Vascular Registries

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Editor's Choice – International Validation of the Vascular Registry of Switzerland, Swissvasc: A VASCUNET Report

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WHAT THIS PAPER ADDS

Validated registries are critical for surveillance and quality control in vascular surgery. Studies based on high quality national registries describe population based outcomes well. Comparisons of these outcomes with randomised trials provide an insight into the generalisability of the trial results. Internal and external validity of registry data, however, are paramount for a meaningful comparison. The VASCUNET collaboration has an established template for registry validation, which was used for validation of the Swiss vascular registry, Swissvasc. The analysis showed excellent external ($\geq$ 99%) and good internal validity for aortic (94.4%), carotid (92.8%), and infra-inguinal bypass procedures (90.1%) registered in Swissvasc.

Objective: Data validity and completeness are essential for registry data, and a meaningful interpretation of differences between countries can only be made if the data are robust within each of the countries. Therefore, the VASCUNET collaboration has performed validation of several vascular registries and so far published the validation results of national vascular registries of Sweden, Denmark, and Malta. The findings of the validation of the Swissvasc Registry, the vascular registry of Switzerland, are presented here.
Methods: Five of 34 hospitals participating in Swissvasc were visited by two international validators. Independent evaluation of the procedures of carotid endarterectomy, infrarenal abdominal aortic aneurysm (AAA) repair, and bypass surgery for lower extremity arterial disease (LEAD) was performed. Local administrative data and Swissvasc Registry data were compared for external validation, as well as registry data of 15 randomly picked cases within each group with data from individual patient records for internal validation.
Results: Hospital administrative data identified 265 carotid, 399 AAA, and 399 LEAD procedures, whereas Swissvasc identified 265 carotid, 398 AAA, and 395 LEAD procedures. Four LEAD procedures were found in hospital administrative data but not in Swissvasc. External validity was 100% for carotid, 99.8% for AAA, and 99% for LEAD. In internal validation, 5.2% of the variable data were missing in Swissvasc, and 2.4% were different from data in patient records, resulting in external validity of 92.8% for carotid, 94.4% for AAA, and 90.1% for LEAD.
Conclusion: The VASCUNET template was used for international validation of registry data and demonstrated that Swissvasc is a reliable system of quality data collection for the participating vascular centres, with excellent external validity and good internal validity. Quality of the Swissvasc registry data was clearly superior to local administrative data.

Keywords: Abdominal aortic aneurysm, Carotid surgery, Lower extremity arterial disease, Quality improvement, Validation, Vascular registry
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INTRODUCTION

VASCUNET is a collaboration of vascular registries within the European Society for Vascular Surgery (ESVS). The collaboration strives to study contemporary practices in different countries and healthcare systems, and possibly improve outcomes.[1,2] Since the first VASCUNET meeting in Lisbon in 1997, many registries have joined. Currently, VASCUNET comprises more than 40 members from 26 different nations (https://esvs.org/vascunet/). Similarly, in the USA, the Society for Vascular Surgery Vascular Quality Initiative (SVS-VQI) was developed in 2011.[3] Subsequently, the International Consortium of Vascular Registries (ICVR), a

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coordinated registry network within the Medical Device Epidemiology Network, was founded as an amalgamation of VASCUNET and SVS-VQI.[1] VASCUNET and the ICVR have published several studies assessing international practice patterns and outcomes for surgical treatment of vascular disease, including abdominal aortic aneurysm (AAA), carotid endarterectomy (CEA), peripheral arterial disease, popliteal aneurysms, and lower limb amputations.[4–13]

To allow international quality registry collaboration and the development of high quality outcome registry studies, data variables need to be harmonised, whilst data collected and shared need to be true and complete to avoid selection bias.[13,14]

To assess data validity in participating registries, VASCUNET has developed a distinct methodology for independent evaluation of registries.[15] This methodology was pioneered in the validation of the Hungarian vascular registry,[16] and was later repeated in the international validation of the Swedish vascular registry[17] as well as the vascular registries in Denmark[18] and Malta.[19] The present study is part of the ongoing VASCUNET project of systematic validation of national registries in the network. The Swiss vascular registry, Swissvasc, is the fifth national vascular registry to be validated within VASCUNET. This report presents the findings of the Swissvasc validation.

