

International Validation of the Danish Vascular Registry Karbase: A Vascunet Report

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WHAT THIS PAPER ADDS

High quality national registries describe population based outcomes, and comparison of these with outcomes of randomised trials gives important information about the generalisability of the trial results. However, internal and external validity of registry data is crucial for a meaningful comparison. The Vascunet collaboration has started validation of the participating registries, and this study reports the results of the third validation. Two independent validators investigated the Danish vascular registry, Karbase. The analysis shows excellent (>95%) internal and external validity for aortic and carotid procedures registered in Karbase.

Objectives: Vascunet has previously published an international comparison of registry data within vascular surgery. Data validity and completeness in participating registries is essential for a meaningful interpretation of differences between countries. The Vascunet collaboration has therefore developed a methodology for validation of international vascular registry data, previously used for validation of two national registries. This study aimed to assess the internal and external validity of the Danish vascular registry, Karbase, by independent Vascunet validators.

Methods: Three of seven hospitals performing vascular surgery, covering 51% of carotid operations and 78% of abdominal aortic aneurysm (AAA) repairs in Denmark in 2016, were visited by two international validators. Independent evaluation was performed of carotid endarterectomy and AAA repair. Local administrative data were compared with Karbase registry data. External validation compared the numbers of cases in these two systems of data collection. Internal validation compared data accuracy and completeness with individual patient records.

Results: Hospital administrative data identified 227/231 carotid and 522/576 abdominal aortic aneurysm (AAA) procedures, whereas Karbase identified 230/231 carotid and 567/576 AAAs. External validity was 99.6% for carotids and 98.4% for AAAs. In internal validation, 1.0% of variables were missing in hospital data whereas 1.7% were missing in Karbase. Data contained within the data fields of Karbase and hospital data were the same in 95.2% (95% CI 91.6–98.8%) for carotids and 97.4% (95% CI 95.4–98.8%) for AAAs.

Conclusions: This study used the Vascunet template for international validation of registry data and demonstrated that Karbase is a reliable system of quality data collection for Danish vascular surgery, especially regarding endpoints. Data quality in the Karbase registry was clearly superior to local administrative data.

Keywords: Abdominal aortic aneurysm, Carotid surgery, Quality improvement, Validation, Vascular registry

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INTRODUCTION

Vascunet is an international registry collaboration, initiated to support quality improvement in vascular surgery through international quality registry collaboration. The Vascunet collaboration was initiated over 20 years ago, at the ESVS

meeting in Lisbon in 1997 and involves national and regional vascular surgical registries in Europe and Australasia. Several studies assessing international practice patterns and outcome for surgical treatment of vascular disease have been performed by Vascunet, including abdominal aortic aneurysms (AAA), carotid endarterectomy (CEA) and stenting, peripheral artery disease (PAD), popliteal and internal iliac artery aneurysms, as well as amputations.^{1–11}

Two key components of international quality registry collaboration involve validity of data, and harmonisation of

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data variables.^{10,12} The Vascunet group and the international consortium of vascular registries (ICVR) have developed minimum datasets for quality registries in AAA, carotid disease, and PAD to establish a basis for data harmonisation.^{13,14} For the validity of the data, there are two key questions: Are all cases recorded in the registry (external validity)? Are the recorded data complete and correct (internal validity)? To assess data validity in participating registries, Vascunet has developed a distinct methodology for independent evaluation of quality registries. This methodology was pioneered in the validation of the Hungarian vascular registry,¹⁵ and was recently repeated in the international validation of the Swedish vascular registry.¹⁶ The current study is part of the Vascunet project of systematic validation of national registries in the registry network. The Danish vascular registry, Karbase, is the third national vascular registry to be validated within Vascunet. The current report presents the findings of the Karbase validation.

