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Internal validation of the Portuguese National Registry of Vascular Procedures – abdominal aortic aneurysm module

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ABSTRACT

INTRODUCTION: Medical registries are key tools for monitoring healthcare quality. In 2019, the Portuguese Society of Angiology and Vascular Surgery (SPACV) launched the *Registo Nacional de Procedimentos Vasculares* (RNPV), to collect nationwide data on vascular surgical procedures within the Portuguese healthcare network. The initial chapter focused on abdominal aortic aneurysms (AAAs) and has been in existence for five years. The value of interpreting such data is directly tied to its validity and completeness. Therefore, we aim to present the findings of the first internal validation of the RNPV–AAA module.

METHODS: Four of the 20 institutions included in the RNPV were visited by three independent validators. Data from procedures performed between 2021-2022 for AAA were evaluated. Registry data from 27 variables of 15 randomly selected cases per centre were compared with data from individual patient records for internal validation. The primary endpoint was internal validity. Secondary endpoints were data discrepancy and missing data.

RESULTS: Sixty AAA cases across 4 institutions, totalling 405 data fields per centre and 1620 data fields across all cases, were compared with the original registration. An internal validity of 96.0% was observed. Overall, 1.1% data fields were missing, and 3.0% of data discrepancies were observed. Baseline characteristics (4.6%) presented the highest rate of mismatch, followed by procedure-related (3.6%) and outcome data (1.4%). Mismatch was more common in continuous data, with 15.0% mismatch in pre-operative creatinine and 16.7% in the largest aortic diameter. Follow-up data (not included in this internal validation) were missing in up to 54% of patients.

CONCLUSION: The first validation of the RNPV–AAA chapter revealed reassuring results with a high degree of correspondence. Although conducted across a comprehensive set of variables, the missingness in long-term data remains noteworthy. Continuous data are more likely to be related to mismatched records, though the clinical implications are uncertain. Further external validation is anticipated.

Keywords: Registries; Validation; Vascular Surgery; Abdominal Aortic Aneurysms.

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INTRODUCTION

Medical registries are important tools for monitoring healthcare quality, practice patterns and clinical outcomes for multiple diseases. They represent an essential tool for benchmarking and quality improvement. Findings arising from this data can drive positive improvements in healthcare systems and, ultimately, patient outcomes. For vascular surgeons, the VASCUNET consortium, founded in Lisbon in 1997, remains one of the most relevant structures addressing this topic.[1] Notably, the Portuguese Society of Angiology and Vascular Surgery (SPACV) joined this endeavour in 2019, following the creation of Registo Nacional de Procedimentos Vasculares (RNPV). It aims to capture nationwide data on patients undergoing vascular surgical procedures across the Portuguese public and private healthcare. The initial module focused on abdominal aortic aneurysms (AAA), and in 2022, a module covering the treatment of extracranial cerebrovascular disease was created.[2-4]

The value of interpreting and acting on this data is directly tied to its validity and completeness. To ensure this, we sought to perform internal validation of the RNPV–AAA module using the methodology outlined in the VASCUNET Validation Template.[5] To date, no prior formal publication has addressed the internal validity of the RNPV–AAA module. Although a preliminary assessment was included in a previous publication by Ribeiro et al., a structured internal validation according to the VASCUNET methodology has not yet been reported.[6]

METHODS

RNPV Setting

RNPV is a voluntary, population-based registry with nationwide coverage that captures patients treated for vascular diseases by vascular surgeons on the mainland of Portugal and in the autonomous islands. It includes dedicated modules on AAA and extracranial carotid disease. Currently, in the former, 19 institutions (with an estimated nationwide coverage of 90%) are included, including public and private for-profit centres.[2] All university hospitals adhered to the registry since its inception.[2,3]

