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ESVS POSITION STATEMENT

The ESVS Guidelines Provide a Solid Scientific Basis to Treat Patients with an Abdominal Aorto-iliac Aneurysm in Europe and Beyond

In a recent issue of the *European Journal of Vascular and Endovascular Surgery,* Bradbury *et al.*[1] discussed extensively the process behind the five year long development of the 2020 National Institute for Health and Care Excellence (NICE) guideline for abdominal aortic aneurysm (AAA): diagnosis and management, and exposed, in plain view, the differences between the recommendations in the published version[2] of this guideline and those (previously unpublished) made by the guideline development committee appointed by NICE. Earlier, Powell and Wanhainen[3] analysed the differences between the European Society for Vascular Surgery (ESVS) 2019 clinical practice guidelines on the management of abdominal aorto-iliac artery aneurysms[4] and the official 2020 NICE AAA guideline.[2]

To close any possible controversy, this editorial re-states the official position of the ESVS regarding the management of patients with abdominal aorto-iliac aneurysm, which can be read in detail in its 2019 clinical practice guidelines on this topic.[4] As Powell and Wanhainen have reported, most of the differences in the recommendations between the ESVS and the NICE guidelines for AAA are related to their different methodology and perspectives.

Briefly, NICE guidelines take into consideration only randomised controlled trials (RCTs), grade individual pieces of evidence, have a very strong health economic perspective, and are directed at healthcare practitioners, providers, and patients in the United Kingdom. The NICE guidelines committee is multidisciplinary, with an emphasis on patients being involved in discussions, but does not include vascular specialists using recent technological advances in AAA repair. The latest guidance translates into a lack of support for the use of endovascular techniques for complex or juxtarenal AAA repair and an absence of recommendations regarding the important issue of centre volume for these repairs. In addition, some of the recommendations provided for women in the NICE AAA guideline do not use the most recent evidence or suffer from underrepresentation of women in RCTs.[3]

Using the same grading system as the European Society of Cardiology, the ESVS clinical practice guidelines rate evidence obtained from RCTs as the highest quality (level A if at least two RCTs or a meta-analysis; level B if only one RCT), but also consider data from registries and observational studies (level of evidence C) to formulate recommendations. The individual quality of RCTs or observational studies is not rated, which must be acknowledged as a methodological weakness. ESVS guidelines are developed by experts in their field, who have adequate knowledge to assess new technologies and address a large range of clinical practice questions. This also allows for some recommendations based on expert opinion only (evidence level C). ESVS guidelines aim at supporting best clinical practice in Europe and beyond, acknowledging the wide range of health infrastructure and economic differences, and should be considered as an advisory document, with national adaptations of some of the recommendations to be anticipated.

Several important points should be emphasised. One is the inclusion of data from registries and observational studies to support recommendations in the ESVS guidelines. A vascular registry is not only the best tool for controlling centre and practitioner performance quality, and for allowing continuous quality improvement, but also provides real world evidence. In a high quality registry, all patients are included prospectively, while in most RCTs, the large number of exclusion criteria often results in only a very small proportion of patients being included, representing a study group that may be quite different from the patient group with whom practitioners deal on a daily basis. Obviously, to ensure its optimal quality, a registry should be carefully checked for external and internal validity, to ensure the absence of selection mechanisms that would result in some patients being excluded from the registry and to verify the validity of the data and the proportion of missing data.[5]

Furthermore, registries offer an appropriate tool for the examination of long term outcome, for example when registries are linked to the national database. This is particularly crucial after elective endovascular aortic repair (EVAR) as its risk of long term AAA related death is higher than after elective open surgical repair and persists even 10 years after the primary EVAR.[6] We wish to take this opportunity to re-emphasise the ESVS position statement, which underlines that long term evaluation should be an integral part of the clinical implementation of new vascular treatments.[7]

While recognising that data obtained from RCTs represent the highest level in the pyramid of evidence, we strongly believe that, as appropriate, recommendations in clinical guidelines should also be supported by registries or formulated as expert opinions, as long as any conflict of interest is reported and vetted. To exclude real world

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experience means, for example, that a recommendation to use a parachute when jumping out of an airplane cannot be formulated, as there has not been any RCT comparing the outcomes of people using a parachute with those who did not.

The recommendations on required minimum volume (>20 cases per year — Class I) and on desired minimum volume (>30 cases per year — Class IIa) are another important aspect of the ESVS AAA guidelines, while the NICE AAA guideline does not provide volume recommendations. Indeed, several reports showed, in both crude and risk adjusted analysis, a significant volume outcome relationship after open repair for either intact or ruptured AAA.[8–10] However, the volume effect on in hospital or 30 day mortality is less obvious after EVAR. A volume outcome relationship probably exists after EVAR also, but may only be apparent in long term results.[11]

Volume is probably a proxy measure for a wide range of structures and processes, including surgeon specialisation, staffing levels, number of intensive care beds, and institutional participation in research. Given the weight of accumulated evidence, the question is not whether higher volume vascular centres achieve better results, but why high volume regionalised practices are not being universally adopted internationally? Compliance with guidelines on hospital volumes should be strongly encouraged by national and international surgery societies and their implementation monitored by local regulatory boards, ensuring the safe, efficient, cost effective treatment of the greatest number of patients with AAA.[12]

Numerous other important recommendations formulated in these AAA guidelines could also be re-emphasised, but this is not the purpose of this editorial. To conclude, due to their limited scientific inclusion, the NICE AAA guidelines failed to produce firmly anchored, widely applicable standards, which have led to confusion amongst clinical practitioners. The ESVS clinical guidelines, regularly updated and one of the educational pillars of our scientific society, provide guidance for the delivery of the best possible care to our patients, in Europe and beyond.[13,14]

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