MATERIALS AND METHODS

The Karbase registry was founded in 1989, as a co-operation of local registries. In 1996, a central registry was established, and the whole population of Denmark was covered by it. The local hospitals are responsible for data collection and entry into the registry database. The registry has been developed over the years, and now contains more than 190 000 procedures. Registration of vascular operations is mandatory. The registry reports and evaluates performance of all vascular centres using a set of quality indicators, that are published openly online and in the annual reports.¹⁷ Surgeon specific results are only available locally, and not published, similar to the practice in the Swedvasc registry.

The validation of the Karbase registry was performed by two independent validators (M.A., G.M.). The validators visited three of the seven hospitals in Karbase. The hospitals were picked randomly by the validators, but in a way that allowed validation on a single visit, and notified four weeks in advance, which was necessary for preparation of administrative data files and registry data files to be compared.

The hospitals included in the validation were Aarhus University Hospital, Odense University Hospital, and Rigshospitalet. All hospitals were visited by both validators (M.A., G.M.). Both external validation and internal validation were performed for each hospital. All actual procedures were included in external validation, while internal validation was performed for 15 randomly picked patients in each hospital, therefore 95% CI were only calculated for internal validation.

External validation

In external validation the Karbase data were compared with the hospital administrative data. The Karbase data were provided by the national representative of the Danish registry (Nicolaj Eldrup), while the hospital administrative data were handed over by the hospital administration. All the required information was available for all patients operated

Table 1. Data fields compared for internal validation: Karbase against in hospital electronic patient records

CEA	AAA
Sex	Sex
Age	Age
Smoking	Smoking
Diabetes	Diabetes
Operation date	Operation date
Operation code	Operation code
Operation side	AAA diameter
Indication for operation	AAA type of operation
Degree of stenosis	AAA ruptured/non ruptured
Shunt	AAA planned/unplanned
Enderterectomy method	Blood loss
Cardiac complications	Cardiac complications
Nerve injury	Renal failure
TIA post-op	Limb ischaemia
Stroke post-op	Abdominal compartment
Re-op bleeding	30 day mortality
Re-op other	90 day mortality
30 day stroke and death	Survival days
Survival days	

In each participating hospital a random Karbase sample of 15 carotid cases and 15 abdominal aortic aneurysm was checked against electronic patient records.

AAA = abdominal aortic aneurysm; CEA = carotid endarterectomy; TIA = transient ischaemic attack.

on for carotid artery stenosis and for AAA in the three visited hospitals from 1 January 2016 until 31 December 2016. Data included all operation codes both for carotid and endovascular and open AAA procedures, date of surgery, and the patient's identity code.

The external validation was performed by cross linking the patient's identity codes including the operation date between hospital records and Karbase data both on carotid operations and on infrarenal aortic aneurysm procedures.

Internal validation

For internal validation, a random sample of 15 carotid cases and 15 AAA cases was chosen by the validators at each hospital. Variable values from 19 data fields for carotid cases and 16 data fields for AAA cases were checked manually against the electronic patient records. Table 1 shows the data fields that were checked in the internal validation. Possible results for the check were correct, incorrect, or missing variable value in the registry. The data discrepancy was calculated as the sum of missing and incorrect variables in the registry.

RESULTS

The visited hospitals covered 51% of the carotid artery procedures (231/450) within the Karbase registry in 2016, and 78% (576/735) of the AAA operations.

External validation

The data search identified 231 patients who underwent carotid procedures in the three hospitals in 2016. Overall,

five patients were not found in the Karbase registry, but after a thorough check it was revealed that two patients were in the registry with a different carotid code. In two patients the operation was cancelled, so the administrative data were incorrect and only one patient was really missing in the registry. Four of the 231 patients were missing in the hospital administrative records. External validity for carotid procedures in the Karbase registry was 99.6%. [Table 2](#) shows a detailed overview of the results of the external validation for carotid procedures.