Participants of the RNPV - AAA module

The AAA module of the RNPV includes patients submitted to both elective and urgent degenerative aortoiliac aneurysm repair involving the abdominal aorta (Crawford extent 4 thoraco-abdominal aortic aneurysms [TAAA], pararenal, juxtarenal and infrarenal aorto-iliac aneurysms). Crawford extent 1-3 TAAA, isolated iliac artery aneurysms without aortic involvement and aneurysms of non-degenerative aetiology are excluded. Isolated common iliac aneurysms were suitable for inclusion when the disease involved or the repair encompassed the infrarenal abdominal aorta.[4] Procedures for endoleak or to improve sealing after EVAR are also excluded. Participating centres acquired local ethics committee approval before inclusion in the registry. Willing patients signed a pre-specified informed consent for participation.

Database and data source

In this registry, a list of predefined variables is routinely collected, encompassing demographic characteristics, operative details, short-term (30-day and in-hospital) and long-term (up to 5-years) outcomes. Baseline data includes date and mode of admission (urgent/elective), age, gender, comorbidities defined according to ICD-10 (diabetes mellitus, cardiac, pulmonary and cerebrovascular disease), and other baseline characteristics (ASA classification, aneurysm extent, maximum aortic aneurysm diameter, surgical indication, prior aortic surgery, proximal and distal neck angulations and diameter).[7]

Surgical details include the type of repair (open surgical repair [OSR] or endovascular repair), clamp location in OSR, specific endovascular technique (EVAR, EVAR + IBD, F/BEVAR), stent-graft brand, model, configuration and dimensions, proximal and distal sealing lengths, adjunctive procedures, estimated intraoperative blood loss and intraoperative complications. Also, there is room for manual reporting (as free text) of other potentially relevant intra-operative occurrences.

Thirty-day (short-term) outcomes include need for re-operation, haemorrhage requiring reintervention, red blood cell and fresh frozen plasma transfusions within the first 48h, infection (with pre-specified locations), stroke (disabling or non-disabling), adverse cardiac events, kidney failure requiring renal replacement therapy, respiratory failure requiring mechanical ventilation, bowel ischaemia requiring resection, abdominal compartment syndrome (and the need for laparostomy, if applicable) and death, consistent with the VASCUNET Dataset Template.[8,9] When registering a patient, it is expected that complete 30-day data is reported. Follow-up data (past 30 days) is also captured, including the need for reintervention and mortality (at 1 and 5 years). This data is not mandatory, left at the discretion of participating centres and investigators. Considering this, follow-up data were not included in this validation procedure.

Patient registration is performed in a dedicated web-based platform and entered by vascular surgeons from admission to follow-up outcomes. Registered data is pseudonymised and stored on a secure server, accessible only to authorised members of the RNPV Committee and RNPV investigators.

For this internal validation procedure, a prespecified set of baseline, procedure-related, and postoperative data was selected, Table 1.

Endpoints

The main endpoint was internal validity (accuracy). Secondary endpoints are missing data and data discrepancies. Data accuracy was defined as an exact match between original and validator records. Data discrepancy was defined as a lack of an exact match between the original and validator recordings. Missing data was defined as any missing variable value for any of the pre-specified variables analysed. Missing follow-up data was considered when at least one year had passed since surgery without a corresponding 1-year follow-up record. Also, non-recorded mortality within one year of surgery was considered as missing follow-up.

Table 1. List of variables used for the internal validation procedure

Baseline Characteristics	Patient registry identifier
	Birth Date
	Gender
	Date of admission
	Mode of admission
	Diabetes
	Cardiac disease
	Pulmonary disease
	Cerebrovascular disease
	Pre-operative creatinine
	Aortic Extent
	Largest aortic diameter
	Treatment indication
Surgical Details	Date of surgery
	OSR vs endovascular repair
	Intraoperative blood loss
Outcome	Bleeding requiring reintervention
	Infection
	Stroke
	Cardiac event
	Renal Replacement therapy
	Respiratory failure
	Bowel ischaemia
	Abdominal compartment syndrome
	Re-operation
	30-day vital status
	Discharge survival status

