

INVITED COMMENTARY

High Risk and Unfit for Open Repair Are Not the Same

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Fair comparisons choose to compare like with like eg. Bordeaux wine with Bordeaux wine, not Bordeaux wine with champagne. The key issue which emerges from the French registry of endovascular abdominal aortic aneurysm repair in “high risk” patients is the definition of “high risk”. The international disputes over the definitions of “high risk” and “unfit” for open repair make it impossible to compare the different retrospective and registry studies with the results of the EVAR 2 trial of patients unfit for open repair.

EVAR 2 was a properly powered unique randomised controlled trial comparing EVAR and no intervention in patients who were deemed unfit for open repair. The EVAR 2 trialists took a pragmatic approach to fitness for open repair but noted details of respiratory, renal and cardiac risk. The anaesthetists with the surgeons at 41 centres felt that open repair was simply not an option. Therefore it is possible that the majority of EVAR 2 patients would have been classified as ASA IV. We know that some patients randomized to no intervention improved, crossed over to EVAR and did quite well after the delay, whilst others died before intervention. The accent of the trial was to get EVAR performed rapidly to reduce rupture risk and death. The trial results did not show that early intervention with EVAR improved patient survival and the trialists were very surprised at the findings. After a pause, it was realised that the accent should move towards defining and improving fitness. Our findings on this are due to appear shortly in the British Journal of Surgery.¹ The trend is for EVAR to tend to fare better than open repair in terms of operative mortality but benefit of EVAR appears to be greatest in the fittest

patients. Thus, the less fit the patient, the less benefit from EVAR up to the point where in EVAR 2 patients no benefit was found.

In this series by Jean-Baptiste *et al.*² there is some uncertainty how the series was selected with 115 repairs over 5 years and 80% of these classified as “high risk”, although only a small minority, just 18 patients were classified as ASA IV (or similar to the EVAR 2 patients). Most of patients in the series were more similar to the EVAR 1 trial patients and this observation is supported by the 3-year survival rate of 85%. In the EVAR 2 trial, the 3-year survival rate was only 50%. There was no patient randomization and no control group and although the term “intention to treat” is used, this was not a properly conducted trial and excluded patients have not been mentioned.

Those who are unhappy about the results of the EVAR 2 trial, and there are many, should not try and undermine the results by comparing their wine (high risk patients from registries and single centre cohorts) with the champagne of EVAR 2 (randomized controlled trial of unfit patients). To further this debate we need internationally accepted guidelines for fitness evaluation, probably through application of a fitness scoring system, such as we have discussed and applied to the EVAR trial patients.^{1,3}

The contention of the French paper² is therefore not accepted and EVAR 2 remains unfortunately unique in the global experience.

References

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