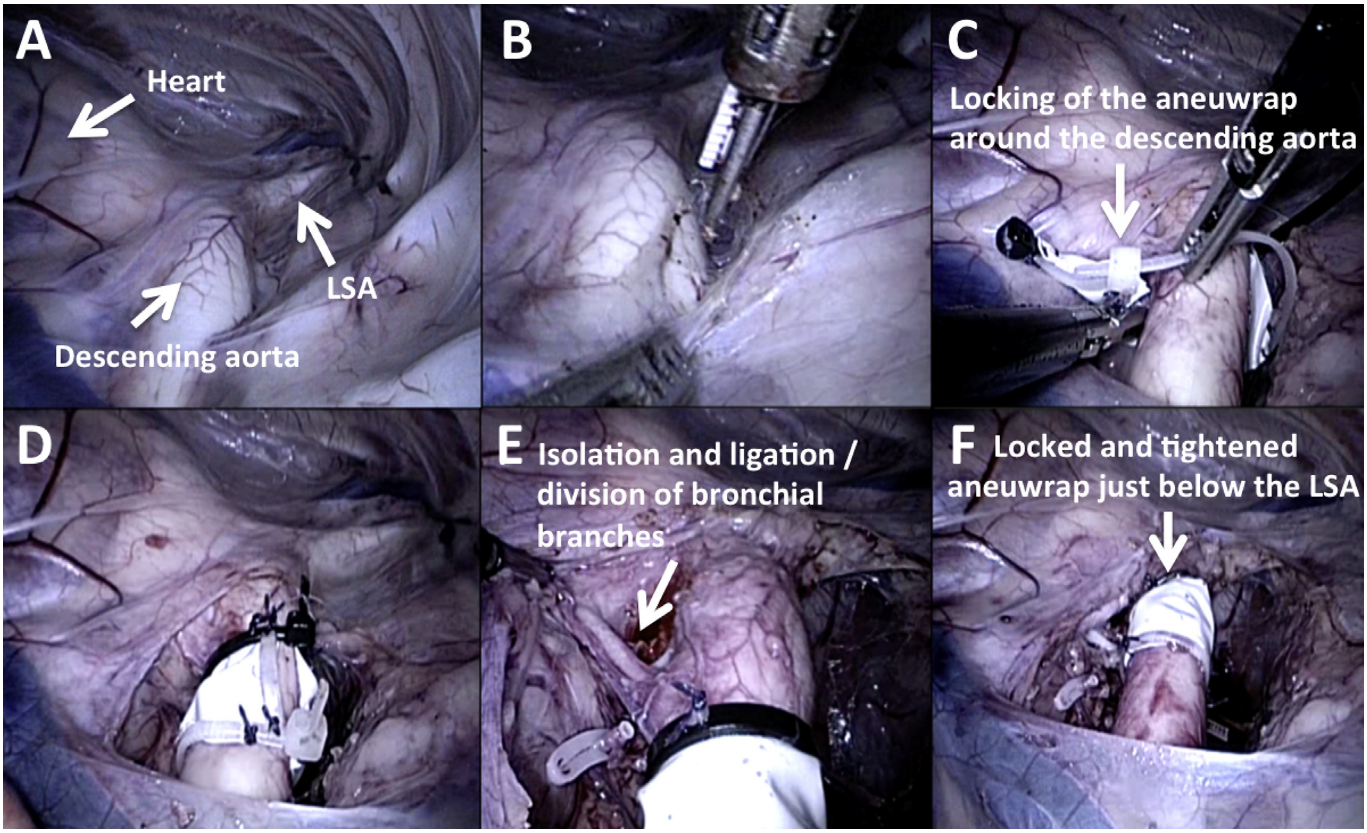

Fig. 3. Thoracic procedure. A–B. Exposure and dissection the mediastinum and its underlying structures. C–D. Locking of the aneuwrap around the thoracic aorta. E. Ligation/diversion of the side branches. F. Locked and tightened wrap just below the LSA.

Spearman's correlation analyses between case number, abdominal operation time, blood loss in abdomen, and thoracic operation time were performed. Results were presented as means ± SD and with 95% confidence intervals two-tailed P-values <0.05 were considered significant. The analyses were carried out using STATA® ver. 13.1 (StataCorp College Station, TX, USA).

3. Results

All 24 (i.e. 12 times 2) operations were completed successfully. Initially the two pigs without any previous abdominal interventions and thus a surgically favorable anatomy underwent the procedures and hereafter the 10 pigs with AAA disease.