MATERIALS AND METHODS

The Swissvasc Registry was founded in 1999, and data capture and registration started in 2004. Swissvasc is a matrix system and collects data on all vascular operations performed by vascular surgeons, including, but not limited to, CEA, varicose vein surgery, arteriovenous fistula for dialysis access, and amputations. All university hospitals in Switzerland and eight cantonal (i.e., regional) hospitals have participated since 2004. At present, 34 public and private hospitals participate. Participation in the Swissvasc Registry is not mandatory; however, comparison of registry figures and the Swiss national health authority statistics[20,21] show that 85 – 95% of vascular operations in Switzerland are captured (Supplementary Material S1). Registration is web based. Operation data are entered by the operating vascular surgeon, whereas discharge data are entered by administrative personnel or study nurses. All hospitals have electronic access to their own data. A formal national validation has not yet been undertaken, except for one region (Canton Zürich), in which external validation for AAA, CEA, carotid artery stenting, and endovascular aortic aneurysm repair (EVAR) was undertaken together with the local authorities. Swissvasc publishes an annual report that includes all participating centres, as well as an overview of the volumes, patient demographics, and some quality indicators.

Validation of the Swissvasc Registry for 2022 (from 1 January 2022 to 31 December 2022) was performed by independent validators (M.A. and M.J.G.), who visited five of the hospitals in Swissvasc. The three validated modules were CEA for carotid artery stenosis, open surgical repair and EVAR for AAA, and infrainguinal bypass operations for lower extremity arterial disease (LEAD). The hospitals were selected randomly, but in a way that allowed validation on a single visit, while at the same time capturing a relatively high proportion of surgical operations carried out in Switzerland. The selection of hospitals was influenced by what was technically possible to carry out within one week, which implies that the hospital can be reached from Winterthur within one to two hours by train, to leave sufficient time on site for the validation. Winterthur was chosen as a base, as the VASCUNET annual meeting 2023 was held in Winterthur. Larger hospitals, such as the three university hospitals (Zürich, Bern, Basel), were chosen to maximise the proportion of operations that were validated. Although most of the private hospitals that carry out CEA, AAA repair, and infrainguinal bypass surgery for LEAD participate in Swissvasc, the validated hospitals were only public hospitals. The hospitals were notified in advance, which was necessary for the preparation of administrative data files and registry data files for comparison. The log trail, however, was available for the validators to confirm that data were not corrected after the hospital was informed about the visit.

The hospitals included in the validation were Kantonsspital St Gallen, Inselspital Bern, University Hospital of Zürich, University Hospital of Basel, and Kantonsspital Winterthur. External and internal validation were performed for each hospital.

External validation

For external validation, the Swissvasc data were compared with hospital administrative data. Swissvasc data were provided by the national registry representative (Dr Thomas Lattmann), while hospital administrative data were provided by the respective hospital administration services. Data included operation codes, date of surgery, and the patient's identity code.

The external validation was performed by crosslinking the patient's identity codes and actual operation codes between hospital records and Swissvasc data. For cases of missing data or mismatch, the electronic patient record was used by the local representative to check which information was correct.

Internal validation

For internal validation, a random sample of 15 carotid cases, 15 AAAs, and 15 LEAD cases was chosen by the validators at each hospital. This was a practical necessity, as time and resources to validate all cases were limited. The website calculator.net was used to randomise anonymised patient identifier numbers. Variable values from 14 data fields for carotid cases, 18 data fields for AAA cases, and 20 data fields for LEAD cases were manually checked against the electronic patient records. The data fields that were checked in internal validation are presented in Table 1. The results were categorised as correct match, mismatch, or missing variable value in the registry. Data discrepancy was calculated as the sum of missing and mismatch variables in the registry.