The total number of AAA operations was 576 in the three hospitals during 2016. Thirty-four of the AAA procedures were not found in the Karbase registry, but the number of real missing cases was only nine. Twenty-three patients had incorrect procedure codes in the administrative data, one patient was registered with an incorrect operation date in the administrative dataset, and one patient was not a Danish resident and therefore could not be registered, as Karbase allows only registration of patients with a Danish national identification number ([Table 3](#)). Fifty-four procedures in the Karbase registry were missing in the hospital administrative dataset. The nine real missing procedures resulted in 98.4% external validity for AAA procedures in the Karbase registry.

Internal validation

Internal validation was performed on 15 carotid and 15 AAA cases at each hospital. Altogether, 855 data fields for carotid cases and 810 data fields for AAA cases were checked. Fifteen data fields (1.0%) were missing in patient records, while 25 data fields (1.6%) were missing in Karbase. In 37 cases, the information in the data fields in Karbase was different from information in the patient records. Altogether, data discrepancy for carotid cases was 41 of 855 variables, whereas data discrepancy for AAA cases was 21 of 810. The internal validity for Karbase was 95.2% for carotid cases and 97.4% for AAA cases. [Table 4](#) shows a summary of the internal validation results.

Table 2. External validity in the three hospitals

	Hospital			Total
	1	2	3	
<i>Carotid</i>				
Total number of procedures	97	48	86	231
Procedures in ADM data	97	45	85	227
Procedures in Karbase	97	48	85	230
Missing procedures in ADM data	0	3	1	4
Missing procedures in Karbase	0	0	1	1
External validity of Karbase	100%	100%	98,8%	99.6%
<i>AAA</i>				
Total number of procedures	107	238	231	576
Procedures in ADM data	106	187	221	528
Procedures in Karbase	105	207	224	536
Missing procedures in ADM data	1	32	21	54
Missing procedures in Karbase	2	0	7	9
External validity of Karbase	98.3%	100%	96.9%	98.4%

AAA = abdominal aortic aneurysm; ADM = administrative dataset.

Most of the internal validity issues for AAA were for smoking status (9/45) and aneurysm diameter (7/45), whereas the most frequent discrepancy for carotid cases was related to indication for surgery (stroke or TIA; 6/45). The endpoints used as quality indicators by Karbase included 30 day mortality for AAA and 30 day mortality and stroke for carotid surgery. There were two missing entries for post-operative TIA or stroke in the registry; however, in the actual cases, there was no TIA or stroke reported in the patient records. Mortality in Karbase is obtained from the population registry and therefore 100% reliable. [Supplementary Tables S1–S4](#) give a detailed overview of the internal validation results.

DISCUSSION

Data completeness and validity are the key issues for quality registries, as they are crucial for reliable conclusions on vascular operations and outcomes.^{12,18} If this is accomplished, international audit, based on the results of everyday practice can be performed. Complete and valid data in the national registries enable the Vascunet collaboration to conduct population based international outcome analysis. There is growing acceptance in favour of the publication of outcomes, mostly at unit level, and the position that unit outcomes should be treated as classified information is hardly defensible.

Usually, one would want to validate various types of hospitals; however, the Danish vascular surgery service is highly centralised with only seven units performing vascular surgery, of which four are university hospitals, two are central hospitals, and one is a local hospital. Consideration was made of including the local hospital into the validation, but it was decided not to because the caseload was much lower, allowing validation of a much smaller proportion of all cases in external validation.

Validation is not a once only activity, and must be repeated at regular intervals, preferably with both national and sometimes international validators. At present, many registries do not have an established protocol for validation of registry data against all possible sources, and this study may be helpful in developing standard validation protocols for vascular and other registries.

In this study, the Karbase registry had excellent external validity, with only a few cases that were not reported to the registry. The main discrepancy in this validation process was related to cases that were present in the Karbase registry, but not in the local administrative data. This was possibly because the actual files were working files for the local administration. Most of the discrepant entries were not found in the national administrative file when the discrepancies were double checked. For future validations, use of national hospital episode statistics rather than local administrative data may be preferable.