Laparoscopic interventions: Overall mean operative time was 143 ± 41 min with a standard deviation of 28.7 SD. Operation 1–2 took 154 ± 31 min (±43.8 SD). Operation 3–7 took 164 ± 12.5 min (±11.2 SD) and 8–12 took 118 ± 21 min (±16.9 SD). When looking at the procedures carried out on animals with AAA disease, the final mean operative time (operation 8–12) was significantly faster than the first (operation 3–7) with $p = 0.001$, and a strong negative correlation between case number and operation time was noticed ($rho = -0.76$, $p = 0.004$) (Fig. 4). The Aneuwrap was successfully placed and tightened around the aneurysm neck just below the renal arteries. We also identified and ligated all the aortic side branches that were encountered. We identified a mean of 2.6 (Range 2–4) lumbars along the aneurysm. No major intraoperative complications were seen. In pig number 7 a large retroperitoneal abscess was encountered adjacent to the proximal part of the aorta resulting in distorted anatomy and consequently complicated surgery and an additional bleeding of 450 ml. Despite this, the mean blood loss was only around 75 ml (Range 10–450 ml), and a strong negative correlation between case number and blood loss was noticed ($rho = -0.66$, $p = 0.021$).

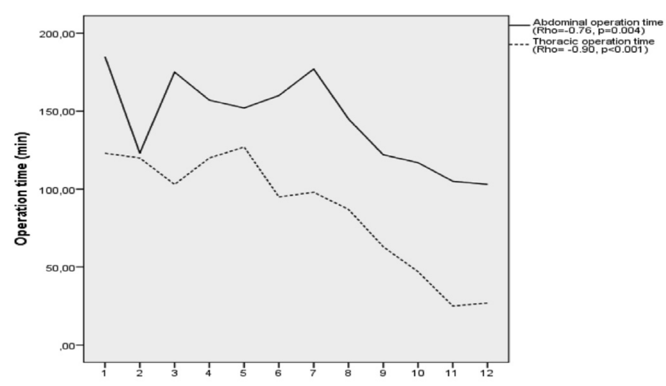

Fig. 4. Graphic illustration of the association between case number and operation time in abdomen and thorax (Learning curves).

Thoracoscopic interventions: Overall mean operative time was 86 ± 51 min with a standard deviation of 37.1 SD. Operation 1–6 took 115 ± 16 min (±12.7 SD). Operation 7–12 took 58 ± 36 min (±30.5 SD), $p = 0.002$. Consequently, operation 7–12 were carried out significantly faster than operation 1–6. In addition, an even stronger negative correlation between case number and operation time was noticed compared to the abdominal surgical time ($rho = -0.90$, $p < 0.001$) (Fig. 4).

The Aneuwrap was successfully placed and tightened around the aorta just below the left subclavian artery. A mean of 2.25

(Range 1–3) thoracic aortic side branches were identified and ligated. One pig died in relation to anesthesiological issues after the intentional deflation of the left lung due to respiratory problems and cardiac arrest and therefore not found to be directly procedure related. Therefore, an additional pig was operated to attain the 12 pigs in the series. Besides this no major intraoperative complications were seen during the thoracoscopic procedures. Blood loss was a modest 50 ml or less (Mean 10 ml) during all procedures. A summary of the results can be found in Table 1.

4. Discussion

The intended procedure of treating potential endoleaks type 1A and/or convert an unfavorable aneurysmal neck to a suitable landing zone by means of aortic banding, and ligate spinal- and lumbar arteries imitating persistent type 2 endoleaks, was feasible in all cases with no direct procedure related complications. The duration of the procedures rapidly and significantly decreased from 2.5 h to less than 2 h for the laparoscopic part and from around 2 h to just under half an hour for the thoracoscopic part, indicating a learning curve.

It has been found, that after a 2 year follow up the mean area size of the aneurysmal neck, despite initial successful EVAR treatment without any type I endoleakage, increases up to 0.68–0.77 cm^2/year faster than after conventional open surgery, which especially is seen after the deployment of self-expanding endografts [19]. Therefore, is seems natural to try to reinforce the outside, and in fact the concept of aortic banding has been described earlier and has been found feasible in previous non-aneurysmal animal studies, small clinical series and case reports [18,20–23]. We perform the interventions on our previously described reproducible porcine model with continuous expanding infra-/juxtrarenal AAAs, and due to the actual aneurysm and its surrounding fibrosis (which could simulate the conditions encountered around inflammatory aneurysms) we believe, that this model simulates a more challenging and realistic clinical setting with clinical potentials. It would of course have been desirable, if the model also had a thoracic aneurysm, but so far we haven't been able to successfully induce these. Nevertheless, we think the described thoracoscopic technique would largely have been the same, but of course more surgically challenging.

