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

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General discussion implications

and

1. MAIN GOALS AND CORRESPONDING FINDINGS

The main goals and corresponding findings of this thesis were:

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

In **Chapter 1**, a learning curve analysis of the introduction 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. No significant changes occurred between the three consecutive treatment groups regarding major adverse events (MAE) and 30-day mortality, although fewer cardiac complications occurred in the thirty most recently treated patients. Due to the set-up of this study and the available data, the shape of the underlying learning curve could not be provided. This chapter identified qualitative factors experienced by the endovascular treatment team (ETT) as a positive contributor to the learning process. Interviews with ETT members in 2017 were researched for these factors and compared to contributive elements known from literature. Adequate communication, mutual trust, and a clear authoritative structure 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, such as lessons learned during conferences. Some of these findings might seem obvious. 'Of course, team members should adequately communicate', readers might think. The interviewees, however, offered practical tools for implementation. For example: 'thinking out loud' within the operating room. The fact that these factors were explicitly mentioned, 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.

Descriptives on the number of fenestrations and the complexity scores seemed to imply that complexity increased over time. This was also experienced as such by the members of the treatment team. However, this trend did not reach statistical significance. The discrepancy between the feeling of increased complexity among the ETT and this non-significant trend might be caused by the fact that the complexity score was solely based on stent graft configuration and did not include other factors that might increase complexity, such as treating increasingly frail patients and taking on aneurysms with challenging anatomy. It was hypothesized that with the introduction of complex EVAR, more (frail) patients were treated compared to the open surgical treatment era; a hypothesis that was further investigated in Chapter 3, and will be discussed below.

In **Chapter 2** postoperative outcomes of 82 complex EVAR procedures were presented, with a focus on functional outcomes; a critically important yet underexposed outcome. In the total cohort, almost all patients were able to return home. 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. 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. Of course, the subgroup included in functional analysis is very small. The discharge destinations perhaps provide more useful information in this cohort, as this was registered for almost all patients.

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 **Chapter 3**, the perceived changes in the treated complex aneurysm patient population were further investigated by performing a descriptive analysis of complex aneurysm patients that were treated using either open or endovascular repair between 2008 and 2023. This analysis showed a steady increase in the number of complex aneurysm procedures. 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 the number of major complications, 30-day mortality did not significantly differ between both groups. The frailest complex EVAR patients had a low estimated median survival time of about 3 years. When informing patients about the different treatment options, complex EVAR should not be pictured as non-invasive surgery, as the considerable perioperative risks cannot be ignored. 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.¹ 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, in order to adequately inform patients and to support decision-making. In **Chapter 4**, three CT-assessed parameters of sarcopenia were examined regarding their association with adverse outcomes after complex EVAR. Results showed that PMI, SMI, and LPMA were all associated with mortality. When labeling patients as sarcopenic vs. non-sarcopenic, only sarcopenia based on SMI was associated with mortality. This could indicate that the cut-off values for PMI and LPMA were not suitable for complex EVAR patients. By adding physical performance parameters, a subgroup of severely sarcopenic patients was identified, who had a lower estimated survival. However, this subgroup was considered sarcopenic based on any of the parameters and therefore might be an

overestimation. In addition, analyzing a subgroup within a larger cohort could lead to false positive findings, although the subgroup was defined prior to data analysis and not selected by trial and error. Future research could validate sarcopenia cut-off values for complex EVAR patients. Being able to select high risk patients aids in clinical decision-making and identifies a group that might benefit from prehabilitation strategies.

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

Chapter 5 consisted of an exploratory interview study, interviewing 12 patients in different stages of the treatment process and 5 professionals involved in complex aneurysm care. Although the professionals, like the treatment guidelines, emphasized the appropriateness of conservative management for the frailest patients, most patients did not perceive this as a viable 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. Treating the patient's fear should not be the main reason for complex aneurysm surgery. The reality of this fear, compared to the risks of surgery, should be addressed during preoperative counseling. Professional psychological counseling could be offered, addressing the concerns that might arise when a conservative treatment decision is made.

