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

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CHAPTER 10

Summary, general discussion & future perspectives

SUMMARY

Dutch Surgical Aneurysm Audit

Clinical audits are used to measure and improve quality of health care and are embedded in the current Dutch care landscape.[1] Besides serving as a tool for physicians to improve their care, a clinical audit also provides information to other stakeholders (e.g. patients, administrators and health insurers) in a time where transparency about practice and outcome is essential.

Since 2013, all patients undergoing abdominal aortic aneurysm (AAA) surgery in the Netherlands are required to be registered in the Dutch Surgical Aneurysm Audit (DSAA).[2] From these patients, information about indication, process and outcomes of care is collected and subsequently be used to calculate quality indicators. At the start of the DSAA, around 3500 patients were registered by 61 hospitals each year. Since the expansion of the DSAA in 2016, with patients undergoing thoracic aortic surgery and AAA revision surgery, this annual number has now reached around 4000 patients. Due to the merging of hospitals and centralization of complex care, currently 59 hospitals are performing AAA surgery in the Netherlands.

Initially, the stakeholders had the need to be able to monitor postoperative mortality and to be able to make a fair comparison between hospitals on this outcome measure. However, due to the low event rate of postoperative mortality in elective AAA surgery, little variation between hospitals was observed, and this did not provide any leads for quality improvement. As a result hereof additional quality measures for AAA surgery were investigated concerning the indication, treatment and outcome measures. As DSAA has full national coverage it is real world data and therefore the data is also suitable for analyses of epidemiological issues.

From the first analyzes of the DSAA we have learned that elective AAA surgery is frequently performed on patients with a smaller aortic diameter than in which surgery is recommended in the guideline (males ≥55mm and females ≥50mm).[3] As early intervention has proven to be not beneficial and can lead to unnecessary adverse outcomes for patients, this required further investigation.[4,5] In **chapter 2** we showed that guideline deviation regarding the aneurysm diameter for elective repair is present in 17% of patients and happens more frequently in males, young patients, patients without co-morbidities, patients treated with endovascular aneurysm repair (EVAR) and in lower hospital volumes. There is a wide variation (2-40%) in guideline deviation regarding the treatment of small aneurysms between Dutch vascular surgical units (VSU, i.e. hospitals). Subsequently, when the variation in guideline deviation was evaluated over time, VSUs that rarely deviate from the guideline could be identified, as well as VSUs that structurally did. In order to get more insight into reasons to deviate from the guideline, an online questionnaire was distributed among all Dutch VSU. These questionnaires showed that there is agreement among Dutch VSUs on acceptable reasons to perform elective surgery on patients with a small aortic aneurysm, such as saccular shape

of the aneurysm and a large iliac component. However, the extent to which the indications mentioned in the questionnaire occur in actual practice (DSAA data) varied. Lastly, when we asked VSUs to estimate their own percentage of guideline deviations regarding aortic diameters, their estimations were in 75% not concordant with their actual practice and lower than as registered in the DSAA. From these results, we concluded that VSUs are not always aware of their own practice. By integrating the percentage guideline deviation regarding aneurysm diameter into the feedback system of the audit since 2018, VSUs can now easily monitor their own practice which may help to decrease unbeneficial elective surgery and the variation in practice.

Although a saccular shape of the aneurysm was reported by Dutch VSUs to be an acceptable reason for early surgical intervention as the asymmetrical shape of a saccular aneurysm might predispose them to rupture, we found little scientific evidence to support this. Based on case reports and case series of which the largest included 78 saccular shaped abdominal aortic aneurysms (SaAAA), current European and American guidelines suggest that early surgical treatment of SaAAAs is recommended but no threshold for intervention is provided.[6-8] As aneurysm shape was registered in the DSAA since 2016, we were able to compare clinical presentation, treatment and outcome between the relatively rare SaAAAs and more common fusiform shaped AAAs (FuAAA) in the Dutch population as is addressed in **chapter 3.** SaAAA was registered in 6.1% (6.5% elective, 4.8% acute) of all patient in the DSAA. Patient characteristics between SaAAA and FuAAA were comparable, except acute SaAAA patients were more often female compared to acute FuAAA patients. In line with the prevailing belief that SaAAA are more likely to rupture, elective patients with a SaAAA were operated at smaller diameters than elective FuAAA patients and the majority of elective SaAAA patients were undergoing surgery with a diameter <55mm. More striking was the finding that acute SaAAA patients were significantly more often presented with smaller diameters than acute FuAAA patients. This difference resulted in a relative risk (RR) on an acute presentation of >3 in SaAAAs with diameters <55mm compared to FuAAAs of the same size and >15 in SaAAAs with diameter <45mm. These findings support the current idea that SaAAA should be electively treated at smaller aortic diameters than FuAAAs. The exact diameter threshold for elective repair of SaAAA is difficult to determine, but a threshold of ≥45mm seems acceptable. In both the elective and acute setting, SaAAA and FuAAA had similar surgical treatments and no differences were found in postoperative outcomes.

