Complex aortic aneurysm management: from technical outcomes to patient-centered insights

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SUMMARY

Introduction

An aortic aneurysm is a dilation of the body's greatest artery to at least 1.5 times its usual size. The aorta has multiple side branches to vital organs, such as the kidneys. An aneurysm can arise in each part of the aorta. When it includes or is located close to side vessels, it is called a *complex* aneurysm. Aneurysms are asymptomatic and therefore usually go unnoticed until (imminent) rupture occurs. Aortic aneurysm rupture is highly lethal, with the risk of rupture increasing as the aneurysm enlarges. Once the risk of rupture exceeds the risks of surgery, a treatment decision has to be made. Treatment is usually recommended once a complex aneurysm reaches a diameter of 6 cm.

Previously, open surgical repair (OSR) was the only available treatment option for complex aortic aneurysms. During OSR, the aneurysm is reached by opening the abdomen or retroperitoneal cavity. The 'diseased' part of the aorta is replaced by a graft. The need for aortic clamping, single-lung ventilation, and long-lasting anesthesia exposes the patient to an immense hemodynamic impact. Building on experience in conventional aneurysm care, *complex endovascular aortic repair* (complex EVAR) has been developed as a less invasive treatment option. Large abdominal incisions are no longer necessary. Instead, access is gained via the groin, to deploy a stent within the aneurysm. The aneurysm sac remains, but the blood circulation into this diseased part of the aorta is cut off and now flows through the stent. In order to maintain visceral perfusion, the aneurysm's side vessels are included in the stent by using fenestrations (circumferential windows in the device) or branches. It was mainly introduced as a treatment option for frail patients, considered unfit for OSR.

This exponential technical development, literally, comes at a cost. Fenestrated and branched stents are usually custom-made for each patient to exactly align with the patient-specific anatomy. In addition, it is hypothesized that with the introduction of complex EVAR, more (frail) patients are being treated, which further contributes to health care costs. Aside from monetary drawbacks, there are technical difficulties involved. Complex EVAR requires advanced technical appliances, a multidisciplinary treatment team, manufacturer contracts, and the ability to provide the necessary postoperative care and follow-up. Therefore, the implementation of complex EVAR is a demanding process, not possible in every treatment center. Another important consideration when treatment options expand, is deciding which patients should be treated. This not only means deciding between complex EVAR and OSR, but also between conservative treatment of awaiting the natural course of the aneurysm for the frailest patients. Although less invasive compared to OSR, complex EVAR still comes with considerable perioperative risks and rehabilitation. The fact that treatment is technically possible, does not necessarily mean that each patient will benefit from it. For some patients, complex EVAR might be a bridge too far.

This thesis examines how complex EVAR was implemented in a tertiary referral center in the Netherlands; the Leiden University Medical Center (LUMC). It presents the first postoperative outcomes, with a focus on postoperative functioning. It discusses the learning curve and the qualitative aspects that are important when implementing a new technique. In addition, it focuses on patient selection; what changed with the introduction of complex EVAR, and which factors might be associated with negative postoperative outcomes? The final part focuses on perioperative information provision and lessons learned from complaint procedures regarding aortic aneurysm care.

Main goals and corresponding findings

1. Analyzing the introduction of complex EVAR within the Leiden University Medical Center; a medium-volume tertiary referral center (Part 1).

A learning curve analysis of complex EVAR in the LUMC was presented based on the first 90 patients that were treated. A decrease in operating time and length of hospital stay implicated that technical learning took place. Fewer cardiac complications occurred in the thirty most recently treated patients and procedure complexity seemed to increase, while no significant changes occurred between the three consecutive treatment groups regarding other major adverse events (MAE) and 30-day mortality. Interviews with the endovascular treatment team (ETT) members identified factors experienced as positive contributors to the learning process. Adequate communication, mutual trust, and a shared sense of responsibility were among the contributive factors found in our results and in literature. The element of 'mutual learning' was added; sharing knowledge beyond what is strictly necessary among team members. Some of these findings might seem a bit obvious. 'Of course, team members should adequately communicate', readers might think. The fact that these factors were explicitly mentioned, however, indicates that such behavior is not always self-evident. Interviewees tend to highlight things that stood out or surprised them, rather than stating what is considered obvious.

Postoperative outcomes of 82 complex EVAR procedures performed between 2013 and 2020, showed that almost all patients were able to return home. Fifteen patients (18.3%) were temporarily admitted to a rehabilitation center. A subgroup analysis of 23 patients included in functional performance follow-up at 12 months, showed that 5 of them suffered functional decline, mainly by losing independence in bathing, getting dressed, and shopping. Four patients of this subgroup were deceased at 12 months post-surgery. Studies on conventional EVAR and OSR showed comparable numbers of functional decline and higher numbers of non-home discharge. Functional decline following complex EVAR is definitely not negligible in an absolute sense, especially when mortality is taken into account, yet these results remain relatively promising compared to other research, given the frailty of this group.

2. Identifying changes in the treated complex aneurysm population and analyzing whether sarcopenia could serve as a predictor of adverse outcomes in patient-selection (Part 2).

