Endovascular aortic aneurysm repair

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Summary and conclusions

Summary

Endovascular aortic aneurysm repair (EVAR) offers a minimally invasive alternative to traditional open aneurysm repair. Compared to conventional open repair, EVAR has the advantage of a less extensive operative exposure by circumventing transcavitary incision. Moreover, EVAR reduces tissue ischemia due to little interruption of flow and the possible use of regional and local anesthetics. EVAR is ideally suited for the higher-risk patient with poor cardiac, pulmonary, or renal performance and for those with prior aortic operations. However, this relatively new technique is not applicable in all patients with aortic aneurysms and it is associated with complications not seen in open repair. This thesis focuses on alternative strategies for EVAR. The aim is to provide new techniques to widen the indication of EVAR and to treat and prevent complications that are associated with EVAR.

Commercially available endografts all require sufficient proximal en distal aneurysm neck length for secure fixation and aneurysm exclusion. Patients with complex aortic aneurysms, like those extending to the pararenal aorta, are therefore not candidates for standard EVAR. Conventional open surgical repair of these complex aneurysms is a real challenge due to the location of this part of the aorta high in the retroperitoneum and just below the diaphragm. It involves wide aortic exposure and interruption of blood flow to abdominal organs that have little tolerance for ischemia. These factors contribute to the appeal of a less invasive approach. In an effort to overcome these problems fenestrated and branched endografts have been designed. These endografts allow for aneurysm exclusion while incorporating one or several essential aortic branch vessels into the seal of the graft. The blood flow to the branch vessels is preserved through holes (fenestrations) or by branches incorporated in the fabric of the endograft.

The first two chapters describe a branched endograft system that has been developed for the treatment of short or no-neck aortic aneurysms. The device is a modular system containing a main endograft and separate branch grafts. After creation of fenestrations into the proximal part of the main endograft, it is mounted on a modified delivery system. This system is equipped with a partial deployment feature to allow optimal maneuverability and ensuring longitudinal and rotational maneuverability for proper alignment of the fenestrations with the vessel ostia. The separate branch grafts are composed of a balloon-expandable stent that is covered with an extended tube of expanded polytetrafluoroethylene (ePTFE) over which is molded a silicone flange. The silicone flanges are designed to easily slide into the

fenestration and the target vessel, lock into place, and create a fluid-tight seal with the main endograft.

In **Chapter 2**, the feasibility of the branched endograft system is tested. In a porcine model (n=4) supra- and juxtarenal aortic aneurysms were created by suturing a saccular Dacron patch into an anterior aortotomy. Angiography was performed to determine the exact location of the renal arteries. Accordingly, an appropriately sized aortic endograft was customized with fenestrations to match the ostia of the renal arteries. Following partial deployment of the aortic graft, separate branch grafts were placed in the renal arteries followed by full deployment of the main endograft. In all trials post-procedure angiography revealed aneurysms exclusion without signs of endoleak and with patent renal arteries. At autopsy, the main endograft and all side branches proved to be adequately placed with intact connections between main endograft and branch-grafts. The procedure was performed within reasonable operating time, blood loss and amount of contrast agent used. Concluding, in this animal model, endovascular repair of complex aneurysms using a modular branched endograft system is feasible in a reliable, predictable and limited time consuming fashion.

Chapter 3 describes the deliverability, deployment, and acute performance results of the branched endograft system in a human cadaver circulation model (n=6). A circulation model was created in 6 non-aneurysmal human cadavers to evaluate the deliverability, deployment, and acute performance of a modular branched endograft system for treatment of aortic aneurysms containing essential branch vessels. Two fenestrations were created in an appropriately sized aortic main endograft. Under fluoroscopic guidance, the main endograft was advanced to the target site and the fenestrations were aligned with the ostia of the renal arteries. Branch grafts were placed through the fenestrations into the renal arteries. The outcome was evaluated by post implant angiography and autopsy. Eleven branch grafts were deployed at the target site. All targeted renal arteries showed good patency. At autopsy, all main endografts were adequately deployed, and 10 of 11 branch grafts were locked in place. In this model, deliverability and deployment of the modular branch graft system is feasible in a reliable, predictable, and timely fashion.
Delivery of fenestrated and branched endografts to the aortic arch routinely utilizes the femoral arteries for access. However, the distance between the access point and the target site makes it difficult to maneuver the usually large-caliber delivery sheaths, especially in patients with tortuous, calcified, stenotic iliac arteries.