Internal Validation Procedure

Between November and December 2024, internal validation, following the VASCUNET Validation Template, was conducted.[5] Four centres - Unidade Local de Saúde Santa Maria (ULSSM), ULS Almada Seixal (ULSAS), ULS São José (ULSSJ) and ULS Gaia Espinho (ULSGE), were chosen. This choice was based on their availability to participate, their geographic distribution across the country, and their expected case volume, ensuring a feasible and representative validation process. Internal validation was performed on site for ULSSM and ULSAS by an external auditor (TR). At ULSSJ and ULSGE, data validation was conducted by vascular surgeons from each institution who had no direct involvement in the registry's development, management or data entry and who were fully blinded to the original registry data (GA for ULSSJ and PC for ULSGE). Per centre, a sample of 15 AAA patients was randomly selected. To ensure unbiased random case selection, the

random identification number sequence was obtained using the random number generator function available at www.calculator.net, performed by one investigator (TR) for all sites. Cases occurred and registered between January 1st 2021, and December 31st 2022, were considered. There were no validation limitations based on gender, aneurysm extent, surgical technique or urgency of repair. Then, variables from 27 data fields were re-registered and compared to the original registration in the dedicated database. It was ensured that the investigator responsible for the internal validation was blinded to the original reporting until data assessment was performed. Possible results for the variable comparison were correct, incorrect, or missing. Continuous and categorical data correspondence were considered correct only when an exact value match was observed. For internal validation, the maximum aneurysm diameter was measured ad hoc on the last available pre-operative CT scan. Pre-operative creatinine values were derived from the final blood workup documented before surgery. All remaining baseline characteristics, surgery and post-operative data were collected by reviewing hospital charts. Results are reported as counts and percentages, pseudonymized. Three data-quality domains were assessed: accuracy, missing data, and discrepancies between registry entries and hospital source records.

Statistical methods

Descriptive statistics (counts and proportions) were applied.

