

RESEARCH LETTER

International Validation Of Vascular Registries — The VASCUNET Validation Template

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Quality registries are used increasingly for surveillance and quality improvement in vascular surgery in many countries, as well as for international studies.¹ Internal and external validity are crucial if registry data (or any other research data) are used in any analysis or comparison study.² The international registry collaboration VASCUNET has therefore conducted validation of participating registries and developed a template for internal and external registry validation. External validation assesses the completeness of registration, that is if all operations performed in the actual category (e.g., carotid surgery, abdominal aortic aneurysm surgery) at the actual site are registered. Internal validation assesses whether the variable values in the vascular registry are complete and correct, in accordance with the hospital record.

VASCUNET has previously performed registry validations for the Hungarian vascular registry in a pilot study³ and validated vascular registries in Sweden,⁴ Denmark,⁵ and Malta.⁶ In these studies, external validity was found to be between 97% and 100%,^{2–5} while internal validity showed some variation between the variables, with lower validity for smoking status, and higher validity for peri-operative complications and outcomes. The results of these validations are highly valuable, as they show, which variables are valid enough to allow further analysis and comparison between studies. The results also highlight the importance of repeated validation studies. The VASCUNET validation method was developed and refined during the different validations, and the aim of this communication is to describe the validation process.

A vascular registry that is going to be validated in the following year is chosen during the VASCUNET annual meeting held during springtime. A research subgroup made up of a few VASCUNET members, independent from the registry to be validated, is then tasked to draw the validation process of the actual registry based on the VASCUNET template. The hospitals to be validated are chosen in dialogue between the representative of the

vascular registry and the validators. There is no official standard operating procedure. However, the selection of the specific procedures and the hospitals to be validated is performed with the aim of obtaining the best possible overview of registration completeness and correctness in the actual area. The results of the validation are available to the local registry representatives, to allow correction of missing or erroneous data.

Vascular registry data are compared with the hospital administrative data. The registry data file is provided by the vascular registry, while hospital administrative data are provided by the hospital administration. All procedures in the actual category and time period are included in external validation. The data must include procedure or operation codes, date of surgery, and a patient identifier to allow crosslinking of the data sets. The external validity of the registry is defined as the percentage of the total number of operations in the actual category that is captured in the registry. External validity is assessed separately in the different categories. Registrations which are only in the administrative files or only in the registry are double checked by the local representative in the patient's record and categorised as true missing (the operation was performed but not registered) or incorrect registration (the operation was registered, but not performed). An example for the result of an external and internal validation is shown in Table 1. An example for analysis of the reasons for mismatch between administrative data and registry data can be found in Table 3 in the publication about the validation of the Danish Vascular registry Karbase.⁵

For internal validation, a random sample of 15 cases per category (e.g., carotid surgery) is chosen. For these cases, variables from 15 to 20 data fields, preferably the most relevant for the category, are checked manually against the patient records. Variable values from the registry are compared with data in the patient records. To honour ethical practices, a licensed doctor from the chosen hospital, who is blinded for the registry data, looks up the variables in the patient records. Possible results for the variable comparison are correct, incorrect, or missing variable value

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Table 1. Example for external and internal validation of the Danish vascular registry Karbase in three hospitals.⁵

Procedure	Hospital			Total
	1	2	3	
Carotid surgery				
Total number of procedures	97	48	86	231
Procedures in administrative data	97	45	85	227
Procedures in Karbase	97	48	85	230
Missing procedures in administrative data	0	3	1	4
Missing procedures in Karbase	0	0	1	1
External validity carotid surgery	100%	100%	98.8%	99.6%
Abdominal aortic aneurysm surgery				
Total number of procedures	107	238	231	576
Procedures in administrative Data	106	187	221	528
Procedures in Karbase	105	207	224	536
Missing procedures in administrative data	1	32	21	54
Missing procedures in Karbase	2	0	7	9
External validity abdominal aortic aneurysm surgery	98.3%	100%	96.9%	98.4%
Carotid surgery				
Patients reviewed	15	15	15	45
Total variables	285	285	285	855
Missing data from hospital records	1	1	2	4
Missing data in Karbase	5	3	15	23
Data discrepancy between Karbase and hospital records	11	10	20	41
Internal validity carotid surgery	96.1%	96.5%	93%	95.2%
Abdominal aortic aneurysm surgery				
Patients reviewed	15	15	15	45
Total variables	240	240	240	720
Missing data from hospital records	2	6	4	11
Missing data in Karbase	0	1	1	2
Data discrepancy between Karbase and hospital records	9	8	4	21
Internal validity abdominal aortic aneurysm surgery	96.3%	96.7 %	98.3%	97.1%

Data are presented as *n*, unless stated otherwise. Validity is presented as a percentage.

in the registry. Internal validity for each variable is defined as the percentage of correct variable values in the registry. An example for results of the internal validation of the Danish vascular registry is available in the fourth table in the actual publication.⁵

Previous validations of vascular registries have shown an external validity of over 97% and internal validity of over 95%, confirming that the actual registries are a reliable source for information and quality improvement. However, there remains a long way to go before all member registries have been validated. Funding and the necessary workforce may prove a challenge particularly for large registries. The next registry to be validated with the presented method will be Swissvasc — the vascular surgery registry of Switzerland.

Finally, validation of registry data is not a one time action but must be performed regularly to ensure that the best possible quality data is used for contemporary studies.

CONFLICT OF INTEREST

None.

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