Evaluating abdominal aortic aneurysm and carotid artery surgery in the Netherlands: variations in indication, treatment and outcomes measures

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CHAPTER 1

Introduction & outline of this thesis

INTRODUCTION

Due to the growing demand for openness about quality of healthcare and tools to improve healthcare during the beginning of this century, multiple clinical audits have been initiated in several medical specialties in the Netherlands and other Western countries. Clinical audits were first introduced by Codman in 1916 and are nowadays frequently used as an instrument to measure and improve quality of healthcare.[1] A clinical audit is defined as 'a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change'.[2]
In 2011 the Dutch Institute for Clinical Auditing (DICA) was founded to organize and facilitate the initiation of nationwide audits in the Netherlands, offering a uniform format.[3] In accordance with the original idea of Codman, audits were formed based on a cycle. It starts with the collection of information on a certain topic, followed by evaluating the results in order to identify areas for improvement. Subsequently changes can be implemented and in the following period one can evaluate whether the changes had the desired effect. An essential part of this quality assessment is that performance is compared to the performance of other healthcare providers, as this would stimulate providers to improve their performance. Through these audits, doctors intend to improve the outcomes of Dutch healthcare and, as a result, to contribute to the reduction of healthcare costs.

The Dutch Surgical Aneurysm Audit

The Dutch Surgical Aneurysm Audit (DSAA) was initiated by the Dutch Society for Vascular Surgery (Nederlandse Vereniging voor Vaatchirurgie: NVvV) in 2012 and was facilitated by the Dutch Institute for Clinical Auditing (DICA).[3,4] From 2013, all hospitals performing abdominal aortic aneurysm (AAA) surgery in the Netherlands were obligated to register all patients undergoing AAA surgery in the nationwide DSAA. Following the Donabedian model, information on the structure, process and outcomes of surgical aneurysm care were collected.[5] By registering this information quality of care could now be monitored and vascular surgeons could be provided of benchmarked information about their care.

Stakeholders

Although the DSAA was initially formed by and for vascular surgeons for quality improvement reasons, other stakeholders also contributed to the development of the audit so that it could serve several purposes. For the Dutch Healthcare Inspectorate (Inspectie Gezondheidszorg en Jeugd: IGJ) and the Dutch National Institute for Healthcare (Zorginstituut Nederland: ZIN), the DSAA could be used to supply information for quality indicators, necessary for the monitoring of patient safety.[6,7] The patient association for cardiovascular diseases (Hartenraad) intended to use the information from the DSAA to support individual patients in choosing a healthcare provider.[8] Finally, Dutch healthcare insurers were interested in the comparison of hospitals outcomes, so they could well informed purchase care for their policyholders.[9]

Quality indicators

During the formation of the DSAA, the NVvV collaborated with these stakeholders to decide which information needed to be registered and to eventually form a set of quality indicators of care.[10] The indicators were categorized by structure, process and outcomes of care and would be measured for each individual hospital. The questions which surgical outcomes best reflect quality of care and in which hospital volumes AAA surgery should be annually performed were important discussions when forming these indicators. The primary outcome measure of the DSAA was decided to be postoperative mortality within 30 days after surgery or during the initial admission (30-days/in-hospital mortality). Additionally, postoperative complication, postoperative reinterventions and readmissions were also registered.

The development of quality indicators is a continuous process in which the variables registered in the audit and the set of quality indicators is annually evaluated and adjusted if needed. After the first 3 years of auditing, the quality outcome indicators were first made public via a transparency portal.[11]

First results from the DSAA

With the DSAA being fully operational from January 2013 and all 65 hospitals performing AAA surgery participating, roughly 3350 AAA patients were annually registered between 2013-2014, of which 78% undergoing elective surgery, 6.3% undergoing surgery because of an acute symptomatic AAA and 16% because of a ruptured AAA.[12] The majority (75%) of elective patients was undergoing the more minimal invasive Endovascular Aneurysm Repair (EVAR) and the remaining 25% conventional Open Surgical Repair (OSR). In patients with an acute symptomatic and ruptured AAAs the percentage of treatment with EVAR was respectively 54% and 34%.

