

CORRESPONDENCE

The Awakening of Alice

Over the last 10 years, endovascular treatment of complex aneurysms involving the visceral arteries and thoraco-abdominal aortic segment has attracted considerable interest within the vascular community, while also inevitably raising expectations. Accordingly, the evolution of less invasive technologies for treating a potentially lethal pathology (which generally develops in frail, elderly patients), in conjunction with dramatic improvements in stent graft technology and intraoperative imaging strategies has led to excellent presentations being delivered by clever and skilled pioneers, one consequence of which has been a “temptation” for the rest of the vascular surgical community to follow suit.

In this respect, we feel that the recent Editorial by Verhoeven et al.,¹ despite their expertise in this field, has understated the true lessons to be learned regarding this evolving technology. The Editorial’s basic message was that in order to achieve the best results you must be a highly skilled surgeon, with enormous experience, working in an expert centre with an up-to-date hybrid room, equipped with the best imaging facilities. To prove their point, they quote recently published studies showing excellent short-term results, with a low perioperative mortality (2.4%), almost no endoleaks, and a very high target vessel patency.^{2,3} Faced with these statistics, who could possibly disagree? Unfortunately, the Editorial’s message, albeit seductive, reminds us of Alice in Wonderland, who fell asleep and then started to dream of a wonderful magical world.

The reality, however, and as was observed in the independently controlled Windows trial,⁴ is somewhat different for the following reasons: (1) uncontrolled, self-reported outcomes represent a poorer level of evidence, even if the authors are thorough, honest, and hard working. Put simply, they rarely reflect “real-life results”. (2) Very few institutions have the time, financial resources, or manpower to gather such results. As surgeon’s job is primarily to treat patients and improve surgical management or technology, he may not be aware of patient’s clinical status changes, even when careful follow-up visits are scheduled. (3) We have learned from the Windows Trial that tracking patients was very challenging, with more than 10% of patients being lost within the system, only to be found after protracted searching within academic institutional and/or family doctor records or via either the patients families or the National PMSI database. Of great importance, some of the “missing” patients had died or suffered severe complications that had gone unnoticed by the responsible centres. (4) It is (to us) otherwise too simplistic to explain any less than favourable results by simply blaming the learning curve.

To minimise any chances that the learning curve may have compromised outcomes, the Windows Trial involved (a) anatomical feasibility that was double-checked by an

independent core laboratory and the Cook core laboratory, and (b) clinical technical support by an expert proctoring surgeon was provided wherever necessary. Once the trial was completed, it was found that there was no statistical difference (in terms of mortality) between the two highest volume centres (Lille and Creteil) and the five less experienced ones.⁴

We also strongly believe that there is more to learn from mistakes than from success. The Windows Trial enabled us to identify risky procedures (despite strict selection criteria) and to then find ways of improving results. It also underlined the poor outcomes associated with postoperative renal insufficiency, spinal cord ischaemia, as well as limb and mesenteric ischaemia. Technical strategies have now been developed to prevent these complications, such as high-dose heparin, reducing the volume of contrast injections,⁵ or treating the patients in a two- or three-staged procedure.

From the Windows Trial, we also learned that the rejection rate of potential candidates for FEVAR and BEVAR (by the participating centres) was up to 40%,⁴ raising the difficult question of what should be done for these patients? The authors of the Editorial almost omitted to mention any alternative treatment options such as parallel grafts, chimneys, snorkels, on-table fenestrations (and even open surgery), all of which may offer a successful outcome in difficult or urgent cases. It is also important to be aware that the cost-effectiveness of FEVAR and BEVAR over open repair remains questionable.⁶ Finally, some patients are too frail to undergo even one of these less invasive procedures. A recent paper from Resch et al.⁷ has shown that 54% of patients died during the 10-year period of study, suggesting that “even if we can do it, should we?”

In conclusion, vascular surgeons (such as us) strongly believe in the new development of endovascular approaches for the treatment of complex aortic procedures. However, important lessons must be learnt, and all of the alternative techniques should be mastered before launching such a programme. Otherwise surgeons and patients will face exactly what Alice faced when she awakened: the dull reality.

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Response to “Re: The Awakening of Alice”

It was with great interest that I read the various comments from Jean-Pierre Becquemin and his colleagues in response to our recent editorial.^{1,2} I agree with the authors that it is occasionally difficult to match results produced from high-volume expert centers in the “real world”. Examples include the “Bolia subintimal angioplasty technique” or (more relevant to this debate) the results of open thoracoabdominal aortic aneurysm (TAAA) surgery. However, it is still our primary task to provide the best possible patient care, especially in pathologies that require more complex surgery.

If one wishes to embark on treating TAAAs with fenestrated and/or branched grafts, a number of prerequisites are necessary. These include (i) *dedicated* surgeons who want to *invest* in these techniques in order to acquire much-needed expertise; (ii) *perfect organization* with regard to *logistics*, including access to a *hybrid room*; and (iii) the creation of a *professional team*, including anesthesiologists and nurses. While I agree that not all of these prerequisites require a high-volume center, there should be no doubt that this type of complex pathology is best treated in large-volume centers. There is simply no place for amateur behaviour or inexperienced operators, as even minor technical errors can be costly to the patient, as we have all experienced.

Pioneers have to take new techniques forward and should report their results. In order to help others move forward, we fully agree with the authors that these reports should provide more detail regarding indications, limitations and lessons learned. Fenestrated endovascular aortic aneurysm

repair (FEVAR) has become a standardized technique in our center, with low mortality and excellent midterm results. We also agree that follow-up should be enforced, and the fact that so many patients were not followed up in the Windows trial could be interpreted as a lack of organization and dedication. Our paper on 10 years of experience in TAAA branched grafting concluded that “too high-risk” patients should not be treated at all. Indeed, the highest-risk patients had a higher early mortality and lower survival.³ We also agree that patients who are unlikely to survive for 2 years after their surgery will not (by definition) have benefitted from the repair. Our conclusion in that article was meant to help other centers. Obviously, it is difficult for surgeons to deny a patient treatment when he or she has been referred as “a last resort”, but we have to learn from experience and help others not to make the same mistakes.

It was a little disappointing that the authors considered our published work to be of lower evidential quality (compared with the Windows trial). They have reported that there was no statistical difference in mortality between the two high-volume and the other five centers in the Windows trial, but (by their own criteria) this type of post-hoc analysis is also “lower-quality evidence” as the numbers are too small to enable any meaningful comparison. A non-inferiority study would require about 600 patients in each arm to prove that the lack of difference was not due to a type II error. In other words, the Windows Registry was never powered to prove this statistical difference.

Our caveat emptor editorial was intended to warn colleagues about problems associated with uncritically developing endovascular programmes for treating complex TAAAs and to motivate them to invest more in organization, logistics, and team approaches. Dedicated endovascular teams can perform standard FEVAR after thorough training, even in lower-volume centers. However, for triple and quadruple FEVAR cases, the imaging requirements are clearly higher (longer fluoroscopy times, including lateral viewing) and the operative risks inevitably increase. For cases of branched TAAA, all of the prerequisites discussed above should be met in order to address numerous potential intraoperative complications. It is, therefore, shameful that politics and/or professional organizations are not able (or unwilling) to promote the centralization of treatment for patients with complex aortic pathology. As Holt and Thompson recently stated: “if we fail to centralize complex aortic pathology, we will have failed our patients”.⁴

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