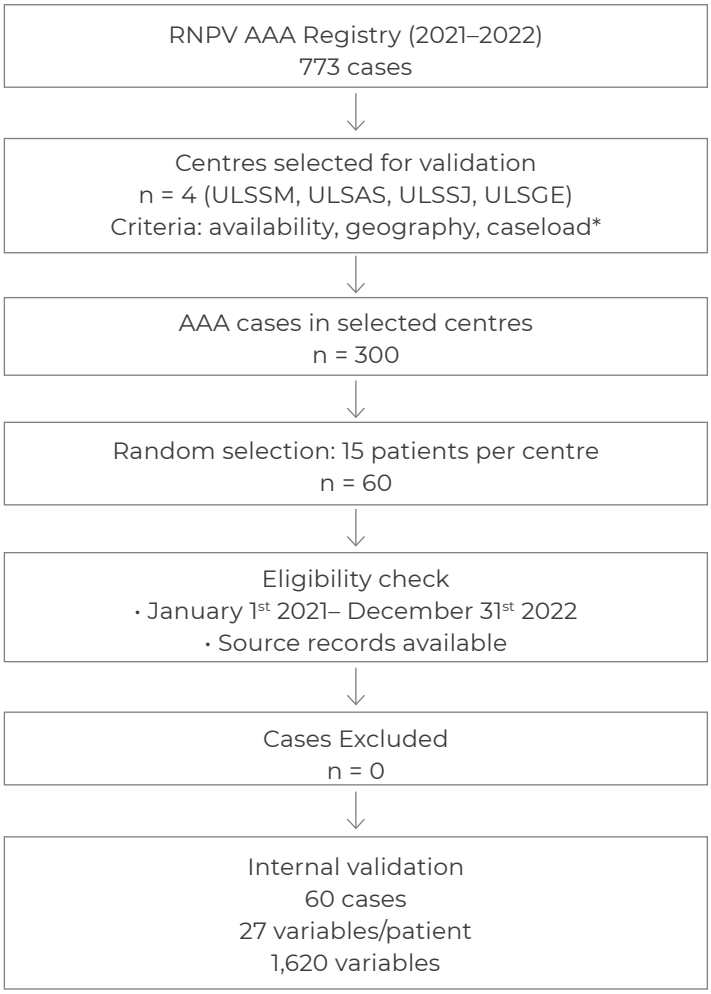
RESULTS

Internal validation was conducted across four institutions, with 15 AAA cases collected per hospital (a total of 60 cases), irrespective of aneurysm extent, surgical technique, or outcome. The caseload of the four visited hospitals corresponds to about 300 (38.8%) of the 773 patients registered within the RNPV between 2021-2022. Regarding the centres included, ULSSM and ULSSJ are two academic teaching hospitals in the Lisbon area. ULSGE is an academic teaching hospital in the Porto area. ULSAS is a community hospital in the metropolitan area of Lisbon. All selected cases from these centres were successfully reviewed, and no patients were excluded after sampling. Missing 30-day outcome data were identified in one patient from centre 3. The selection process for centres and patients included in the internal validation is depicted in Figure 1.

Data Accuracy, Discrepancy and Missing Data

Across all centres, a total of 1620 data fields (405 per centre) were analysed, covering 27 variables spanning baseline characteristics, surgical details and postoperative outcomes. Overall internal validity was 96.0%. The proportion of data mismatch was consistently low across centres, with centre-level internal validity ranging from 94.1% to 98.0%. Overall, 18 data fields (1.1% of total) were missing in the RNPV, while in 48 data fields (3.0%) the information differed between the RNPV and the corresponding hospital records. Missing data was a minor component (27.3%), whereas data discrepancy (73,7%) was the major component of internal including discrepancy and missing data for the 405 variables reviewed at each hospital. Missing data occurred in two centres and was largely attributable to the absence of 30-day outcomes in a single patient from centre 3. Table 3 summarises missing data per variable and at the centre-level. Follow-up data, missing in up to 54.5% of patients, were not included in the internal validation procedure.

Figure 1. Flow diagram depicting the selection of centres, random sampling of cases, eligibility assessment, and final inclusion of 60 cases in the internal validation analysis of the RNPV - AAA chapter



* Centres were selected based on broad geographical coverage, availability to participate and yearly AAA caseload. AAA = abdominal aortic aneurysm; RNPV = Registo Nacional de Procedimentos Vasculares; ULSSM = Unidade Local de Saúde Santa Maria, ULSAS = Unidade Local de Saúde Almada Seixal, ULSSJ = Unidade Local de Saúde São José; ULSGE = Unidade Local de Saúde Gaia Espinho

A data discrepancy occurred in all centres analysed, Table 4. Baseline characteristics (4.6%) presented the highest rate of mismatch, followed by procedure-related (3.6%) and outcome data (1.4%). Continuous (vs categorical data) presented more often mismatch, with 15.0% mismatch in pre-operative creatinine and 16.7% in largest aortic diameter. As we have solely considered an exact match, the clinical relevance of such discrepancy rate is uncertain.

Table 2. Internal validity, discrepancy and missing data of the cases analysed in the four visited centres.

	Centre			
RNPV – AAA module	**1**	**2**	**3**	**4**
Patients Reviewed	15	15	15	15
Total Variables	405	405	405	405
Discrepancy with Hospital Records	16 (3.9%)	10 (2.5%)	14 (3.4%)	8 (2.0%)
Missing data	0	8 (2.0%)	10 (2.5%)	0
Internal Validity	96.1%	95.6%	94.1%	98.0%

Results are presented as counts (percentages)

Table 3. Missing data across the four centres analysed.

