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Controversy continues following final NICE guidelines update

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In the time of Covid-19, pandemic updates have upended the usual election-year news cycle in the United States. Thus many additional newsworthy events, including the release of the long-awaited NICE abdominal aortic aneurysm (AAA) guidelines (https://www.nice.org.uk/guidance/ng156), are passing by largely unnoticed. NICE, an acronym for the National Institute for Health and Care Excellence, is an executive nondepartmental unit of the Department of Health in England. It regularly generates and updates guidelines regarding the optimal use of health technology, as well as clinical practice directives and guidance for social care services and health promotion in the United Kingdom (UK).

NICE was originally established to standardize care provided throughout England by the National Health Service (NHS). It has since developed a well-regarded reputation, particularly in Europe, for rigor in the development of evidence-based clinical guidelines and unsparing assessment of the cost-effectiveness of new technology from the population-health perspective of the NHS, the single payer health system of the UK.

The current guidelines update and contextualize a prior NICE Technology Appraisal of endovascular aortic aneurysm repair, TA167, published in 2009.[1] Moving beyond a focused technology assessment, the guidelines update, entitled NG156, comprehensively addresses all aspects of the evaluation, treatment, and long-term follow-up of AAA disease, with evidence-based recommendations broadly similar to those recently published in Europe[2] and North America.[3] The Guidelines Committee, chaired by Andrew Bradbury, eventually included additional vascular surgeons Alun Davies and Noel Wilson, as well as vascular internists, radiologists, anesthesiologists, geriatricians, nurses, paramedics, and lay members.

The work of the guidelines committee began in March 2015, ultimately encompassing 18 meetings over the next 5 years. Over that period, five original members resigned, including vascular surgeon Matt Thompson, then of St. George's University in London, in 2016. The full history of the process, including the compendium of 24 separate evidence reviews on topics ranging from risk factors predicting the presence of an AAA to managing complications following repair, as well as the remaining supporting documentation, is found at https://www.nice.org.uk/guidance/ng156/history.

Release of the draft guidelines for public comment from stakeholders in 2018 generated considerable controversy regarding recommended methods of AAA repair. Specifically, draft guideline 1.5.3 stated: "do not offer endovascular repair to people with an unruptured infrarenal AAA if open surgical repair is suitable." This was followed by additional mandates to not offer endovascular repair simply on the basis of anatomic complexity or medical comorbidity or for complex AAA repair outside of the auspices of a clinical trial (draft guidelines 1.5.4, 5 and 6, respectively). Endovascular aneurysm repair (EVAR) was recommended only as an alternative for management of ruptured AAA vs traditional open repair, with no specific preference for either method recommended for most patients.

Responses to the draft guidelines were received from dozens of professional organizations, health systems, and medical device manufacturers across the UK, ultimately extending to nearly 700 pages (https://www.nice.org.uk/guidance/ng156/documents/consultation-comments-and-responses-2). Feedback was distilled into 16 distinct themes, ranging from evidence demonstrating an increased perioperative mortality for open surgical repair (OSR), as well as increased theater time (and subsequent expense), hospital stay, and rehabilitation expenses as compared with endovascular repair, to concern regarding how proficiency and familiarity with EVAR for managing ruptured AAA could be maintained by surgeons and centers if all other applications of this technology (elective, complex, etc.) were discouraged.

In their point-by-point response to the comments, the Guidelines Committee consistently defaulted back to their preference for data collected from randomized trials, "… as, despite the efforts the authors of observational studies have made to provide balanced cohorts, randomization remains by far the best defense against confounding." In other words, despite the passage of time, the evolution of devices and practice patterns in relationship to EVAR (eg, overnight or same day surgery, shift to ultrasound vs computed tomography follow-up,

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etc.), the primary data source for these updated recommendations remains the ACE,[4] EVAR-1,[5] DREAM,[6] and OVER[7] trials, the last three of which provide long-term results through 2019. Appendix D includes the hundreds of publications considered but not felt to be sufficiently rigorous for inclusion in this analysis.