Chapter 4 describes the current practice of elective open surgical repair (OSR) for AAA in the Netherlands with a focus on the hospital volume in which these procedures are performed. With EVAR being standard care in the elective setting, the use of OSR has decreased and is performed in only 22% of patients undergoing elective AAA repair in the Netherlands, containing a selected group of patients with most likely more difficult aneurysms.[9] In contrast to elective EVAR in which postoperative mortality decreased to <1%, postoperative mortality after elective OSR remained unchanged at 5%. With the aim

to improve postoperative outcomes after elective OSR, patient characteristics associated with postoperative mortality in the DSAA and the association between hospital volume and postoperative mortality were evaluated. Female sex, increasing age, pulmonary co-morbidities, preoperative hemoglobin and preoperative creatinine levels have shown to be independently associated with postoperative mortality after elective OSR in the Dutch population. Despite the fact that OSR is decreasingly performed, no distinction is made between EVAR and OSR within the current Dutch volume standard of 20 elective AAA procedures per hospital per year.[10] Because of this, elective OSR is performed in 59 hospitals in the Netherlands, in which the total elective OSR volume (during a period of 6 years) varied from 1 to 141. Between hospitals the adjusted postoperative mortality ranged from 0-16%. Due to the low mean annual volumes, no hospitals with a significantly higher postoperative mortality could be identified. Additionally, annual hospital volume of elective OSR was not associated with postoperative mortality after elective OSR in the current Dutch population. Based on these findings we could not substantiate a volume standard for elective OSR.

Previous studies comparing postoperative mortality between EVAR and OSR in patients with a ruptured AAA (RAAA) have shown conflicting results. Whereas observational studies suggested a survival benefit after EVAR, no randomized controlled trial studies have confirmed this.[11-16] Both study designs have their drawbacks. As the benefit of EVAR in the elective setting is clear, it is expected that this benefit of EVAR should also apply in the acute setting, but this had not yet been demonstrated. In **chapter 5** the difference in in postoperative mortality between EVAR and OSR in RAAA patients was evaluated with three different statistical techniques, using DSAA data.
Of all RAAA patients undergoing acute surgery in the Netherlands, 62% was treated with OSR and 38% with EVAR. Patients were treated in 61 hospitals, and percentage of treatment with EVAR varied from 0-100%. The crude postoperative mortality after OSR was 34.9% and 22.6% after EVAR. With standard linear regression analysis and propensity score (PS) analysis adjusting for observed confounders a significant 30 days/in-hospital survival benefit of 12.3% and 13.2% respectively, could been demonstrated for RAAA patients undergoing EVAR, compared to RAAA patients undergoing OSR. Using instrumental variable (IV) analysis (pseudo-randomization) to adjust for observed and unobserved confounders, a postoperative survival benefit (statistical non-significant) of approximately 8.9% was seen in EVAR patients. Additionally, hospitals were divided in two groups based on the percentage of EVAR in RAAA patients, with the median as cutoff point. Patients operated in hospitals with a high percentage of EVAR (38-100%EVAR) in RAAA patients had a 2.0% lower crude postoperative mortality compared to patients operated in hospitals with a low percentage of EVAR (0-37%EVAR) in RAAA patients.