Table 1. Data fields compared for internal validation (n = 5 hospitals).

Carotid endarterectomy	Abdominal aortic aneurysm (AAA)	Lower extremity arterial disease (infrainguinal bypass)
Sex	Sex	Sex
Age – year of birth	Age – year of birth	Age – year of birth
Smoking	Smoking	Smoking
Diabetes	Diabetes	Diabetes
	Creatinine	Creatinine
		Cardiac insufficiency
	AAA diameter	Ischaemic heart disease
	AAA type of operation	
	AAA planned or unplanned	
Operation date	Operation date	Operation date
Operation code	Operation code	Operation code
Operation side		Operation side
Clinical problem (indication)	Clinical problem (indication)	Clinical problem (indication)
Vascular pathology		Vascular pathology
Endarterectomy method	Technical approach (open repair/EVAR)	
Prosthetic material		Prosthetic material
	Operation time	
Clavien–Dindo*	Clavien–Dindo*	Clavien–Dindo*
Stroke po		
		Re-operation
	Discharged to	Discharged to
Date of follow up	Date of follow up	Date of follow up
		Major amputation

AAA = abdominal aortic aneurysm; EVAR = endovascular aortic aneurysm repair; po = post-operatively.
* In hospital death is covered by the Clavien–Dindo classification of complications (variable value, 5 = deceased). For AAA and lower extremity arterial disease, death is also available through the Discharged to variable with a specific variable value (0 = deceased).

RESULTS

The visited hospitals covered 32.2% (265/822) of carotid artery procedures, 41.6% (399/959) of AAA operations, and 39.6% (399/1 007) of LEAD operations within the Swissvasc registry in 2022. Swissvasc covers 85 – 95% of vascular operations performed in Switzerland (Supplementary Material S1), based on comparison with figures from the Swiss national health authority statistics.[20,21]

External validation

The search identified 265 patients who underwent CEA in the five hospitals in 2022. In the Swissvasc registry, 266 entries were found, of which one was an exploration of the carotid artery, which was excluded (regarded as an extraction or filter issue). All other patients were found in the Swissvasc registry. External validity for CEA in the Swissvasc registry was 100%. Four of the patients were not in the administrative data file, which in all cases was due to filter issues, and four patients were reported with an incorrect operation date in the administrative data.

The total number of AAA operations was 399 in the five hospitals during 2022. Only one of the AAA procedures was not found in the registry, resulting in an overall external validity of 100% for AAA in the Swissvasc registry. In the administrative data, eight entries were missing, which may be due to filter issues, and coding errors were found in 15 cases.

The total number of infrainguinal bypass operations was 399 in the five hospitals during 2022. Four procedures were not found in the registry, resulting in an external validity of 99% for the Swissvasc registry. Ten procedures were missing in the hospital administrative dataset, and coding errors were found in 13 cases.

A detailed overview of the results of the external validation for CEA, AAA, and LEAD (infrainguinal bypass) procedures are presented in Table 2. An overview of the reasons for missing and coding errors are presented in Table 3.

Internal validation

Internal validation was carried out on 15 carotid, 15 AAA, and 15 LEAD cases at each hospital. Altogether, 210 data fields for carotid cases, 270 data fields for AAA, and 300 data fields for LEAD cases were checked at each hospital, adding to a total of 3 900 data fields. In 204 (5.2%) of the data fields, data were missing in Swissvasc. In 95 (2.4%) of the data fields, the information in Swissvasc was different from information in the patient records. Altogether, data discrepancy for carotid cases was 76 (7.2%) of 1 050 variables, while data discrepancy for AAA cases was 75 (5.6%) of 1 350 variables. and data discrepancy for LEAD cases was 148 (9.9%) of 1 500 variables. The internal validity for Swissvasc was 92.8% for carotid cases, 94.4% for AAA cases, and 90.1% for LEAD cases. A summary of internal validation results is presented in Table 4.