In accordance with other European countries, postoperative mortality after elective EVAR was 0.7%. Postoperative mortality after elective OSR however, was slightly higher with 5% (compared to 3.2% in Sweden).[12]

Since the outcomes of the DSAA are intended to be used for benchmarking hospitals as objective as possible, taking into account differences in patient characteristics between hospitals, Lijftogt et al. have conducted research into case-mix models for AAA surgery.[13,14] In the design of the DSAA it was decided to record variables from the VP POSSUM prediction model, a widely used and extensive model for prediction of postoperative mortality in various surgical procedures.[15] Lijftogt et al. concluded that a minimal set of patient characteristics, including sex, age, pulmonary comorbidities, urgency of surgery, aneurysm diameter, CGS, preoperative hemoglobin, creatinine and ECG, was sufficient.[14] Furthermore, they concluded that the added value of case mix correction is small in the case of an outcome measure with a low event rate and little variation between hospitals, as is the case with postoperative mortality in elective EVAR. Despite that, it has been decided to apply case-mix correction with this smaller set of variables in the DSAA to minimize the possibility of a hospital being disadvantaged in the comparison of outcomes.

Outline of the thesis

Due to the previously mentioned low mortality in elective AAA surgery, it turned out to be difficult to distinguish between hospitals on this outcome measure. In addition, the lack of variation in postoperative mortality also did not offer any leads for improvement initiatives. For the purpose of internal quality improvement, additional quality measures had to be sought and explored. From the start of the DSAA in 2013, extensive information was collected about patient characteristics, care processes and outcomes. With this sea of data, new facts came to light and, above all, new questions regarding the variation in indication, treatment and outcome measures of AAA surgery in the Netherlands arose, forming the basis of this thesis.

Indication

To prevent aortic rupture, international guidelines recommend elective surgery in patients with an AAA with a diameter of 55 mm or more in males and 50 mm or more in females.[16,17] These thresholds have been studied extensively and early elective surgery is not beneficial for patients with diameters below these cut-off values.[18-22] In the DSAA 17% of elective AAA patients was reported to have a smaller diameter than these thresholds, with variation between hospitals. In **chapter 2** we evaluated patient and disease characteristics associated with performing surgery on patients with smaller aneurysm diameters than recommended. We additionally performed a survey under Dutch vascular surgical units (VSUs) in order to investigate reasons for deviation from the diameter guidelines, with a focus on how VSUs expect to deviate from the guidelines compared to their actual deviation.

The diameter guidelines are based on the risk of rupture in fusiform shaped AAAs, which accounts for 95% of all AAAs. It suggests that elective surgical treatment in the less commonly presented saccular shaped AAAs is indicated at smaller diameters, as there is a longstanding believe that the asymmetrical shape of a saccular AAA might predispose them to rupture. However, guidelines fail to give a threshold for elective treatment in saccular AAAs, since no large case series of cohort studies have been performed. In **chapter 3** we aimed to present an overview of the experience with saccular AAAs in the Netherlands, evaluating differences between patients with a saccular and fusiform AAA in patient characteristics, clinical presentation, treatment and outcomes in order to substantiate a treatment threshold.

Treatment

EVAR has become standard of care in the treatment of elective abdominal aortic aneurysms, being performed in the majority of elective patients with a postoperative mortality decreased to 0.7%.[12,23] This in contrast to the relatively high postoperative mortality in elective OSR of 5% being performed in a selected group of patients, mostly not suitable for EVAR for anatomic reasons. As fewer patients are treated with EVAR, experience in this procedure could decrease and hospitals may not perform the surgical procedure sufficiently to maintain good quality of care.[24,25] However, today no minimum volume standard for elective OSR exist in the Netherlands.