In the search for more distinctive outcome measures in elective AAA surgery, several composite measures have been explored. In **chapter 6** Textbook Outcome (TO), a composite measure

including all desired outcomes, is described for elective AAA surgery and tested on DSAA data. The scientific committee of the DSAA decided that TO is achieved if no intraoperative complications, no postoperative surgical complications, no re-intervention, no prolonged hospital stay (LOS) (EVAR ≤ 4 days, OSR ≤ 10 days), no readmission within 30 days after discharge and/or no postoperative mortality within 30 days after surgery or at discharge did occur. Due to the difference in type of surgery, different definitions for LOS were used between EVAR and OSR. TO was realized in 71% of EVAR patients and 53% of OSR patients. The main reasons why TO was not achieved were a prolonged LOS in both surgical procedures, re-admissions after discharge for EVAR patients and postoperative complications for OSR patients. With TO a greater inter-hospital variation was observed compared to single outcome indicators, especially in OSR. Variation remained mostly within the confidence intervals making it difficult to identify 'best practices'. However, by using TO individual hospitals can see where they can improve to achieve desired outcomes. TO is therefore initially particularly suitable as an instrument for internal quality improvement and not for hospital comparison. Since 2019 TO is included in the DSAA feedback system for hospitals.

While the focus in clinical auditing is often on immediate visible postoperative outcomes, it is also important to consider the more long-term outcomes when measuring quality of care. Besides long term mortality, secondary aortic related reinterventions is an important measure. Previous studies have already shown that with the increasing use of EVAR, the number of aorta-related re-interventions has also increased.[17-19] Since the expansion of the DSAA in 2016, all secondary aortic reinterventions (SARs) performed in the Netherlands were also registered in the audit, making it possible to generate long-term outcomes by linking data. Because this data has only recently been added, it is not yet possible to make statements about the incidence of re-interventions, but with the first analyses of this data we were able to provide insight into the scope of the problem in **chapter 7**. In two years of time, 691 patients underwent a SAR in the Netherlands, which counts for almost 10% of all AAA procedures annually performed. The most frequent indication for SARs were endoleaks. The majority of SARs was performed in an elective setting and more than half with an endovascular procedure. Postoperative mortality of SARs was comparable with results after primary AAA repair, in all urgency settings.

When linking data, approximately a quarter of SAR patients was previously registered in the DSAA for their primary AAA repair (2013-2017), which implies that the remaining three quarters had their primary AAA repair before the start of the audit (<2013) and therefore information on their primary AAA repair is lacking.

In the subgroup of SARs with linked data, the vast majority of SARs followed after primary DSAA registered EVAR procedures (169/181). When looking at the stent types used in their primary AAA repair, an overrepresentation of endovascular aneurysm sealing system grafts was seen. Only half of the primary EVAR procedures could again be treated with an endovascular procedure during SAR. Furthermore, one-fifth of patients with a primary elective AAA procedure underwent an acute symptomatic or ruptured SAR. With more

years of auditing, the proportion of SARs that can be linked to their primary intervention will increase and eventually be complete, making it possible to provide a national incidence of SAR and to evaluate SAR-rates between surgical techniques. Additionally, by evaluating SAR rates between stent types the audit can serve as a tool to detect stent related problems.

Dutch Audit for Carotid Interventions

Since June 2013, all patient undergoing carotid artery interventions in the Netherlands are registered in the Dutch Audit for Carotid interventions (DACI).[20] In **chapter 8** it is shown that the DACI could be successfully implemented in the Netherlands with nationwide coverage of all hospitals, allowing the evaluation of quality of carotid endarterectomy (CEA) care nationally and between hospitals. From its start, approximately 2500 patients are registered in the DACI by 52 hospitals annually. After the first years of auditing we concluded that CEA is performed with an overall low mortality and (major) stroke/death rate. Additionally, there was a reasonable guideline adherence regarding the indicator time-to-intervention, with 75% of symptomatic patients undergoing surgery within 2 weeks after first hospital consultation. Whereas time-to-intervention showed significant variation between hospitals, outcome indicators as mortality and (major) stroke/death are not very distinctive due to low overall event rates and no hospitals with a significantly higher event rate. The lack variation in these indicators hampers a national hospital comparison in the era with a minimum volume of 20 CEA per year per hospital. However, 9 hospitals with a significantly lower major stroke/death rate than the national mean could be identified, from which others possibly could learn. Additionally, with the use of DACI data, the following predictors for major stroke/death after CEA in symptomatic patients could be identified: age, female gender, severe respiratory diseases, presenting with cortical symptoms.