All but one of the interviewees underwent surgery, introducing selection bias. Including more patients who opted against surgery could nuance these patient perspectives. However, the decision not to treat is usually initiated by the treatment team, rather than the patient themselves. Patients' main concerns regarding surgery were not wanting to end up in a nursing home and the fear of losing independence. This is consistent with the literature findings in Chapter 2 on functional performance and emphasizes, again, the importance of research into functional outcomes.

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 their 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. A patient journey was provided, which is a relatively new concept in health care. It provides insight in the path from diagnosis to treatment and could be used by professionals to identify the needs of patients and to inform patients on what to expect after receiving a complex aneurysm diagnosis. Of course, this patient journey is center-specific; not every step will be the same for each hospital and it should therefore be adjusted according to the center-specific care pathway. A simplified version of the patient journey could then be provided to the patient.

The interviews in Chapter 5 seemed to imply that, overall, patients were satisfied. However, patient dissatisfaction is not rare. In **Chapter 6**, patient complaints were researched, by analyzing ten years of Dutch medical disciplinary law on aortic aneurysm care. Forty-eight first instance and 19 appeal cases were included. Most cases concerned an accusation of a missed diagnosis. As this can have devastating outcomes, it is understandable that it causes distraught among patients and their relatives. You could wonder whether a national screening program would diminish these cases by early detection of aneurysms. Trials have shown a positive effect of screening programs on aneurysm related mortality, and screening has been proposed in the ESVS 2019 guideline.^{2,3} However, evaluation of screening programs in other countries showed mixed results. A study in Sweden indicated that the reduced mortality was more likely due to smoking cessation. In addition, screening could lead to overdiagnosis and avoidable surgery.^{4,5} The Dutch Health Council seems to tend more towards these negative findings by advising the Ministry of Health, Welfare and Sports against implementing a screening program.⁶

Courts attach great importance to the obligation of adequate documentation. Overall, information noted in the patient's file is considered accurate, unless there are plausible grounds to question its reliability. This is not because the courts favor medical professionals over plaintiffs, but is understandable given the fact that medical records are often the only source of information available to the courts. Although time consuming, documentation should be thorough. Another main finding of Chapter 6 is that inadequate communication often contributed to the complaint. This indicates that patients often experience a lack of effort on this front. Although this might not always lead to disciplinary culpability, it is very much undesirable. 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. Chapter 5 aids in this matter, as it offers valuable insights in the patient perspective.

Several points of critique have been expressed against Dutch disciplinary law, one being its potential negative effect on defendants. Disciplinary trials cause stress, self-doubt, and the feeling of being criminalized and powerless.^{7,8} Some feeling of guilt or increased cautiousness is not necessarily problematic, but psychological and work-related problems are unwanted consequences. After all, this goes against the quality improvement goal of disciplinary law. On the other hand, research has shown that knowledge on disciplinary law among health care workers leaves something to be desired. Verdicts provide valuable insight in the analytical framework of the courts. Knowledge on the trial process and seeking legal assistance could diminish the feeling of being powerless.

2. RECENT LITERATURE

During the years it took to write this thesis, new insights on the main interests emerged. This shows that complex EVAR is a topical issue, but it can diminish the completeness of the chapters that were written before these insights were published. Therefore, this paragraph will briefly discuss the most recent findings in complex EVAR, relevant to this thesis.

