Response to Letter from Prof. Legemate Regarding “Number needed to treat: analyzing of the effectiveness of thoracoabdominal aortic repair” by Miller et al.

We thank Professor Legemate for his comments regarding the paper by Miller et al. but feel we must respond to his criticism of the ESVS’s and the EJVES’s decision to accept the paper, respectively, for presentation and publication. With regard to the ESVS meeting, each submitted abstract is scored blindly by up to six people who are either members of the EJVES Editorial Board or EJVES reviewers with a good ‘track record’. As Miller’s abstract was scored among the top 35 submissions, it was accepted for oral presentation. The degree to which an abstract reflects the accompanying paper varies as does the skill of those that write the abstracts. However, I question whether a more elaborate process, perhaps involving submission of an extended abstract or the full paper, is actually feasible, when picking out the approximately the top 10% for presentation. Concerning acceptance for the journal of papers presented at annual meeting, they are sent to three reviewers the same as any other paper submitted for the journal. The explicit critique raised by Prof. Legemate on the use of historic data and the lack of details regarding survival data, was also raised by the reviewers. The paper was accepted upon revision, as I felt data represented the best available. Here I would like to emphasise, that the decision of accepting a paper for the journal, is with the editor alone.

Neither the board nor the reviewers decide—they advise.

I thank Prof. Legemate for drawing the attention to these selection processes and excuse the delayed response.

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Prof. Legemate1 identifies the use of remote historical controls, whose characteristics are divergent in several ways from our population, as a fundamental methodological flaw, which renders our findings ‘both misleading and meaningless’. We considered the issues of historicity and match at length before we submitted the abstract, and we debated this point with commentators from the audience in Dublin and with reviewers of the manuscript in the publication process. We freely admit that the match with our cohort is less than ideal, but we reiterate our point that the study of Bickerstaff2 and colleagues represents the best evidence we will ever have about the natural history of thoracic/thoracoabdominal aortic aneurysm.

Fundamentally, Prof. Legemate’s criticism is about quality of evidence, and it is based on the generally accepted evidence-based medicine doctrine that clinical trials represent the ultimate in clinical research evidence. This is generally true, but is not so in this case.

Watchful waiting clinical trials in vascular surgery are different than the kinds of clinical trials that evidence-based guidelines hold in highest esteem. The difference is that the natural history of aortic aneurysms is widely enough understood that equipoise is disrupted when aneurysms reach a certain threshold, and surgical treatment—the treatment being studied—is extended to patients in the non-surgical group. That is to say, vascular surgery trials are never run out to the bitter end (e.g. Lederle3). Crossover triggers involve aneurysm size and rate of expansion, which have been shown to increase risk of rupture, and the crossovers are used for ethical, rather than scientific, reasons. How have size and rate of expansion been shown to increase risk? By observational natural history studies, such as the one we used for our comparison. Therefore, we have clinical trials—which reside at the top of the evidence hierarchy—that have crossover rules based on ‘impure’ observational data. It is a peculiar irony that, when we compute number needed to treat using the kind of data that force crossover to surgery in clinical trials, we are taken to task for not using data from clinical trials!