

EDITORIAL

Towards Society Regulated Regionalisation of Aortic Aneurysm Surgery in The Netherlands

Regionalisation of vascular surgical care has been a global topic of debate for over a decade. Simultaneously with the centralisation of vascular surgery in the United Kingdom¹, the Dutch Society for Vascular Surgery (D-SVS) agreed on a blueprint for regionalisation of vascular surgery in the Netherlands within 15 regions, each serving approximately one million inhabitants. Therefore, a national document on aortic aneurysm surgery was written in 2013 as part of a Program for Health Care Efficiency from the National College of Health Insurances.² The document described quality and volume criteria for hospitals performing aortic aneurysm surgery and compulsory participation in the Dutch Surgical Aneurysm Audit (DSAA)³. Additionally, criteria were defined for allowing centres to start a program for complex aortic aneurysm surgery. The aortic document was accepted in the general assembly of the D-SVS, but due to a presumed low sense of urgency and a lack of enforcement from both within the D-SVS as well as from outside the vascular community, no significant regionalisation was initiated, in sharp contrast to the synchronous and successful regionalisation process of cancer surgery in the Netherlands.

This resulted in a series of questions at the annual meetings of the D-SVS in 2018, as well as from national health regulatory bodies, and led to increased concern within the D-SVS and its board. Two main issues of concern were identified, based on data from the DSAA. Due to the decline of open abdominal aortic aneurysm (AAA) repair, the yearly volume of open cases had become critically low (< 10) in more than half of the hospitals and mortality outcomes varied significantly between centres. Furthermore, due to the initiation of endovascular aortic programs in many centres, complex endovascular aortic surgery was performed in even lower numbers than open AAA surgery (< 5 per year), basically resulting in decentralisation of complex aortic care. This contrasted with open thoracic and thoraco-abdominal aortic surgery, which traditionally had been centralised to only a few specialised aortic centres.

Hence, the board of the D-SVS initiated the following stepwise process to create a revised “Aortic Consensus Document” using an inclusive bottom up approach.

COLLECT DATA ON VOLUME – OUTCOME RELATIONSHIP AT A NATIONAL AND INDIVIDUAL HOSPITAL LEVEL

Data were retrieved from the DSAA, our nationwide prospective, compulsory, and verified quality registry, in which all patients undergoing primary (j)AAA surgery in the Netherlands have been registered since 2013. From 2016 and onwards, also patients undergoing revisional, thoracic (DTAA) or thoraco-abdominal aortic aneurysm (TAAA) repair have been registered.

Open abdominal aortic aneurysm surgery

Three years data (2016 - 2018) revealed a national mean mortality rate (30 day) of 4.8% for primary infrarenal open AAA repair, however a worrisome variation was noted, especially in mid-sized hospitals, with 11% of hospitals having a mortality rate > 10%. Of 71 hospitals, 57 performed open AAA surgery of which more than half only had an annual volume of less than 10 (range 1 - 99 per three years).

Complex endovascular aneurysm repair procedures

Only the number of complex endovascular aneurysm repair (c-EVAR) procedures (= fenestrated EVAR [FEVAR] / branched EVAR [BEVAR] / thoracic EVAR [TEVAR]) per hospital was obtained from the DSAA (2016 - 2018). Of 71 hospitals, 34 performed c-EVAR procedures, with only a few centres performing the vast majority of c-EVAR (70% of BEVAR procedures were performed by four major aortic centres). Around 50% of hospitals performing FEVAR were doing < 10 cases per three years, 70% of hospitals performing BEVAR were doing < 10 cases per three years, and 40% of hospitals performing TEVAR were doing < 10 cases per three years.

CREATE AWARENESS WITHIN THE DUTCH SOCIETY FOR VASCULAR SURGERY OF THE STATUS OF AORTIC SURGERY IN THE NETHERLANDS AND STIMULATE QUALITY IMPROVEMENT

A summary of volume and outcome of open AAA surgery over a three year period extracted from the DSAA was sent to each vascular surgery department. This was accompanied by a survey asking to reflect on its own practice and results and to suggest measures to improve the quality of aortic surgery in the Netherlands. All vascular surgery departments responded and at the following annual meeting the survey was presented anonymously. The most frequently suggested improvements were: 1. routinely perform open aortic surgery with two vascular surgeons, 2. use of dedicated anaesthetic teams, and 3. regionalisation.

GATHER EVIDENCE ON MINIMUM REQUIRED VOLUMES FOR AORTIC PROCEDURES

Open abdominal aortic aneurysm surgery

In recent years, reports from large datasets, such as the International Consortium of Vascular Registries (178 302 patients)⁴, the UK Hospital Episodes Statistics Database for the Getting It Right First Time Programme (31 829 patients)⁵ and the Australasian Vascular Audit database (14 262 patients)⁶ have demonstrated a hospital or surgeon volume outcome relationship for open AAA surgery. Furthermore, a recent paper reported on centralisation of AAA treatment into 10 selected hospital units with > 30 cases per year in Catalonia (approximately half the size of the Netherlands), which decreased short term mortality after both intact AAA and ruptured AAA repairs (4.7% vs. 2.0%, $p < .001$ and 53.1% vs. 41.9%, $p = .028$; respectively), primarily due to improved outcome of open repair (8.7% vs. 3.6%, $p = .005$).⁷ The latest ESVS AAA guideline recommends an overall minimum volume of open and endovascular AAA repairs of 20 per centre, but preferably > 30.⁸ In the latest analysis of the International Consortium of Vascular Registries an annual centre volume of 13 to 16 open AAA repairs was reported as the optimum threshold associated with the greatest mortality risk reduction after open intact AAA repair.⁴