In **chapter 9** it is explained how the quality indicator time-to-intervention was established and how it should be interpreted. The guideline to treat patients with a symptomatic carotid stenosis within 2 weeks after the first hospital visit is based on a post-hoc meta-analysis of two randomized trials, performed in 1981-1996.[21-24] In this post-hoc meta-analysis, 14 days was chosen as cut-off values, in which revascularization within this term appeared to be more effective in preventing a recurrence of transient ischemic attack (TIA) or ischemic stroke than outside this term and in which revascularization after 12 weeks was not considered useful. It should be noted that 14 days is a chosen number rather than an outcome of a calculation and that in practice it is a sliding scale in which earlier intervention is more effective in preventing a recurrent stroke. Establishing a quality indicator as time-to-intervention stimulates physicians to improve multidisciplinary collaboration and to organize their care pathways more effectively. Such an external stimulus is beneficial for the total cohort of symptomatic patients undergoing CEA, in order to prevent the maximum number of strokes. However, care should be taken that this quality indicator is not seen as a dividing line within which intervention is effective and beyond which is not.

An important nuance to be made is that the aforementioned studies measured the time interval from the moment of first symptoms or last symptoms until surgery. Though, the quality indicator start measuring from first hospital consultation. As previous research has shown that there is an average pre-hospital (patient related) delay of 7 days, it is chosen to only measure the interval in which hospitals can influence when defining the quality indicator.[25] Hospital factors associated with delay in time to intervention were found: age, prior CEA, presenting with ocular symptoms and an indirect referral.[26]

GENERAL DISCUSSION AND FUTURE PERSPECTIVES

Development/improvement of the audit and indicators

New quality indicators have emerged as a result of developments in vascular surgical care and new insights, among others based on information from the audits. More years of registration in the DSAA and DACI will have to show whether the introduction of new indicators has also contributed to the improvement of processes of care and eventually the outcomes of care. Feedback about processes of care will likely lead to improvements more easily, since it generally clearly indicates where to act on. This is in contrast to most single outcome indicators, which often requires further research to discover why hospitals score poorly on the relevant outcome. Although awareness of your outcomes alone can contribute to improve performance, it is especially important that hospitals are given clear tools to be able to improve, such as in Textbook outcome and Failure to Rescue.[27-29]

Since the expansion of the DSAA in 2016, SAR procedures and interventions of the thoracic aorta have also been registered. Additionally, since then a distinction between infra, juxta and suprarenal aneurysms of the abdominal aorta was made within the DSAA. With time, more insight into these subgroups will become available. As discussed in chapter 7, it will be possible in due course to determine the incidence of SAR procedures per surgical technique and in addition, the audit can serve as a tool to detect problems with stent grafts.[30]

Thoracic aortic procedures often overlap with abdominal aortic procedures, not only because they merge anatomically but also because the experience of one procedure contributes to the experience of the other. In endovascular procedures, it is also important to be able to distinguish between procedures in which branches of the aorta are individually stented or not, as these are technically more difficult procedures with a higher risk of perioperative complications.

Currently, no volume standards have been set for the performance of branched aortic interventions. In the first years of registration of the thoraco-abdominal and supra-renal aneurysms we found that some hospitals perform these procedures frequently and some only sporadically.[9] The results of branched aortic interventions and the volume in which they are performed will be a point of attention in the coming years.

Collaboration with other medical specialties / audits

As certain procedures on the thoracic aorta are also performed by cardiothoracic surgeons, contact has been sought with the Dutch Association of Cardiothoracic Surgeons.[31] The cardiothoracic surgeons register all their procedures in their own quality registry 'Dutch Heart Registration'(NHR).[32] By organizing the DSAA and the NHR in such a way that aortic procedures are registered similarly, these data files could be combined in the future in order to obtain a complete overview of the procedures performed per hospital. It is debatable whether these numbers could be added together with regard to a volume standard. Vascular surgeons and cardiothoracic surgeons often function as two separate departments, which makes it

questionable whether these procedures can be seen as a shared experience. Nevertheless, it is first of all important to make these data transparent.
The scientific committee of the DACI has looked into a possible collaboration with the 'Dutch Acute Stroke Audit' (DASA), as patients with a symptomatic carotid stenosis are also registered in the DASA because of their neurological presentation. An important and still unanswered question is the number of patients with symptomatic carotid stenosis who will have a recurrent stroke while waiting for carotid endarterectomy, preventing them from undergoing surgery. Originally, all patients with a transient ischemic attack or ischemic cerebrovascular accident (CVA) were registered in the DASA. However, because of the enormous registration burden due to the case load, it was decided to focus the audit on ischemic CVAs. As a result, a large part of the DACI patients is no longer included in the DASA, leaving this question unanswered.

