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INVITED COMMENTARY

Great Power Brings Great Responsibility: Some Thoughts About a Promising Approach to Standardised Data Assessment in Registry Studies

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Behrendt et al. have generated a lucid core set of items specific for acute limb ischaemia (ALI), which could enable standardised data collection in vascular surgical registries.[1] This cooperation is a promising approach towards creating a comparable framework for the assessment of "big data" gained from prospective registries, leading to more reliable and valid results. Furthermore, these criteria may be used as an objective benchmark to evaluate each registry in which they are used.

From our perspective, it is the efforts made thus far to facilitate the consensus decision between experts from 15 different countries following the Delphi protocol that should be stressed. However, there are some relevant limitations as mentioned by Behrendt et al. that require discussion. All efforts to realise such a consensus should lead eventually to more reliable and valid results in registry studies. Hence, each consensus recommendation that might be applied to reach this desirable aim must be verified critically, as each could be a source of bias in itself.

The current study should be seen as a cornerstone of an ongoing process, leading to improved evidence in future vascular registries, which could narrow the gap between fiction and truth. As mentioned, the consensus is mainly based on the opinion and experience of colleagues from Europe and the United States. Colleagues from Asia, Australia, and South America, whose contribution is urgently required to create a complete image of the medical treatment reality of acute or chronic limb ischaemia, should be involved in future. Regarding the methodology of the consensus protocol, the participation of two or more external scientists as additional "critical voices" could be considered. By implementing external quality control, the risk of observer bias, which is relevant in the non-blinded setting of the consensus process, especially during the last panel of the Delphi Consensus process, could be minimised.[2] It would be desirable to involve the patients' point of view by including different patients' interest groups in the decision making process.[3]

Finally, following the title of our invited commentary, we believe that Behrendt et al. and all participants bear a great responsibility. The relevance and validity of so called "big data" for healthcare research are under debate.[4] Consequently, the authors' project requires continued critical self evaluation, as it will legitimately have a relevant impact on subsequent vascular surgical research.

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