Complex endovascular aneurysm repair

At initiation of the revision of the “Aortic Consensus Document”, there was no available evidence for a minimum caseload per year in the literature. Moreover, c-EVAR outcomes are usually only reported from centres of excellence. This underlined the necessity to explore volume outcome relationship for c-EVAR. Therefore, a retrospective analysis was performed using DSAA data on volume outcome relationships in fenestrated and branched EVAR and showed a significantly lower mean peri-operative mortality (2.5%) in high volume centres (> 13 cases annually) compared with low volume centres (10% mortality in < 9 cases annually). There was a non-linear association between annual hospital volume and mortality after adjustment for confounders, showing optimal performance for hospitals performing at least 20 cases annually.⁹

USE A BOTTOM UP APPROACH TO GENERATE A NOVEL “AORTIC CONSENSUS DOCUMENT”

The abovementioned data were frequently shared within the D-SVS through different digital channels and general assemblies, emphasising social responsibility, and comparing the current vascular surgery situation with the successful centralisation of cancer surgery. Vascular surgeons (maximum one per hospital) were invited to join the “aortic task force”. This task force of 27 vascular surgeons was divided into two groups (open AAA repair and c-EVAR). Several meetings were organised, mostly digitally due to Covid-19 restrictions, both with the individual groups as well as all together to share and discuss standpoints. After three months, a writing committee

of seven vascular surgeons was formed, representing different hospital settings (non-teaching, teaching, and university). Main discussion points were the minimum required volumes and the obligation to have cardiothoracic surgery availability in hospitals performing thoracic or thoraco-abdominal endovascular procedures. In contrast, rapid consensus was achieved on minimum hospital requirements like advanced imaging possibilities, 24 hour access to open and endovascular care, and intensive care. In the document only pre-defined minimum volumes as dictated by relevant national institutions, such as the Dutch Surgical Society and National Network for Acute Care (10, 20, 40 or 50 interventions per year) could be used. A first revision was performed by the board of the D-SVS. The third and final version of the “Aortic Consensus Document” was discussed and accepted by a large majority in the Annual Meeting of the D-SVS in November 2021 and embedded in a Network Consensus Document.

Requirements to perform open abdominal aortic aneurysm surgery

There was no consensus on a minimum annual hospital volume for open AAA surgery. Therefore, a minimum hospital volume of 40 AAA repairs (open and endovascular) was set to be allowed to perform open AAA repair. With an annual volume of 40 AAA repairs the whole hospital chain would get sufficient exposure to open abdominal surgery, including AAA repair. Furthermore, 40 annual AAA procedures was already the minimum required volume to be allowed to treat ruptured AAA in the Netherlands. For EVAR only, the recommendations of the 2019 ESVS Guidelines⁸ were maintained.

Requirements to perform complex endovascular aneurysm repair

There was agreement that only performing a handful of c-EVAR per year is highly undesirable. In the current document three anatomical categories (juxtarenal AAA, TAAA and DTAA) were defined. For each individual category a minimum annual hospital volume of 10 was set to be allowed to perform endovascular treatment of juxtarenal AAAs, (chEVAR/FEVAR), TAAAs (F/BEVAR) or DTAAAs (TEVAR) respectively. An exemption was made for hospitals performing at least 20 c-EVAR procedures combined in the three above mentioned categories but not reaching a volume of 10 per category (for example eight FEVAR, four BEVAR and eight TEVAR procedures). Although our own research had shown slightly higher numbers as a possible threshold for optimal outcomes, no broad consensus could be reached on a scientifically more robust annual threshold of 20 procedures per anatomical category. However, it is important to understand that agreeing on a minimum annual volume of 10 c-EVAR procedures would already have a significant impact towards regionalisation of c-EVAR. Furthermore, it was agreed that level 1 trauma centres should be allowed to perform urgent TEVAR regardless of their total volume of c-EVAR. Most trauma centres are high

volume vascular centres. Lastly, availability of cardiothoracic surgery was not deemed strictly necessary for thoracic and thoraco-abdominal endovascular interventions, if centres have clear and written agreements in place on collaboration with a cardiothoracic centre for referrals, intervention, and complication management.

Conclusion

Despite available evidence for a volume outcome relationship for both open AAA surgery and c-EVAR, the necessary change of practice towards regionalisation of aortic aneurysm care had been insignificant during the last decade in the Netherlands. However, using data from the national aneurysm audit to define the problem, to stimulate self reflection and generate evidence for regionalisation, and with an inclusive bottom up approach the D-SVS recently created and approved an “Aortic Consensus Document” with clearly defined hospital requirements and minimum annual volumes for open and endovascular AAA surgery and complex EVAR. This agreement will be shared with the national regulatory bodies. Performance and compliance will be evaluated through the national registry and embedded within regional vascular networks.

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