Most of the internal validity issues were due to missing variables in all subgroups, whereas true data discrepancy, when the registered variable value is different from the

Table 2. **External validity in the five hospitals.**

Variable	Hospital					Total
	1	2	3	4	5	
Carotid endarterectomy						
Total procedures	31	41	99	15	79	265
Procedures in ADM data	31	39	98	15	78	261
Procedures in Swissvasc	31	41	99	15	79	265
Missing procedures in ADM data	0	2	1	0	1	4
Missing procedures in Swissvasc	0	0	0	0	0	1
External validity of Swissvasc – %	100	100	100	100	100	100
Abdominal aortic aneurysm						
Total procedures	52	142	79	79	47	399
Procedures in ADM data	52	142	76	79	42	391
Procedures in Swissvasc	52	141	79	79	47	398
Missing procedures in ADM data	0	0	3	0	5	8
Missing procedures in Swissvasc	0	1	0	0	0	1
External validity of Swissvasc – %	100	99.2	100	100	100	99.8
Lower extremity arterial disease (infrainguinal bypass)						
Total procedures	52	104	87	45	111	399
Procedures in ADM data	52	104	87	43	103	389
Procedures in Swissvasc	52	104	86	86	108	395
Missing procedures in ADM data	0	0	0	2	8	10
Missing procedures in Swissvasc	0	0	1	0	3	4
External validity of Swissvasc – %	100	100	98.8	100	97.3	99

Data are presented as numbers unless otherwise stated. ADM = hospital administrative data; Swissvasc = Swiss vascular registry.

Table 3. **Reasons why patients were identified in administrative data but not in Swissvasc and *vice versa* ($n = 5$ hospitals).**

Hospital number	Swissvasc	Administrative data
Carotid endarterectomy		
1	All registrations correct; no missing entries	All registrations correct; no missing entries
2	All registrations correct; no missing entries	Two missing entries; one due to filter issue, one true missing
3	All registrations correct; no missing entries	One patient missing, possible filter issue; four operations with incorrect operation date
4	All qualifying operations recorded and no missing entries; one extra miscoded operation in the registry	All registrations correct; no missing entries
5	All registrations correct; no missing entries	All registrations correct; one missing entry owing to discharge the following year, therefore not in file
Abdominal aortic aneurysm		
1	Two registrations with wrong operation code; no missing entries	Six registrations with incorrect code; no missing entries
2	Three registrations with incorrect code; one missing entry; one miscoded operation in addition in the registry	57 code mismatches compared with registry. In most cases registry coding was correct; no missing entries
3	One entry with missing date; one entry with missing operation code; no missing entries	Ten entries with incorrect operation code; two entries with incorrect operation date; three missing entries
4	One entry with incorrect operation code; no missing entries	11 entries with incorrect operation code; no missing entries
5	All registrations correct; no missing entries	12 entries with incorrect operation code; five missing entries
Lower extremity arterial disease (infra-inguinal bypass)		
1	All qualifying operations recorded and no missing entries; one extra miscoded operation in the registry	Two extra miscoded operations in ADM data
2	All registrations correct; no missing entries	Five extra operations in ADM data owing to a filter issue
3	All registrations correct; one missing entry	Five extra operations in ADM data due to coding issues
4	All registrations correct; no missing entries	Two missing entries in ADM data; six extra entries owing to coding issues
5	All registrations correct; three missing entries	Eight missing entries in ADM data

ADM = hospital administrative data.

Table 4. Internal validity in the five visited hospitals.