2.1 Recent literature on Part 1

Mesnard 2023 et al. performed a learning curve analysis of a single early-career vascular surgeon and compared his outcomes to an experienced colleague within the same high-volume treatment center. The early-career operator had prior independent (T)EVAR experience in about 250 procedures, took part in over 50 complex EVAR procedures as a resident, and performed 24 procedures under direct supervision of his experienced colleague. A cumulative sum analysis showed that the individual performances of both surgeons regarding morbidity and mortality, were equal. In addition, there was no clear initial learning curve effect for the early-career surgeon, as outcomes were favorable from the start and remained stable thereafter. This indicates that complex EVAR can be safely adopted by early-career surgeons with previous experience and training in (complex) aneurysm care. It should be noted, however, that these results are surgeon-specific and that the early-career surgeon in this study had quite a lot of experience already.⁹

Borzák 2022 et al. provided a complex EVAR learning curve of a treatment team experienced in conventional EVAR, in a small-volume hospital. The first 20 FBEVAR procedures, performed over the course of two years, were analyzed. Thirty-day mortality (5%) was comparable to higher-volume centers, although the initial technical success of 65% was lower. The authors decided that complex EVAR can be safely adopted by a (low-volume) treatment center experienced in conventional EVAR. However, a Dutch nationwide study on hospital volume associated mortality after complex EVAR, showed that an annual volume of 13 or greater was associated with less perioperative mortality compared to hospitals with a volume of less than 9 cases per year.¹⁰ A study among 15 centers performing complex EVAR in the United States showed no difference in outcomes between low (1-3 cases/year) and high-volume (4-6 cases/year), although it could be argued whether a center performing 6 cases per year can be determined as high-volume.¹¹

2.2 Recent literature on Part 2

In 2021, a nationwide cohort study was announced in the United Kingdom, comparing clinical and cost-effectiveness of open repair vs. complex EVAR (UK-COMPASS).¹² Patients undergoing conservative management are included to perform a quality-of-life comparison between surgically treated and medically managed patients. One of the goals was to establish the clinical and cost utility of FEVAR in patients considered unfit for OSR, and to compare this against non-surgical management. Early findings have

been presented during the Vascular Society of Great Britain and Ireland annual scientific meeting. These results indicate that on the long term, all-cause mortality was lower for OSR compared to FEVAR, although FEVAR does appear to be equivalent to OSR in case of short-neck aneurysms. In addition, FEVAR presented with significantly more mid-term reinterventions compared to conventional EVAR. Based on these preliminary results, it was posited that patients who survive surgery might not gain the survival benefit treatment teams hope for, which emphasizes the need for adequate patient selection.^{13,14}

2.3 Recent literature on Part 3

Efforts are being made to incorporate patient preferences into the decision-making process in vascular surgery. The OVIDIUS trial (Operative Vascular Intervention Decision Making Improvement Using SDM tools) investigated whether decision support tools, such as apps and consultation cards, would aid in this matter. These tools significantly improved the level of shared decision-making and knowledge of vascular surgery patients, although in a subgroup analysis of AAA patients this was not significant. It did show, however, an increase in the number of AAA patients choosing non-surgical treatment choices when using such tools (21.4% vs. 28.8%), without being associated with a lower quality of life or greater decisional conflict. This further supports our findings that conservative management is an underexposed topic in current decision-making practice.¹⁵

3. GENERAL LIMITATIONS

Study-specific limitations have been discussed in each of the previous chapters and in paragraph 1 of the current chapter. Below, the remaining general limitations of this thesis will be presented.

One of the main goals of this thesis was to analyze the implementation and outcomes of complex EVAR within the LUMC. Inclusion was therefore limited to the number of patients being treated in this center, which results in a relatively small patients cohort compared to multi-center studies or studies within high-volume centers. The external validity of the results is therefore confined by restricted generalizability. Words like 'might', 'could', 'potentially', and 'possibly' are often added to the statements presented. A second limitation is the fact that the idea of analyzing the implementation and outcomes of complex EVAR arose several years after its introduction. Data were gathered retrospectively, and analyses were therefore limited to the data that were present in patient files.