To overcome these problems in **Chapter 4** the feasibility of a direct videoscopic approach to the descending thoracic aorta for endograft delivery to the aortic arch is examined. In a porcine model (n=3) via a left-sided thoracoscopic approach a double purse-string suture was placed on the aorta of 3 pigs via a thoracoscopic approach. Subsequently, the aorta was cannulated in the center of the purse-string. A 22-F delivery catheter was advanced under fluoroscopic control over a guidewire via a trocar into the proximal aorta. After deployment of a tubular endograft, the catheter was withdrawn from the aorta while simultaneously tightening the purse-string suture, without aortic cross clamping. The outcome was evaluated by post implant angiography and autopsy results.
The procedure was successfully completed in all animals. Hemostasis was obtained in all animals after withdrawal of the delivery catheter and tightening the purse-string suture. Autopsy proved all purse-string sutures to be adequately placed and all endografts deployed in the correct position. In conclusion, a direct videoscopic approach to the descending thoracic aorta proved a feasible technique for endograft delivery to the aortic arch in a porcine model.
EVAR has complications not seen with open repair. The most frequent is the occurrence of an endoleak, i.e., persistent blood flow outside the endograft and within the aneurysm sac. A type I endoleak is defined as a sealing failure at one of the attachment sites of the graft to the vessel wall. Currently available endografts rely on radial force, appendages such as hooks and barbs, and suprarenal bare stent deployment for improved fixation. Failure in proximal fixation may result in a type I endoleak, which is associated with increased risk for aneurysm growth and later rupture. Fenestrated and branched endografts might have a role in improving proximal fixation. Because they can be deployed further into the non-aneurysmal section of the aorta without impairing blood flow to the renal and visceral arteries, larger surface contact between the graft and aortic wall is created.

Chapter 5 describes an in vitro study that investigates proximal fixation of a fenestrated and a modular branched endograft, in comparison with an infrarenal endograft with suprarenal bare stent fixation and a conventional hand-sewn anastomosis.
In this study human aortas were obtained at autopsy and transsected 20 mm below the renal arteries to mimic an infrarenal aneurysm neck. In random order, the infrarenal (A); fenestrated (B) and branched (C) endografts were deployed in the aorta similar to clinical practice. Using a hydraulic material-testing machine, longitudinal traction was applied to the distal end of each endograft until migration occurred, thus defining the displacement force (DF). Subsequently a hand-sewn infrarenal anastomosis was tested in a similar manner. The median DF for A was

4.67 N (3.82-6.37), the DF increased to 9.17 N (8.03- 10.81, p=0.0005) for B, and 16.95 N (14.78-19.67, p=0.0005) for C. A median force of 89.16 N (83.40-105.23) applied to the conventional anastomosis resulted in tearing of the aorta along the suture line.
Fenestrated stent-grafts, especially with additional branch-grafts provide improved proximal fixation compared to an infrarenal endograft with suprarenal bare stent fixation. However, none of the tested endografts approached the optimal time proven fixation, the hand-sewn anastomosis. In future, branched endografts might enlarge the pool of anatomically feasible aneurysms suitable for EVAR and also improve long-term success of EVAR in infrarenal aneurysms currently treated with standard endografts in terms of migration.

The most prevalent endoleak is a type II endoleak, which is the result of retrograde filling of the aneurysm sac through small aortic branches, such as the lumbar arteries and the inferior mesenteric artery (IMA). The occurrence of type II endoleak after EVAR remains a vexing dilemma. Interventionalists debate their significance, as some have been associated with AAA stability or even shrinkage, while others resolve spontaneously. Traditional believe is that further intervention is required when an increase in aneurysm size is diagnosed, or when type II endoleaks remain persistent more than 6 months during follow-up. Several endovascular techniques have been developed to treat these endoleaks. When these techniques fail conversion to open repair may be the last option. Endoscopic surgery may offer the same advantages as endoscopic general surgery in terms of patient recovery, postoperative pain, and length of hospital stay. Therefore, endoscopic type II endoleak repair seems an attractive treatment option.

