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Beyond the AAA guidelines: core outcome sets to make life better for patients

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The new European Society for Vascular Surgery (ESVS) guidelines on the management of abdominal aortic aneurysms (AAA) were produced by clinicians for clinicians, but for the first time in the history of ESVS guideline production the AAA guideline development process included input from the patients affected by the recommendations [1]. Even from the small patient contribution to these guidelines, and similar patient input to recent AAA repair trials, it is clear that the important outcomes for patients and their relatives may be very different from those usually considered important by vascular surgeons. In the IMPROVE trial it was observed that for patients, getting back home quickly, and without disability, may be more important than survival per se [2]. Time to going home is rarely reported in clinical trials of AAA repair.

It is also evident from reading the new AAA guidelines that there are many recommendations based on weak evidence [1]. From a total of 125 recommendations in the AAA guidelines, only 7 could be supported by enough evidence to assign them as class I, level A. There remains uncertainty for many critical areas that may affect large numbers of patients or vascular services. For example, recommendations for the use of secondary cardiovascular prevention for patients with small AAA (Recommendation 21, class IIa, level B) and the treatment of type II endoleak (Recommendation 88, class IIa, level C) are based on limited/heterogeneous evidence. This is in part because evidence synthesis across different studies is hampered by inconsistent outcome reporting [3].

For these two main reasons, the development of Core Outcome Sets (COS) for Vascular Surgery, applicable across Europe, is needed urgently. COS are collections of key outcomes which should be reported in all studies involving a certain patient group. The means of measuring the selected outcomes also need to be carefully defined using validated tools (e.g. for quality of life) or agree definitions for outcomes such as time to going home. COS need careful scoping before development, including the range of clinical circumstances covered (e.g. all AAA studies versus interventional studies only, elective and/or emergency procedures, with or without re-interventions) and the stakeholders who need to be involved. They are developed using a two-phase process involving an identification phase and a rigorous consensus phase. The identification phase usually involves a systematic review of what outcomes have been used previously, together with a variety of techniques including focus groups and expert panels. The subsequent consensus phase usually employs a Delphi survey, where the level of consensus should be predefined. Key to both of these phases is the involvement of patients in addition to other stakeholders (clinicians, other healthcare professionals and sometimes industry or social care professionals). This is important at the identification phase, as there are an increasing number of examples of where patient identified outcomes which had never been the subject of prior research [4]. The development of a COS for trials in oesophageal resection surgery recently also highlighted the importance of including patients in the consensus phase, where some of the items eventually adopted as essential were voted as not essential by healthcare professionals during the first round of the consensus process [5]. COS have been developed for conditions as diverse as cancer resection, osteoarthritis and pain management [5-7]. Vascular surgeons have been slow to adopt this methodology: the authors were only able to identify two such projects in the COMET (Core Outcome Measures in Effectiveness Trials) database, an international registry of COS development projects [8]. Achieving an agreed international consensus provides an additional challenge but can be accomplished using expert panels and conference workshops.

What benefits would COS for AAA repair and other vascular diseases bring? Primarily this would put patients at the centre of care through focusing the generation of evidence on outcomes that are important to patients, not those that are important to surgeons. The delivery of patient centred care is the foremost task for every doctor, including vascular surgeons. As we have seen in the ESVS AAA

guideline development process and the IMPROVE trial, the needs of the patient are perceived quite differently by vascular surgeons and patients [1,2]. Therefore, there is an urgent need to address this disconnect. Returning to the example above from the IMPROVE Trial [2], comparing outcomes between endovascular and open repair for ruptured AAA, we can conclude that; had the trial restricted reporting to only traditional outcomes such as 30-day-mortality and number of major cardiovascular complications, outcomes of apparently vital interest to the patient with a ruptured AAA, such as returning home quickly without disability, would have been missed. Since patients presenting with AAA are often eligible for a wide range of complex procedures, knowing the priorities of patients in combination with knowledge on a diversity of meaningful outcomes for AAA repair would seem essential in successfully tailoring an AAA repair strategy for each individual patient. Establishing COS for AAA repair that reflect patient priorities will ensure that these outcomes are monitored and assessed in clinical practice, clinical registries and clinical audits as well as in AAA research, effectively putting the patient at the centre of care and aiding decision-making for health professionals.

Concerning implementation of COS in AAA and other vascular research, the benefits of COS documented in other research areas should be expected [9]. Reduced heterogeneity, by ensuring that AAA trials that address similar clinical questions use the same outcomes, will ultimately facilitate evidence synthesis and meta-analyses. Reduction of selective outcome reporting will lead to reduced reporting bias. And lastly, increasing the relevance and impact of AAA trials, through involvement of all AAA stakeholders (patients, care givers and health professionals), will minimise the risk of trials delivering statistically significant findings but with little or no clinical relevance.

Randomised trials are costly and often take many years to report, whilst technology advances rapidly. Given this situation, guidelines will continue to need to synthesize evidence from registry data and observational studies. The use of COS based reporting in such studies would facilitate evidence synthesis and produce better quality evidence for the future.

We suggest that the development of COS should be conducted in parallel with all future ESVS guidelines and hope that such an initiative would be considered sympathetically. For now, we intend to initiate this process with AAA repair and wish to widen the initiative to more countries than the authors of this viewpoint represent.

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