Missing Variable	Centre 1	Centre 2	Centre 3	Centre 4
Baseline Characteristics				
Patient Registry identifier	0	0	0	0
Birth date	0	0	0	0
Gender	0	0	0	0
Date of admission	0	2 (13.3%)	0	0
Mode of admission	0	0	0	0
Diabetes	0	0	0	0
Cardiac disease	0	0	0	0
Pulmonary disease	0	0	0	0
Cerebrovascular disease	0	0	0	0
Pre-operative creatinine	0	0	0	0
Aortic Extent	0	0	0	0
Largest aortic diameter	0	0	0	0
Treatment indication	0	0	0	0
Surgical Details				
Date of surgery	0	2 (13.3%)	0	0
OSR vs endovascular repair	0	0	0	0
Intraoperative blood loss	0	3 (20%)	0	0
Outcome				
Bleeding requiring reintervention	0	0	1 (6.7%)	0
Infection	0	0	1 (6.7%)	0
Stroke	0	0	1 (6.7%)	0
Cardiac event	0	0	1 (6.7%)	0
Renal replacement therapy	0	0	1 (6.7%)	0
Respiratory failure	0	0	1 (6.7%)	0
Bowel ischaemia	0	0	1 (6.7%)	0
Abdominal compartment syndrome	0	1 (6.7%)	1 (6.7%)	0
Re-operation	0	0	1 (6.7%)	0
30-day vital status	0	0	0	0
Survival status at discharge	0	0	1 (6.7%)	0

Table 4. Data discrepancy across the four centres analysed.

Data Discrepancy	Centre 1	Centre 2	Centre 3	Centre 4
Baseline Characteristics				
Patient Registry identifier	0	0	0	0
Birth Date	0	0	0	0
Gender	0	0	0	0
Date of admission	0	0	0	0
Mode of admission	0	0	0	0
Diabetes	0	0	0	1 (6.7%)
Cardiac disease	1 (6.7%)	1 (6.7%)	0	1 (6.7%)
Pulmonary disease	1 (6.7%)	0	1 (6.7%)	0
Cerebrovascular disease	2 (13.3%)	0	0	0
Pre-operative creatinine	4 (26.6%)	1 (6.7%)	3 (20%)	1 (6.7%)
Aortic Extent	1 (6.7%)	1 (6.7%)	1 (6.7%)	0
Largest aortic diameter	2 (13.3%)	2 (13.3%)	3 (20%)	3 (20%)
Treatment indication	0	0	0	0
Surgical Details				
Date of surgery	0	0	0	0
OSR vs endovascular repair	0	0	0	0
Intraoperative blood loss	2 (13.3%)	4 (26.6%)	2 (13.3%)	0
Outcome				
Bleeding requiring reintervention	0	0	0	0
Infection	1 (6.7%)	1 (6.7%)	1 (6.7%)	0
Stroke	0	0	0	0
Cardiac event	1 (6.7%)	0	1 (6.7%)	0
Renal Replacement therapy	1 (6.7%)	0	0	0
Respiratory failure	0	0	1 (6.7%)	0
Bowel ischaemia	0	0	0	0
Abdominal compartment syndrome	0	0	1 (6.7%)	0
Re-operation	0	0	0	0
30-day vital status	0	0	0	1 (6.7%)
Survival status at discharge	0	0	0	0

Results are presented as counts (percentages). **OSR –** Open surgical repair

DISCUSSION

The accuracy and completeness of medical registries are critical for understanding epidemiological trends, assessing therapeutic strategies, and harmonizing treatment protocols across patient populations and diverse geographical distributions. Therefore, registry validation is a fundamental process that ensures the recorded data is both representative and reliable. In the case of the RNPV, internal validation of the AAA module revealed an internal validity rate exceeding 95%, with about 1% of missing data and 3% hospital records. This validation process was conducted in accordance with VASCUNET recommendations for vascular surgery AAA registries validation.[5] To ensure unbiased results, vascular surgeons who were selected to perform the validation process were uninvolved and blinded to the registry data they assessed.