Variable	Hospital					Total
	1	2	3	4	5	
Carotid endarterectomy						
Patients reviewed	15	15	15	15	15	45
Total variables	210	210	210	210	210	1 050
Mismatch with hospital records	7	2	7	5	1	22
Missing data in Swissvasc	1	40	0	2	11	54
Data discrepancy between Swissvasc and hospital records	8	42	7	7	12	76
Internal validity – *n/N* (%)	202/210 (96.2)	168/210 (80.0)	203/210 (96.7)	203/210 (96.7)	198/210 (94.3)	974/1 050 (92.8)
Abdominal aortic aneurysm						
Patients reviewed	15	15	15	15	15	45
Total variables	270	270	270	270	270	1 350
Mismatch with hospital records	6	8	8	1	1	24
Missing data in Swissvasc	0	22	1	0	28	51
Data discrepancy between Swissvasc and hospital records	6	30	9	1	29	75
Internal validity – *n/N* (%)	266/270 (98.5)	240/270 (88.9)	261/270 (96.7)	269/270 (99.6)	241/270 (89.3)	1 275/1 350 (94.4)
Lower extremity arterial disease						
Patients reviewed	15	15	15	15	15	45
Total variables	300	300	300	300	300	1 500
Mismatch with hospital records	10	6	4	26	3	49
Missing data in Swissvasc	8	22	3	26	40	99
Data discrepancy between Swissvasc and hospital records	18	28	7	52	43	148
Internal validity – *n/N* (%)	282/300 (94.0)	272/300 (90.7)	293/300 (97.7)	248/300 (82.7)	257/300 (85.7)	1 352/1 500 (90.1)

Data are presented as numbers unless otherwise stated.

value reported in the patient record, was rare (approximately 2%). Six entries for post-operative stroke after CEA were missing in the registry; however, in the actual cases, no transient ischaemic attack or stroke was reported in the patient records. A detailed overview of the internal validation results is presented in Supplementary Tables S1 – S3.

DISCUSSION

Complete and valid data are crucial for quality registries, and certainly a prerequisite for monitoring the outcomes of vascular operations and quality improvement.[14,22] Like other VASCUNET registries, Swissvasc regularly publishes outcome analyses including quality indicators for every unit. This is essential to identify undesired variation in results, which can be addressed with quality improvement projects.

In the present study, the Swissvasc registry showed outstanding external validity, with only five of 1 063 cases that were not reported to the registry, one AAA operation, and four infrainguinal bypass operations. Data collection is only required by law in the Zürich Canton. Therefore, this excellent result is probably due to the organisation of the registry, with administrative personnel being responsible for the registration of vascular operations and cross checking registrations with the administrative files. Four cases were missed by the administrative data owing to coding errors, indicating that the authorities could validate and improve their administrative data by cooperation with registries.

Internal validity was $\geq$ 90% for Swissvasc, which is slightly lower than the figures for Swedvasc (97% for carotid and 96% for AAA operations) and Karbase (95% for carotid and 97% for AAA operations) validation.[17,18] With a few exceptions, the detected data discrepancies were below 10%, and without indication for a systematic pattern for the missing data. More importantly, only 2% of the checked variables showed a mismatch between the registry data and data in the patient records. Therefore, the Swissvasc Registry is a reliable source for quality indicators. Clearly, it would be desirable to reduce the number of missing entries to further improve the data source for registry based studies.

Independence of the validators is critical for an unbiased validation process;[16] therefore, validators from other countries were selected to validate Swissvasc. One of the validators (M.A.) is fluent in German, thus there were no language issues concerning the validation.

Limitations

The proportion of operations that was covered in the validation was 32% of carotid procedures, 42% of AAA procedures, and 40% of infrainguinal bypass procedures performed in the participating hospitals in 2022. Although it was not possible to cover all hospitals (public and private), the authors have no reason to believe that the outcome would be different if all hospitals were analysed.

Furthermore, the number of hospitals was higher than for the Karbase validation, thus capturing more patient data. In addition to carotid and AAA surgery, infrainguinal bypass surgery (for LEAD) novel validation was included, resulting in an increased workload and indeed very close to the capacity limit of the validators.