The qualitative data in Chapter 1, 5, and 6 is analyzed and, in a way, constructed by the researchers. It is therefore prone to bias due to interpretation. Discussing the results between multiple authors with different professions aimed to limit this bias by inviting different views. Information on the authors' roles and perceptions is of interest and will

be provided here. Data analysis in Chapter 5 was performed in collaboration with an interventional radiologist, vascular surgeons, and authors trained in the field of inter-professional teamwork and patient participation. Chapter 6 was written by the author of this thesis, trained in medicine and health law, and by three vascular surgeons, one being a member of a Regional Disciplinary Court. The qualitative results were subject to interpretation, albeit by multiple authors with different views, who reached consensus.

Advancing perceptions and newly published research on complex EVAR led to new insights regarding the way outcomes are best presented. Not only did the endovascular treatment team undergo a learning curve, but, as is common over the course of PhD-research, so did the author of this thesis. The outcomes in Chapter 3 are therefore presented slightly different than in Part 1 of this thesis. For example, technical success was no longer defined in the strict way of 'all arteries treated successfully as planned', according to which each aberration of the preoperative plan would be classified as non-technical success, even if this resulted in a functioning endograft. Instead, a more commonly used definition was used, based on the definition provided by authorities on complex EVAR in the *Journal of Vascular Surgery*.¹⁶ Furthermore, in contrast with Part 1, emergency and Arch-EVAR cases were excluded in Chapter 3 as is done in most other studies. The perioperative outcomes of these patients are significantly worse compared to elective complex EVAR. Including these cases would impede meaningful comparison. It is important to note these changes, as not recognizing them might cause confusion when interpreting the results in the different chapters.

The three different parts of this thesis consisted of quite broad subjects. Although a bit of a platitude, each topic could serve as a thesis subject on its own.¹⁷ It is acknowledged that the results presented in this thesis do not answer all questions that arise. From the start, this has not been the goal of this thesis, as it aimed to provide an overview of the implementation of complex EVAR in the LUMC and to give insight in patient preferences regarding complex aneurysm management. More rigorous analyses could definitely be performed, should more patients be included. This will be further stated in the paragraph on implications for future research below.

4. IMPLICATIONS

4.1 Implications for policy-making

Over the last decade, the quality of aortic aneurysm and dissection care has been a topic of discussion in the Netherlands, with an emphasis on procedure volume and experience of treatment teams. Since 2013, all aortic aneurysms procedures are registered in the Dutch Surgical Aneurysm Audit (DSAA), to monitor surgical outcomes and provide hospitals with feedback on their performances.¹⁸ In 2023, the Ministry of Health, Welfare and Sports introduced a plan to centralize (complex) vascular surgery. According to the

ministry, only high-volume centres of excellence (50-100 surgeries per year) should be allowed to perform certain complicated procedures. The idea is to improve the quality of care by centralizing knowledge and experience.^{19,20}

Although this is an admirable objective and centralization of knowledge, experience and resources has proven to raise performance in the past, the results in this thesis showed that a lower-volume hospital (<20 complex EVAR cases per year) can reach comparable mortality and morbidity outcomes to higher-volume centres, as well as acceptable functional outcomes and patient satisfaction. In addition, we addressed the organizational challenges that come with the introduction of complex EVAR; the need for a dedicated multidisciplinary treatment team, manufacturer contracts, and the ability to be able to adapt to a growing and frailer patient cohort, with complex EVAR becoming the preferred treatment modality soon after its introduction. These challenges should be considered when rearranging the distribution of care.

4.2 Clinical implications

When complex EVAR is implemented in a hospital, attention should be paid to team learning, focussing on the positive learning curve factors proposed in this thesis. In addition, it is important to identify and address patient preferences. For example, the fact that most patients fear functional decline or discharge to a nursing home, could be addressed during consultation by providing data on center-specific postoperative outcomes. Health care professionals should realize that there is a difference in the perception of conservative management between patients and doctors. Most patients regard conservative management as a non-realistic treatment option. The fear of aneurysm rupture seems to be greater than the fear of postoperative complications. For some patients, having to live with the fear of rupture seems like no life at all. They are anxious to undertake activities that provide them joy. The reality of this fear, compared to the risks of surgery, should be addressed during preoperative counseling. Professional psychological counseling could be offered, addressing the concerns that might arise when a conservative treatment decision is made.