Merging of different data sources

DICA is investigating whether data from individual audits, including the DSAA and DACI, could be linked to existing databases, such as electronic patient records (EPR) and Vektis. When patient data needed for the audits could be directly and easily extracted from the EPRs, they no longer need to be registered manually. This would greatly contribute to reducing the registration burden.
Vektis has a database in which the financial data of health insurers in the Netherlands is collected.[33] As a result it has information about comorbidities and the date of death for every patient in the Netherlands. Such a link would provide insight into the long-term survival of all patients undergoing aortic and carotid surgery in the Netherlands. This would be extremely meaningful information for efficiency purposes. An obstacle to this link is the new privacy legislation whereby certain personally identifying data may not be registered or used in a quality registry. It is still a question of finding a way in which this data can be reliably linked and in which the privacy of patients is safeguarded.

International collaboration

In 1997, an international collaboration was initiated under the name VASCUNET for clinical and administrative vascular registries in Europe and Australia with the aim of improving the quality, safety and effectiveness of vascular healthcare.[34] There are now 27 countries, including the Netherlands, affiliated with VASCUNET, which can all provide data for certain research projects. By bundling data and thus increasing the patient population, certain epidemiological issues, such as conditions or complications with a low event rate, can be better investigated. Comparing results between countries remains difficult. This is mainly due to the differences in the national organization of quality measurement. The way in which the Dutch health care and its quality monitoring is organized, ensures that all patients undergoing aortic or carotid surgery respectively are registered in the DSAA and DACI. This full national coverage makes our quality registers unique. For the other participating countries, it is not always certain

whether all patients are registered in the national country, or it is actually known that only a selection of hospitals participate in the registration. This hampers a fair comparison of results between countries.

Volume standards and centralization of care

An ongoing discussion is the hospital volume in which certain procedures should be performed. Two conflicting interests intersect: on the one hand, good accessibility of care is desirable in which patients can receive certain care as close to home as possible, and on the other hand, it is important that the team providing the care do this often enough to be able to deliver good quality of care. With the current volume standards of 20 elective AAA procedures and 20 CEAs, there are approximately 60 hospitals across the country that perform these procedures. As described in chapter 4, there is no separate volume standard for elective OSR within AAA surgery, which means that hospitals can perform this procedure once a year. Comparable examples are the treatment complex branched abdominal and thoracic aneurysms and ruptured AAAs. When complex low-volume care is performed in too many hospitals, it is difficult to monitor the quality of care.

A low number of procedures per hospital results in wide confidence intervals in which outliers are difficult to detect. In addition, when the total volume is low a single "event" (for example, mortality or a complication) more or less strongly influences the hospital outcome which makes is difficult to achieve constant outcomes over several years.

In the search for new volume standards, we encounter the same statistical limitations.

As showed in chapter 4, we were unable to demonstrate associations between volume and postoperative mortality in elective OSR. It may be possible that this association is actually not there or that with the current distribution of elective OSR procedures divided over 59 hospitals in the Netherlands, several of which perform only a few procedures per year, we were unable to demonstrate an association. If no decision can be made on the basis of the available data, a consensus should be sought on the basis of reasonableness. We have to ask ourselves how often a surgical procedure must be carried out in order to be able to deliver sufficient quality as a team. Does a procedure have to be performed at least once or twice a month, or even once a week? Regardless of the number, new volume standards will bring about a shift in care with fewer hospitals (and therefore fewer surgeons) performing these procedures and most patients will have to travel further of have to be transported to receive this care.

Focus of the audits

Clinical auditing is a labor-intensive process in which doctors spend a lot of time registering patients instead of providing patient care. Reducing the registration burden is therefore placed high on the agenda. In the DSAA, more than half of the patients registered annually are elective EVAR procedures. In this group, low mortality and postoperative complications have been seen since the start of the audit, which did not change over time and in which no outliers are seen.

In addition to the search for more distinctive outcome indicators, one could also decide to focus the audit on certain areas of attention, where more monitoring is desirable or where potential improvements can be achieved, such as in OSR, complex aneurysms and ruptured AAAs. It is debatable that, in addition to the focus areas, the elective EVAR group would no longer be registered or that only a limited set of variables in these patients would be collected. In the latter case, the continuity of the dataset is preserved and thus also retains a signaling function.

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