Internal validity was over 95% for Karbase, which is comparable to the figures for the Swedvasc validation.¹ With a few exceptions, the detected data discrepancies were not important for quality indicators, or outcome

Table 3. The reason why patients were in administrative data but not in Karbase (A) and vice versa (B)

	A (missing in Karbase)	B (missing in Administrative data)
<i>Carotid</i>		
Hospital 1	2 patients coded PAK 21, but in Karbase registry for carotid	Coded PAF 21 in both cases no missing
Hospital 2	2 patients apparently missing, but operations cancelled – error in administrative data	3 patients missing
Hospital 3	1 patient missing	1 patient missing
<i>AAA</i>		
Hospital 1	14 coding issue 2 patients missing	1 patient missing
Hospital 2	1 coding issue 1 operation date wrong in admin data no missing	32 patients missing
Hospital 3	8 coding issue 7 patients missing 1 non-Danish resident (cannot be registered)	21 patients missing

AAA = abdominal aortic aneurysm; PAK and PAF = operation codes.

Table 4. Internal validity of Karbase in the visited hospitals

	Hospital			Total
	1	2	3	
<i>Carotid</i>				
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	96.1%	96.5%	93%	95.2%
<i>AAA</i>				
Patients reviewed	15	15	15	45
Total variables	270	270	270	810
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	96.7%	97.0%	98.5%	97.4%

AAA = abdominal aortic aneurysm.

analysis, ensuring reliable results regarding quality indicators for the Karbase registry. However, the missing data for post-operative TIA and stroke are serious, as this may result in incorrect results for quality indicators. There is a potential for improving outcome data validity by checking for relevant entries in other registries, such as the stroke registry or the national administrative registry. This implies data transfer between different sources with person identifiable data, and a manual check against electronic patient records in case of conflicting data, which obviously is resource demanding and generates data security challenges that must be addressed. However, the importance of correct results regarding quality indicators cannot be overemphasised.

As Venermo and Lees pointed out, the independence of the validators is a prerequisite for unbiased results in the

validation process; therefore, validators from different countries were chosen to visit Denmark. One of the validators (MA) is fluent in the Norwegian language, which is very similar to Danish, thus there were no language issues concerning the validation. The number of hospitals was lower than for the Swedvasc validation; however, the proportion of operations in the actual year that was covered was larger, with approximately half of the carotid procedures, and close to 80% of the AAA procedures performed in Denmark in 2016 being part of the external validation. The hospitals were notified four weeks in advance; however, there was a considerable mismatch between local administrative and registry data, which equally surprised the local staff and the validators, indicating that improvement of the registry data before the validation is improbable.

The validation of the Karbase registry showed excellent external validity and good internal validity at the three hospitals that were validated. The registry is a reliable source of information for quality assessment of AAA and carotid intervention in Denmark, regarding indication, procedures, and outcomes. Based on this experience, the following is recommended to the Karbase registry. (The present authors are aware of the similarity to the recommendations given to the Swedvasc registry; however, given the similarity of the actual registries and operations this is not surprising.) Procedure codes for identification of operations in administrative data and in the registry should be identical. A national agreement on coding practice is a prerequisite; however, this may be challenging. Sometimes, multiple indications exist (e.g. aortobifemoral graft in a patient with both AAA and lower limb ischaemia due to iliac stenosis), and sometimes the correct module or indication is not obvious (e.g. recurrent intervention on AAA post EVAR from type 1b endoleak – this can be recorded as aneurysm treatment or as treatment for a failing graft). Data fields used for calculation of quality indicators should be scrutinised regularly and validated against all available sources.

The Karbase registry is already engaged in an effort to harmonise variables internationally, and further work in this field is highly recommended.

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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.2019.04.008>.

