INVITED COMMENTARY

Selection Bias and Endoleaks: Can We See Through the Fog?

Frederico Bastos Goncalves [*]

Centro Hospitalar Universitário de Lisboa Central/NOVA Medical School, Lisbon, Portugal

In the current issue of *EJVES*, Nolz et al. provide details on a study of risk prediction for type I or III endoleaks using combined baseline clinical and anatomical parameters.[1] The concept is naturally appealing: if one could use available pre-operative characteristics to determine the risk of important complications such as direct endoleaks, decision making and informed consent would be improved. However, this cannot be adequately demonstrated by the present study.

While it is clear that anatomical characteristics influence risk, we also know that even patients with excellent anatomy develop direct endoleaks. Sometimes no good reason is apparent, but often the cause can be traced to planning or procedural details. Our group has previously shown that optimising the iliac seal zone can reduce graft retraction, excessive dilatation, and consequent endoleaks.[2] Nolz et al. show us that type Ib endoleaks occur most frequently on the left side, which is possibly explained by the fact that the left iliac artery is usually shorter. Detailed work on seal zones by Schuurmann et al. revealed that the proximal optimal positioning of the endograft is achieved in fewer than half of cases, even considering the centre's experience in endovascular aneurysm repair.[3] The conclusion is that pre-operative anatomy is only part of the issue. Demographic characteristics may also influence survival and abdominal aortic aneurysm (AAA) related risk. However, the findings that age and female sex increase risk of direct endoleaks after correcting for confounders has not been demonstrated by several other studies, including randomised controlled trials.

More importantly, the design of this study significantly limits the results. Almost half of eligible patients were excluded. The consequent bias makes everything foggy. Firstly, the exclusion of patients with early endoleaks results in leaving out the highest risk group. The only possible argument for that strategy is follow up stratification by restricting imaging, as suggested in the guidelines.[4] Even

then, it seems odd to exclude early endoleak patients, as these endoleaks are highly clinically relevant and tend to recur. Additionally, only those with computed tomography angiography (CTA) follow up were included, potentially excluding patients considered to be at lower risk (followed by duplex ultrasound only) or having medical conditions precluding CTA. Another important limitation is sample size: in total, there are only 24 events registered in the study. This results in wide confidence intervals and makes the multivariable model unreliable for risk prediction.

Despite the interesting results, there is no great novelty and the risk of bias is large. Reinforcing this is the fact that traditional and well characterised risk factors, such as neck length, neck diameter, and AAA diameter, were not found to be relevant factors. In conclusion, the study by Nolz et al. requires confirmation and should not yet influence current practice. However, it does promote the attractive concept of combining demographic and anatomical factors to improve risk prediction after EVAR.

REFERENCES

1 Nolz R, Schoder M, Baltzer P, Prusa A, Javor D, Loewe C, et al. Application of baseline clinical and morphological parameters for prediction of late stent-graft-related endoleaks after endovascular repair of abdominal aortic aneurysm. *Eur J Vasc Endovasc Surg* 2019;**58**:24–32.
2 Bastos Gonçalves F, Oliveira NF, Josee van Rijn M, Ultee KH, Hoeks SE, Ten Raa S, et al. Iliac seal zone dynamics and clinical consequences after endovascular aneurysm repair. *Eur J Vasc Endovasc Surg* 2017;**53**:185–92.
3 Schuurmann RCL, Overeem SP, Ouriel K, Slump CH, Jordan Jr WD, Muhs BE, et al. A semiautomated method for measuring the 3-dimensional fabric to renal artery distances to determine endograft position after endovascular aneurysm repair. *J Endovasc Ther* 2017;**24**:698–706.
4 Wanhainen A, Verzini F, Van Herzeele I, Allaire E, Bown M, Cohnert T, et al. European society for vascular surgery (ESVS) 2019 clinical practice guidelines on the management of abdominal aorto-iliac artery aneurysms. *Eur J Vasc Endovasc Surg* 2019;**57**:8–93.