Patients experienced a lack of information on what to expect during postoperative recovery. Whether this was really not discussed or a result of bias towards short-term thinking, it is an issue that warrants attention in order to prevent patient dissatisfaction. By repeating information on the recovery period during pre-surgery consultation, at hospital discharge, and during postoperative follow-up, unpleasant surprises can be prevented. In addition, providing this information via a patient expert could have a stronger impact, as a personal story might appeal more to the imagination.

Patients were adamant to talk about the doctor-patient relationship. They appreciated a kind and non-authoritative doctor, who was available to answer questions and allowed for a personal aspect in the doctor-patient relationship. Of course, each doctor's way

of work is different. Independent of one's style, however, it is important to realize that the doctor-patient relationship very much impacts the way patients experience the provided care. This is supported by the fact that miscommunication was often at the root of disciplinary complaints. Clear communication and some level of personal engagement with patients seems important to maintain a satisfactory doctor-patient relationship and to avoid complaints. Several decision support tools (DSTs) have been and are being researched to aid in determining patient preferences. In addition, once a decision to treat is made, a patient journey as presented in this thesis could be used to provide patients insight in the road to come. Once a disciplinary complaint is filed, courts attach great importance to adequate documentation. Overall, information noted in the patient's file is considered accurate, unless there are plausible grounds to question its reliability. Although time consuming, documentation should be thorough.

4.3 Future research

Future research into complex EVAR should include functional performance outcomes. Preserving independence and being able to live at home are factors that complex aneurysm patients find most important. By gathering data on functional performance in a prospective standardized way, sufficient patient numbers can be reached to perform adequate analyses. Preferably, research should individualize the different types of complex EVAR, in order to analyze FEVAR, BEVAR, and Arch-EVAR separately.

In addition, more research should be performed into baseline characteristics that are associated with adverse outcomes after complex EVAR. This would help in decision-making and, if modifiable, could be a target of prehabilitation. Frailty scores and cut-off factors for sarcopenia could be researched in a larger cohort of complex EVAR patients, to compose predictive factors that can be used for complex EVAR patients in general. In addition, effort could be made to construct a complex EVAR complexity score. The complexity score that was used in this thesis, based on stent graft configuration, was not able to depict the perceived increased complexity of the procedures over the years.

With more results on postoperative morbidity, mortality, and functional performance coming to light, we get a better idea of life after complex aneurysm surgery. It shows that a certain frail patient group might not benefit as much from surgery as we had hoped. At the same time, new research suggest that annual aneurysm rupture rates might be lower than previously reported.^{21,22} Treatment is considered opportune if the risk of rupture exceeds the surgical risks. Based on previous research, the treatment threshold for complex aneurysms was established at around 6 cm. However, when rupture and surgical risks change, a new equation must be made. The frailest patients in **Chapter 3**, with a mean aneurysm size of 6.7 cm, had a 1-year mortality of 23.8%, while their cumulative rupture rate at 12 months would have been about 4.5% based on these newest numbers. It might be time to perform research into potentially raising the treatment threshold, as some patients would benefit more from (a longer period of) conservative management.

With the exception of one interviewee in Chapter 5, no complex aneurysm patients that ended up not having surgery were included. Incorporating complex aneurysm patients that received conservative management, would be a valuable contribution to complex EVAR research.²³ Long-term follow-up of these patients can offer insights into the rationale behind opting for non-surgical management, their functional performance, life expectancy, causes of death, and psychological well-being. Such findings are crucial for well-informed decision-making. 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 the discussion 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.

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