Validation was performed as a manual process, which can lead to erroneous results due to human errors. An attempt to limit human error was made by ensuring that both validators checked each other's work and kept a record of all work and changes. An automated electronic external validation of registry data against national inpatient data may be possible,[23] but not internal validation, because patient data are often unstructured in an older electronic patient record system and extraction of the correct parameters would be extremely challenging. Artificial intelligence may have the potential to address these complex issues in future validations; however, suitable tools are yet to be developed.

Conclusion

The external validity for Swissvasc for 2022 was 100% for CEA and AAA, and 99% for LEAD cases. The internal validity for Swissvasc for 2022 was 93% for carotid cases, 94% for AAA cases, and 90% for LEAD cases. Validation of LEAD in Swissvasc is novel and may serve as a model for future LEAD validations. Ongoing validation and revalidation of registries is highly important for any publication based on registry data, like the VASCUNET and ICVR based studies, as data validity is a prerequisite for any reliable analysis of vascular operations and outcomes.

CONFLICT OF INTEREST

None.

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2024.10.016.

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COUP D'OEIL

Managing Phlegmasia Cerulea Dolens in a Rare Combination of Vascular Anomalies

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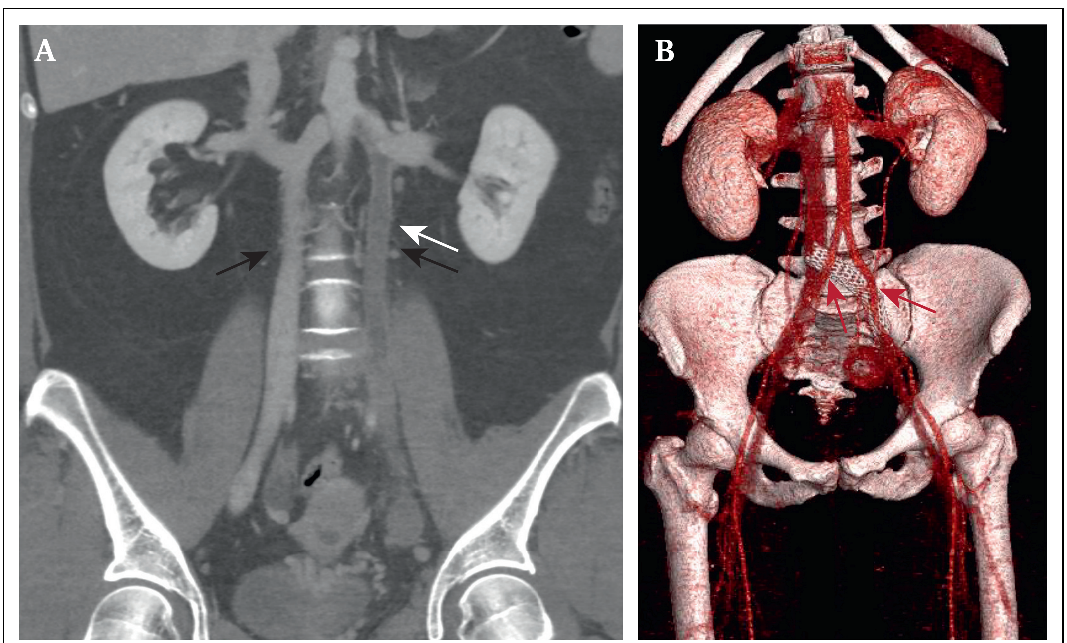

A 45 year old woman, who was a smoker and obese, presented with phlegmasia cerulea dolens. Venous computed tomography showed a duplicated inferior vena cava (IVC) (A, black arrows) with compression at the left iliocaval and right iliac communicating vein (B, red arrows), indicative of May–Thurner syndrome, alongside an extensive deep vein thrombosis (A, white arrow). Urgent pharmacomechanical thrombectomy followed by catheter directed thrombolysis was performed. Persistent inadequate left IVC drainage required balloon dilation and stenting, restoring venous flow through the right IVC (B). At one year follow up, the stent remained well positioned and patent (B), revealing typical venous anatomy.

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