In 2024, the perceived changes in the treated complex aneurysm patient population were investigated by performing a descriptive analysis of complex aneurysm patients that were treated using either open or endovascular repair between 2008 and 2023. Between 2008 and 2023, 122 open procedures were performed, while 119 complex endovascular procedures were performed between 2013 and 2023. When the ETT preferred OSR over complex EVAR, it was mainly based on the aneurysm's anatomy. An important reason for choosing complex EVAR was either the patient's preference (n=49), or the fact that the ETT considered the patient unfit for OSR (n=47). The current practice-based decision-making process seems to be able to select the frailest patients, for whom complex EVAR was preferred. Some of these patients would likely not have been treated in the pre-complex EVAR era. Although less invasive compared to OSR in the early postoperative stage when focusing on complications, 30-day mortality did not significantly differ between both groups. The frailest complex EVAR patients had a low estimated median survival team of about 3 years, with a 1-year mortality of 23.8%.

The fact that treatment is technically possible does not necessarily mean that each patient will benefit from it. This is supported in guidelines stating that elective aneurysm repair is not suitable for patients with a limited life expectancy of 2-3 years. Conservative management might have been a better option for some of our frailest patients. It would be interesting to be able to predict which patients are most prone to adverse outcomes. Some predictive factors might be optimized prior to surgery, such as sarcopenia. Three CT-assessed parameters of sarcopenia were examined regarding their association with adverse outcomes after complex EVAR. Results showed that low muscle mass was associated with higher mortality. However, adequate cut-off values labeling patients as sarcopenic vs. non-sarcopenic have yet to be developed for complex EVAR patients.

3. Identifying pitfalls and discrepancies between the patient and professional perspective in patient information regarding complex aneurysm care (Part 3).

Once the treatment threshold is reached, a decision has to be made. It is important to consider patient preferences. An explorative interview study was performed, interviewing 12 patients in different stages of the treatment process and 5 professionals involved in complex aneurysm care. Although the professionals, like treatment guidelines, stress the possibility of conservative management for the frailest patients, most patients did not regard conservative management as a realistic option. We hypothesized that this is due to the fear of aneurysm rupture; the feeling of 'living with a time bomb'. In this perspective, patients might overestimate the chance of aneurysm rupture, while underestimating their

frailty and surgical risks. The reality of this fear, compared to the risks of surgery, should be addressed during preoperative counseling.

Patients experienced a lack of information on the duration and symptoms of postoperative recovery, even though this is mentioned in the informational folder, and the interviewed professionals claimed to discuss this during consultations. This may reflect a bias towards short-term thinking, with individuals focusing on what they perceive as immediate risks, such as aneurysm rupture and surgical risks, rather than postoperative recovery. It is important to be aware of this phenomenon, as it might lead to dissatisfaction regarding information provision. All patients were adamant to talk about their (positive) experience with the doctor-patient relationship, expressing that this element of the treatment process requires sufficient care and consideration.

Although the interviewees were satisfied with the information provision, it is important to be aware of factors that might cause patient dissatisfaction, or even official complaints. A literature study, analyzing Dutch medical disciplinary law on aortic aneurysm care, showed that most cases concerned an accusation of a missed diagnosis. In essence, inadequate communication often contributed to the complaint. This indicates that patients often experience a lack of effort on this front. Courts attach great importance to the obligation of adequate documentation. Clear communication, patient-involvement in (the reasoning behind) decision-making, and providing sufficient information could increase patient satisfaction, avert complaints, and prevent time-consuming trials.

Conclusion and implications

The introduction of a new technique such as complex EVAR requires a dedicated multidisciplinary treatment team and available resources. Team member should realize that communication, mutual trust, a shared sense of responsibility, and mutual learning contribute to a successful learning curve. In the era in which complex EVAR was introduced in the Leiden University Medical Center, the number of treated complex aneurysms increased, and complex EVAR became the preferred treatment method soon after its introduction. Patient frailty increased, while postoperative morbidity and mortality remained comparable over time and in relation to other treatment centers.

However, the frailest complex EVAR patients, considered unfit for OSR, had a limited survival time. This is the cohort that would likely not have been treated in the pre-complex EVAR era. While professionals involved in complex EVAR care consider conservative management as an appropriate option in select cases, patients often perceive it as an unrealistic choice. Aneurysm rupture is a great fear. At the same time, patients seem to underestimate the surgical risks and have a bias towards short term thinking. This causes some discontent regarding the preoperative information provision. As dissatisfaction regarding communication is a main cause of patient complaints, it is a topic that requires great attention.

A first initiative was made regarding research into postoperative functioning after complex EVAR. Remaining independent and returning home is one of the main patient preferences in deciding whether to undergo treatment. Prospective research in larger patient cohorts could be a next step. To further optimize patient information provision, future research should include complex aneurysm patients that underwent conservative management. Results on their quality and duration of life would be valuable information to add to the decision-making process. A patient's fear of aneurysm rupture should not be the sole reason for surgical treatment. However, this fear often serves as a barrier for discussing all treatment options. Recognizing and addressing a patient's fears and concerns contributes to treatment decisions genuinely reflecting a patient's preferences and quality of life considerations.