As this banding, in addition to simulate the treatment of notionally type 1 endoleaks after EVAR/TEVAR, has the potential to convert non-endovascular treatable cases due to a HNA, it may increase the proportion of patients that can be safely treated endovascularly and reduce the necessity for the use of fenestrated endografts or "chimney" techniques in such cases. Besides being expensive suprarenal fenestrated grafting is also encumbered with risks of losing patency and major postoperative complications (reported in up to 20% of cases), which may be associated with severe consequences such as endoleaks, loss of kidney and fatal acute intestinal ischemia due to occlusion of the renal, celiac and superior mesenteric arteries or cardiac-/cerebral stroke [24–27]. External banding of the distal aorta or common/external iliac arteries to treat type 1B endoleaks or create a distal landing site are other potential options, as are ligation of the internal iliac arteries to treat isolated internal iliac aneurysms. Another potential banding site would be just above the coeliac trunk to create a distal landing zone before TEVAR. In addition, the thoracic wrapping could be used to prevent retrograde dissections in acute type B dissections by strengthening the adventitia and possibly securing the dissection flap.

As in the early era of endovascular interventions, where the endografts were individually fabricated by the physician on site, the external wraps used on patients and in animal experiments so far, have all been made in a similar fashion. Although external banding appears favorable, wraps that offer such solutions are not yet commercially available. Reasons for this could be, that the market seems small and that long term results are missing, although one study with eight patients found patent wraps with no signs of type 1 endoleaks after a mean follow-up time of 38 months [23]. However, one animal study found small patches of medial necrosis in the aortic wall after wrapping [18], and such safety issues may be investigated further before such wraps can become commercially available.

Due to the relative moderate total number of patients seen annually in each vascular center with conditions that could benefit from the surgery, the described interventions may not become an everyday routine procedure in all centers. But as the total number of EVARs/TEVASs and thus the number of OCs is expected to rise, and a learning curve in performing these minimally invasive approaches and later maintenance of this routine is needed, before human interventions can be done safely [28], we believe that selected centers, with both endovascular and laparo-/thoracoscopic expertise, could benefit from our model, and use it as a learning tool in order to practice the surgical procedures prior to similar interventions on humans and hereby reduce the complication rate and the need for OCs in the future.

Table 1
Schematic representation of the laparoscopic and thoracoscopic interventions.

Operation nr.	1	2	3	4	5	6	7	8	9	10	11	12
						Laparoscopic procedure						
AP-AAA/mm.			17	16.8	18.3	15.4	15.6	15.4	15.5	15.8	16.5	16.3
Lumbars	2	3	2	3	2	2	3	2	4	3	2	3
Blood loss/ml.	80	60	30	60	40	50	450	20	40	10	30	20
OP-time/min.	185	123	175	157	152	160	177	145	122	117	105	103
Mean						143 ± 41						
OP-time/min.	154 ± 31				164 ± 12.5					118.4 ± 21		
						Thoracoscopic procedure						
Side branches	2	2	3	2	3	3	2	2	2	1	2	3
Blood loss/ml.	30	50	10	0	0	10	0	20	0	0	0	0
OP-time/min.	123	120	103	120	127	95	98	87	63	47	25	27
Mean						86 ± 51						
OP-time/min.			115 ± 16						58 ± 36			

Animal models have a high degree of face validity that can significantly improve the technical proficiency of both open and laparoscopic/thoracoscopic dissection. However, firstly, for various reasons like cost, ethics, logistics and animal legislations etc. the use of anaesthetized animals for surgical training is not possible in all countries and secondly, in many countries the use of laparoscopy isn't an integrated treatment modality for the vascular surgeon and therefore, he/her does not receive any training in these techniques. In such situations, it might be ideal to ally with, for example, urologists who have more routine in performing laparoscopic or even robotic-assisted endoscopic surgery in the retroperitoneal space. However, we still believe this model also could be considered as a learning tool intended for vascular trainees in practicing open repair of AAAs.

In order to make the described interventions even more minimal invasive and favorable, the possibilities of a minimally invasive retroperitoneal approach could be explored, but nevertheless, we think the described transperitoneal approach still has major advantages over OCs.

Ethical approval

The procedure was conducted under local project license J.nr.2010/561-1844 in conformity with the Danish legislations regarding animal welfare and experimental surgery. Before and during the operative procedures, the pigs were housed at the DCA – Danish Centre for Food and Agriculture, Aarhus University Foulum.

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Author contribution

Brian O. Kloster: Study design, data collection, data analysis, and writing. Jes S. lindholt: Study design, data analysis and writing. Lars Lund: Study design, data collection and writing.

Conflict of interest

The authors declare no conflicts of interest.

Guarantor

Brian O. Kloster.

Consent

Because this study is preformed on animals there is no need/possibility for a written and signed consent.

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