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Invited commentary: Validation is the key to success in registry-based outcome research

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This issue includes a unique paper, the first validation of the abdominal aortic aneurysm (AAA) module of the Portuguese National Registry of Vascular Procedures (RNPV), by Gonçalo Araújo et al.[1] Ever since the creation of the Vascunet collaboration at the ESVS meeting in Lisbon in 1997, it has become clear that the standardisation of definitions and variables as well as the validity of the data, are key factors for the scientific value of quality improvement registries in vascular surgery.[2] The strength of registry-based research is not only based on the fact that large numbers of patients can be included, limiting the risk of type II statistical error.

It is a common misconception that large numbers per se results in high quality research. This misconception reached epidemic proportions during the COVID-19 pandemic when large numbers of non-validated case reports from random centres or physicians were merged, in the misbelief that this added anything substantial to science.[3] Another even more important strength is the fact that the registries are population based, avoiding selection bias, which has haunted surgical research since its beginning. In most single or multicentre studies there is a selection of large academic referral centres, often with a special interest in the subject of the publication, as well as publication bias, since inferior results are seldom published.

The first phase when creating a national vascular registry is to discuss with your peers, both within the country or region, and internationally, in order to define the variables. It is especially important to focus on core variable set that is compatible with the variable set used in registries in other countries, allowing for international comparison. However, the best may turn out to be the enemy of the good, since a too laborious registration will affect inclusion rates negatively.

The second phase is to make as many units as possible to join. There are always some units that hesitate to join, with different arguments such as “What is in it for us?”. When the Swedvasc registry started it was the largest units in Stockholm and Gothenburg, and a remote hospital in the North, who joined last. When a large proportion of the units (70%?) have joined, however, it becomes very suspicious not to participate. “Are they afraid of reporting their poor outcomes?”

Once most (preferably all) units have joined comes the third phase, which is mainly about quality improvement. Here the registry works like a self-playing piano. Per definition, half of the units, and half of the surgeons, perform below average. No one wants be below average, and different strategies how to improve the results are considered. In Sweden we experienced how the district hospitals more often considered to refer the high-risk cases to the University hospitals. This was an ideal approach and resulted in similar results in both categories of hospitals. The patients were the winners!

The RNPV registry has passed these first phases long ago. But what has been experienced in most of the registries collaborating within the Vascunet is that at about this time, the need for validation becomes urgent. When you start to compare your results, you need to be sure that all operated patients were actually registered (external validity), and that the variables (in particular key outcomes, but also risk factors such as co-morbidities) were entered in a correct way (internal validity).

This paper[1] reports the internal validity of the perioperative data and immediate postoperative results. Those results are mandatory, whereas the follow-up data at one and five years (including death) are left at the discretion of participating centres and investigators. As a consequence, follow-up data beyond 30 days were not validated. The variables in the RNPV registry are very similar to those collected in other vascular surgical registries, and follow the recommendations made by the Vascunet collaboration.[4,5]

This first validation is a very important step forward. The methodology is well described in the paper and includes a selection of four centres. This selection “was based on their availability to participate, their geographic

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distribution across the country, and their expected case volume, ensuring a feasible and representative validation process". Some previous validations within the Vascunet have chosen to select the units at random,[6] and at least not to reveal well in advance which units that were to be validated, in order to keep all the units prepared for a possible validation, however, this is not always possible, due to planning and logistical reasons. At each unit, however, 15 operations were selected at random for the internal validation procedure. The outcome of the validation must be regarded as excellent, and we do congratulate our Portuguese colleagues for having established such an excellent registry!

In the future, however, it would be great if also the external validity (completeness) could be evaluated. Ideally, comparison of the vascular registry data with national administrative data from the patient registry should be performed annually or with regular intervals. In Sweden we compared the Swedvasc with the Patient registry, which is used for reimbursement and for statistical reasons, on multiple occasions.[6,7] Very few cases were missing. In the international validation performed by colleagues from the UK and Finland: the external validity was 100% for carotids and 98.8% for AAAs[6], which felt reassuring when comparing results from different units. A more recent international validation of the Swiss registry showed similar results, demonstrating that the Swissvasc registry data was clearly superior to local administrative data.[8]

A recent nationwide study from Portugal on open versus endovascular repair of complex AAAs demonstrated the strength of compiling high quality registry data to advance vascular surgery.[9] The study is an excellent example showing that we have come a long way since the Vascunet was established in Lisbon in 1997. However, there is a long road ahead, and we are excited to see more research from the RNPV registry in the future.

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REFERENCES

1. Araújo G, Ribeiro TF, Queiroz Sousa G, Henriques M, Machado P, Bastos Gonçalves F. Internal validation of the Portuguese National Registry of Vascular Procedures – abdominal aortic aneurysm module. Angiol Cir Vasc 2026;22 :22-9

2. Mani K, Björck M. Alternatives to randomised controlled trials for the poor, the impatient and when evaluating emerging technologies. Eur J Vasc Endovasc Surg 2019;57:598-599.

3. Björck M. Collaborative research: population based data and validation are necessary. Br J Surg 2022;109:578-9

4. Altreuther M, Grima MJ, Lattmann T. International Validation Of Vascular Registries - The VASCUNET Validation Template. Eur J Vasc Endovasc Surg 2023; 66:438-9.

5. Grima MJ, Ancetti S, Pherwani AD, Gonçalves FB, Budtz-Lilly J, Behrendt CA et al. VASCUNET/ICVR AAA collaborative group. Standards for Abdominal Aortic Aneurysm Repair Quality Improvement Registries: A Delphi Consensus Report From VASCUNET and the International Consortium of Vascular Registries. Eur J Vasc Endovasc Surg. 2025; 69:516-21.

6. Venermo M, Lees T. International Vascunet validation of the Swedvasc Registry. Eur J Vasc Endovasc Surg 2015; 50: 802–8.

7. Troëng T, Malmstedt J, Björck M. External validation of the Swedvasc registry. A first-time individual cross-matching with the unique personal identity number. Eur J Vasc Endovasc Surg 2008; 36: 705-12.

8. Altreuther M, Grima MJ. Editor's Choice - International Validation of the Vascular Registry of Switzerland, Swissvasc: A VASCUNET Report. Eur J Vasc Endovasc Surg. 2025; 69:350-6.

9. Ribeiro TF, Quintas A, Soares Ferreira R, Ferreira ME, Bastos Gonçalves F. Nationwide Outcomes of Open versus Endovascular Repair for Complex Infrarenal Neck, Juxtarenal, and Pararenal Abdominal Aortic Aneurysm in Portugal. Eur J Vasc Endovasc Surg 2025; 70:336–43.