In **chapter 4** we first evaluate patient characteristics associated with postoperative mortality after elective OSR in the current Dutch population to improve patient selection for elective OSR. Secondly, the association of hospital volume of OSR and postoperative mortality was investigated in order to explore a possible minimum volume standard for elective OSR.
Whereas randomized controlled trials (RCT) in elective AAA patients showed lower postoperative mortality and morbidity after EVAR compared to OSR, several RCTs could not demonstrate the superiority of EVAR over OSR in patients with a ruptured AAA.[26-29] RCTs contain a selected, relatively homogeneous population, which might hamper the generalizability of the results.[30] Large observational studies that investigated the same topic suggest a lower postoperative mortality in patients with a ruptured AAA treated with EVAR.[31-33] However, observational studies can be biased and adjustment of confounders can be incomplete.[34] An instrumental variable analysis is a pseudo-randomization technique, which is developed to control for unobserved confounders when comparing treatments in observational data.[35] In **chapter 5** we compared postoperative mortality of all consecutive RAAA patients treated with EVAR or OSR registered in the DSAA, using standard statistical methods and instrumental variable analysis.

Outcome measures

When measuring quality of care, there is an ongoing debate about which indicators best reflect quality of care. As previously mentioned, single outcomes indicators in aneurysm surgery often have a low event rate, which result in little variation and does not incite improvements. Furthermore, a single indicator generally seems to give a one-sided perspective and does not reflect the multidimensional aspect of the surgical process.[36]
Textbook Outcomes is a composite measure that was first described in surgical gastro-intestinal oncology.[36,37] As it includes all desirable outcomes of the surgical process, it gives a better impression of the overall quality of care and it increased the variation between hospitals.[38] In **Chapter 6** we define and test Textbook Outcome for elective AAA surgery.
In the evaluation of effectiveness of surgical AAA care, it is important to take, in addition to (postoperative) mortality and complications, long-term secondary aortic reinterventions (SARs) into account. Where elective endovascular aneurysm repair (EVAR) is known to have lower postoperative mortality than elective open repair, it appears that EVAR entails more SARs.[39-41] As mentioned, the use of EVAR has continuously increased over the past decades and is currently used in the vast majority of elective patients, which thereby will eventually also influence the number of SARs. However, it is unclear what the current extent of this problem is on a national scale and what the consequences are for patients. Since January 2016 all patients undergoing a SAR (endovascular or open) following a primary AAA repair are also included in the DSAA. As all data in the audit is collected on a procedural level, information on the primary procedures and corresponding SARs could now be merged. In **chapter 7** we aimed to provide insight in to the national number of SARs following primary AAA repairs in

the Netherlands. Secondly, we have described patient aneurysm and treatment characteristics and outcomes of patients undergoing SAR.

The Dutch Audit for Carotid interventions

Following the example of DSAA, the NVvV also initiated the Dutch Audit for Carotid Interventions (DACI). From June 2013, all patients undergoing carotid artery intervention were registered in this mandatory audit. The structure of the audit was similar to that of the DSAA, with variables for structure process and outcome indicators. There was a national minimum required volume of 20 carotid interventions per hospital. As in the Netherlands carotid stenting is only done in exceptional cases, it is primarily an audit of carotid endarterectomy (CEA). A CEA is primarily performed in patients with a symptomatic high-grade carotid stenosis, to prevent a recurrent transient ischemic attack (TIA) or ischemic stroke.[42,43] Based on studies from Rothwell we learned that a CEA is more effective in preventing a stroke in the first two weeks after the index-event.[44,45] International guidelines therefore recommend performing a CEA in patients with symptomatic carotid stenosis within two weeks after the index event.[46] When forming the DACI, it was important to be able to provide insight into the waiting time for carotid endarterectomy, nationally and also between hospital. The percentage of patients with a symptomatic carotid stenosis undergoing surgery within 2 weeks after the index event became a quality process indicator, in which initially 80% was the minimal standard.[47] As quality outcome indicators, postoperative mortality and, in accordance with international literature, the combined outcome (major) measure stroke and/or death were used. Additionally, rebleeding and cerebral nerve injury were also registered and included in the quality indicators. As in the DSAA, case-mix correction of the postoperative outcomes was performed using the variables of the VP-Possum prediction model.[15]

In **chapter 8** we describe the results of patients with symptomatic carotid artery stenosis undergoing CEA and registered in the DACI during the first years of auditing, in which overall quality is evaluated, as well as the variation between hospitals in process and outcomes indicators. Additionally, patient characteristics associated with major stroke and/or death have been identified. In **chapter 9** we discuss the origin and formation of the 'time-to-intervention' guideline and how it should be interpreted.

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