Chapter 6 presents the results of a retrospective review of patients that underwent endoscopic type II endoleak repair (EER) following EVAR. Between July 1999 and October 2007, 8 consecutive patients with persistent type II endoleaks were admitted or referred to our institution for EER. Procedures were performed by an experienced vascular surgeon and an experienced endoscopic surgeon. During endoscopy branch arteries, were either clipped or ligation was performed. All patients underwent computed tomography-angiography (CTA) on the first post-operative day. Standard follow-up with CTA, magnetic resonance angiography (MRA) and/or duplex ultrasound imaging was carried out at 6 and 12 months and then yearly thereafter.
Mean operative time was 190 (104-355) minutes. One patient died per-operatively, due to a massive venous bleeding. One procedure was redone due to a missed pair of lumbar arteries. Mean hospital stay was 5 days (2-10). During mean follow-

up, 50 (29-91) months, one patient required additional coil embolization for a persistent type II endoleak. Furthermore, four patients were diagnosed with a type I and one with a type III endoleak. Three of these patients required an additional procedure. In conclusion, in this small series, endoscopic type II endoleak repair proves a technically challenging procedure, even when performed by two experienced (laparoscopic) surgeons. With one operative death, two missed type II endoleaks and five patients requiring additional procedures, we conclude that EER was not beneficial.

Chapter 7 describes a systematic review and meta-analysis for fenestrated endovascular aortic aneurysm repair (F-EVAR) for pararenal AAA. Nine studies were included reporting on 629 patients with a total of 1622 target vessels incorporated in endograft design. Between-study heterogeneity was ≤41% for all outcomes (I^2 value). The pooled estimate for technical success (defined as successfully completed procedure with endograft patency, preservation of target vessels and no evidence of type I or III endoleak at post-procedural imaging) was 90.4% (95% confidence interval (CI): 87.7 to 92.5%), The pooled estimate for 30-day mortality was 2.1% (95% CI: 1.2 to 3.7%) and for all-cause mortality 16% (95% CI: 12.5 to 20.4%). Follow-up ranged between 15 and 25 months. The pooled estimate for branch vessel patency during follow-up was 93.2% (95% CI: 90.4 to 95.3%), for renal impairment 22.2% (95% CI: 16 to 30.1%), for new onset dialysis 2.8% (95% CI: 1.7 to 4.6%) and for secondary interventions 17.8% (95% CI: 13.5 to 22.6%).
In conclusion, promising immediate- and mid-term results (up to 2 years) support F-EVAR as a feasible, safe and effective treatment in a relatively high-risk cohort of patients with pararenal aneurysms.

Overall conclusions

1. Endovascular repair of complex aortic aneurysms using a modular branched endograft system is feasible in a reliable, predictable and limited time consuming fashion.
2. A direct videoscopic approach to the descending thoracic aorta proved a feasible technique for endograft delivery to the aortic arch in a porcine model.
3. Fenestrated endografts, especially with additional branch grafts provide improved proximal fixation.
4. Endoscopic type II endoleak repair following EVAR is technically challenging procedure that proved not beneficial.

5. The acute and mid-term results show F-EVAR to be feasible, safe and effective treatment of pararenal aneurysms in a relatively high-risk cohort of patients with pararenal aneurysms.

In this thesis, several new techniques have been examined that may widen the indication for EVAR and prevent or treat complications associated with EVAR. Although some of these techniques have already proven their worth in patient series, ideally, clinical trials need to be performed to properly evaluate the potential advantages over traditional surgical techniques. More than the conclusion of a completed investigation, this thesis is a step towards further research to achieve our goal: to broaden the indication for EVAR to allow more patients to benefit from the minimal invasive advantages of this relatively new technique.