To address the temporal limitations of the randomized, controlled trials, more recently acquired registry data, in some cases risk-adjusted, were considered and integrated into revised models evaluating benefit. In nearly every adjusted analysis, however, the additional input did not significantly change the conclusion that EVAR was not a cost-effective method of AAA repair for the NHS system. And, this interpretation is key to understanding these recommendations—for cost-effectiveness modeling, only UK-specific data were incorporated, based on the assessment that the unique financial fundamentals of the NHS preclude consideration of non-UK-derived data. Given their fixed expenses, reliance on in-patient care, etc., the potential for further evolution of standard EVAR to outpatient interventional platforms (as has been recently reported from Canada and elsewhere, for example) would not significantly impact their cost-effectiveness assessment.

Other observations regarding the evolution of EVAR in the last 20 years including progressively shorter hospital stays, advent of percutaneous deployment, and reduced perioperative mortality rates, are countered with the Committee's contention that outcomes for OSR have improved in parallel, negating any relative advantage conferred for EVAR. Or in the case of the advantage in perioperative mortality accompanying EVAR vs OSR in risk-adjusted analyses, "… it should be possible to optimize systems…" (including further centralization of aortic surgery, a process underway now for some time in the UK) "…so that OSR is also associated with a lower perioperative mortality rate" in the future. And, addressing concerns regarding potential lost experience with OSR and expectation of a "new learning curve" if the pendulum swings back to traditional repair, the Committee responded: "… recommendations encouraging a higher volume of OSR practice could be expected to undo any deterioration in results owing to reduced workload, so it would not be appropriate to base recommendations on data that suffer from this effect."

Despite their general refutation of all comments intended to temper their final recommendations, the final versions posted on the NICE website are just that—tempered. Specifically, the recently finalized guidelines stipulate that surgeons and health systems should:

1.5.3: Offer open surgical repair for people with unruptured AAAs meeting the criteria… unless it is contraindicated because of abdominal co-pathology, anesthetic risk, and/or medical conditions;

1.5.4: Consider EVAR for people with unruptured AAAs who meet criteria… and who have abdominal co-pathology, such as hostile abdomen, horseshoe kidney, stoma or other considerations, specific to and discussed with the person, that may make EVAR the preferred option;

1.5.5: Consider EVAR or conservative management for people with unruptured AAAs… who have risks and/or co-morbidities that contraindicate open repair.

Throughout the document, the authors continually refer to the need to "rebalance" the utilization of EVAR vs OSR for AAA management, a process that is underway in Europe and North America for multiple reasons already. It is also apparent, as a result of the development process and the input of the NICE Executive Board in the final revision, that these guidelines have been rebalanced as well, although not apparently with the blessing of the committee itself, which tweeted out their defiant, persistent preference for the original version a few days later at https://twitter.com/doctorhammond/status/1240589428416004097.

In discussions with Tara Mastracci (Royal Free Hospital, London) regarding the ultimate impact of these guidelines on aortic disease management in the UK, she emphasizes two points: (1) this process underscores the duty of surgeons everywhere to keep track of their own results, through registries such as VQI and its VISION project in the United States, to provide an evidence-based response to efforts to limit or macro-manage vascular practice by regulatory or funding agencies in the absence of future large-scale RCTs in this clinical area, and (2) due to ever-increasing resource constraints on health systems worldwide, surgeons need to embrace participation in these exercises to ensure that their patients' perspectives are well represented when multiple considerations (societal, administrative, financial) are in play.

Suffice to say this will not be the last instance, in our professional lifetimes, where adaptation of new vascular therapeutic modalities will generate controversy and contention. As always, our focus on our patients' best interest, given our holistic understanding of their individual needs, preferences, and vulnerabilities, must be our guide.

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