REFERENCES

- 1 Lees T, Troëng T, Thomson IA, Menyhei G, Simo G, Beiles B, et al. International variations in infrainguinal bypass surgery - a VASCUNET report. *Eur J Vasc Endovasc Surg* 2012;**44**:185–92.
- 2 Vikatmaa P, Mitchell D, Jensen LP, Beiles B, Björck M, Halbakken E, et al. Variation in clinical practice in carotid surgery in nine countries 2005–2010. Lessons from VASCUNET and recommendations for the future of national clinical audit. *Eur J Vasc Endovasc Surg* 2012;**44**:11–7.
- 3 Mani K, Lees T, Beiles B, Jensen LP, Venermo M, Simo G, et al. Treatment of abdominal aortic aneurysm in nine countries 2005–2009: a Vascunet report. *Eur J Vasc Endovasc Surg* 2011;**42**:598–607.
- 4 Menyhei G, Björck M, Beiles B, Halbakken E, Jensen LP, Lees T, et al. Outcome following carotid endarterectomy: lessons learned from a large international vascular registry. *Eur J Vasc Endovasc Surg* 2011;**41**:735–40.
- 5 Björck M, Beiles B, Menyhei G, Thomson I, Wigger P, Venermo M, et al. Editor's choice: contemporary treatment of popliteal artery aneurysm in eight countries: a report from the Vascunet collaboration of registries. *Eur J Vasc Endovasc Surg* 2014;**47**:164–71.
- 6 Behrendt CA, Sigvant B, Szeberin Z, Beiles B, Eldrup N, Thomson IA, et al. International variations in amputation practice: a VASCUNET report. *Eur J Vasc Endovasc Surg* 2018;**56**:391–9.
- 7 Budtz-Lilly J, Björck M, Venermo M, Debus S, Behrendt CA, Altreuther M, et al. Editor's Choice - the impact of centralisation and endovascular aneurysm repair on treatment of ruptured abdominal aortic aneurysms based on international registries. *Eur J Vasc Endovasc Surg* 2018;**56**:181–8.
- 8 Budtz-Lilly J, Venermo M, Debus S, Behrendt CA, Altreuther M, Beiles B, et al. Editor's Choice - assessment of international outcomes of intact abdominal aortic aneurysm repair over 9 years. *Eur J Vasc Endovasc Surg* 2017;**54**:13–20.
- 9 Mani K, Venermo M, Beiles B, Menyhei G, Altreuther M, Loftus I, et al. Regional differences in case mix and peri-operative outcome after elective abdominal aortic aneurysm repair in the Vascunet database. *Eur J Vasc Endovasc Surg* 2015;**49**:646–52.
- 10 Mitchell D, Venermo M, Mani K, Björck M, Troeng T, Debus S, et al. Quality improvement in vascular surgery: the role of comparative audit and Vascunet. *Eur J Vasc Endovasc Surg* 2015;**49**:1–3.
- 11 Laine MT, Björck M, Beiles CB, Szeberin Z, Thomson I, Altreuther M, et al. Few internal iliac artery aneurysms rupture under 4 cm. *J Vasc Surg* 2017;**65**:76–81.
- 12 Venermo M, Mani K, Kolh P. The quality of a registry based study depends on the quality of the data - without validation, it is questionable. *Eur J Vasc Endovasc Surg* 2017;**53**:611–2.
- 13 Behrendt CA, Bertges D, Eldrup N, Beck AW, Mani K, Venermo M, et al. International consortium of vascular registries consensus recommendations for peripheral revascularisation registry data collection. *Eur J Vasc Endovasc Surg* 2018;**56**:217–37.
- 14 VASCUNET Collaboration Website: <https://vascunet.org/>.
- 15 Bergqvist D, Björck M, Lees T, Menyhei G. Validation of the VASCUNET registry. A pilot study. *Vasa* 2014;**43**:141–4.
- 16 Venermo M, Lees TA. International validation of the Swedvasc registry. *Eur J Vasc Endovasc Surg* 2015;**50**:802–8.
- 17 Karbase website (annual reports available in Danish): <http://www.karbase.dk/>.
- 18 Björck M, Mani K. Publication of vascular surgical registry data: strengths and limitations. *Eur J Vasc Endovasc Surg* 2017;**54**:788.