The results of this internal validation procedure were consistent with those reported by other well-established national vascular registries, such as the Swedvasc (96.2%), Karbase (97.4%), and Swissvasc (94.4%).[10-12] Within the RNPV database, 1.1% of data fields were classified as missing,

unreported variable.

Discrepancies accounted for most validation issues (63.7%). These were found in 3% of cases, with the largest variation noted in the recorded value of the maximum aortic diameter. Currently, although there is some variation in diameter measured ad hoc, it is consistent with the known interobserver variability for AAA measurement using CT angiography.[13] Notably, only exact matches were considered valid, which likely contributed to the higher mismatch rate among continuous variables.

Our findings are in line with other VASCUNET-validated registries: Swedvasc reported 5.3% missing data and 3.7% discrepancies; Karbase reported 0.25% missing data and 2.6% discrepancies, while the Maltese registry achieved a 100% internal validation rate.[10,11,14]

The high concordance rate observed in our validation supports the RNPV as a reliable source for quality indicators, establishing a solid foundation for future scientific research and contributing to the continuous improvement of vascular surgical practice in Portugal. This validation process not only ensures the credibility and representativeness of the data but also fosters ongoing enhancement in the quality of vascular healthcare delivery.

Regarding outcome data, one mismatch in 30-day mortality was observed and corresponds to the case of a patient that expired post-discharge, after an uneventful early post-operative course.

This study also uncovers current limitations within the RNPV. First, the relevant degree of mismatch in continuous data. This might reflect different assessment methodologies, rounding errors, as well as inter-observer variability. In future validation procedures, an acceptable error margin could be introduced, assuming it can be demonstrated that clinical significance is not compromised. Also, follow-up data, missing in more than half of cases, is the most important limitation. Longitudinal data is highly relevant for a condition often treated to prevent longitudinal aneurysm-related complications. Therefore, assessing durability (as freedom from aortic-related reintervention) and overall survival are key. As a first step, reporting of this data should be made mandatory. Compared to other nationwide registries, the RNPV lacks direct linkage with other population-based registries, which might be a goal for future improvement and will certainly minimize such errors.[10]

LIMITATIONS

The included centres cover less than half of operations performed throughout 2021-2022 in the participating hospitals. Although institutions covering diverse geographical locations were included, a significant number of institutions, particularly in central Portugal were not included. For-profit private institutions were not assessed, nevertheless, there is little to indicate that the outcome might have been different. The sample size was relatively small, as internal validation was performed in 60 patients (15 per centre), which limits the ability to perform more granular subgroup analyses. In addition, validation was conducted by a single auditor per centre, which may introduce observer-related variability. Nevertheless, all auditors were independent from registry development and data entry, blinded to the original registry data, and followed a standardized validation protocol, mitigating the risk of systematic bias. An in-depth analysis of factors related to missing data or discrepancies was not conducted, preventing the identification of potential systematic biases in reporting.

Validation was conducted manually, which introduces the possibility of errors arising from human oversight. While this risk was mitigated through independent record review, the reliance on a single validator remains a limitation and a potential source of bias. Conversely, the validator was not involved in the original data reporting process, reducing the likelihood of confirmation bias. In addition, internal validation is not subject to potential linguistic barriers, which are more likely to occur in international validation efforts. Finally, external validation has not yet been undertaken, and future implementation of this step will further strengthen the robustness and reliability of the registry.

CONCLUSION

The internal validation of the AAA chapter of the RNPV demonstrated favourable results, with an overall concordance rate exceeding 95%, indicating robustness and reliability of data, which is reassuring. Missing data is minimal, and data discrepancy is more frequent in continuous data. Compared to other international benchmark registries, RNPV's internal validity was similarly strong, positioning this registry as a reliable tool for monitoring quality indicators in vascular surgery in Portugal. External validation of this data is awaited.

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