Evaluation of the ICD-10 system in coding revascularisation procedures in patients with peripheral arterial disease in England: A retrospective cohort study using national administrative and clinical databases

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Summary

Background Many studies evaluating care in hospitals in England use the Hospital Episode Statistics (HES) administrative database. The aim of this study was to explore whether the International Classification of Diseases 10th Revision (ICD-10) system used by HES supported the evaluation of care received by patients with peripheral arterial disease (PAD) who had revascularisation.

Methods This retrospective cohort study used records on patients who had revascularisation for PAD between 1st January 2017 and 31st December 2019 in England, collected prospectively in the National Vascular Registry (NVR) and linked to HES. Patients were excluded if their NVR record did not have a match in HES, due to lack of consent or different admission and procedure dates. Agreement between different presentations of PAD recorded in the NVR and the ICD-10 diagnostic codes recorded in HES was evaluated using the unweighted Kappa statistic and sensitivity and specificity. Agreement between the NVR and HES was also assessed for gender, age, comorbidities, mode of admission, and procedure type and side.

Findings In total, 20,603 patients who had 24,621 admissions were included in the study. Agreement between NVR and HES on patient gender (Kappa = 0.98), age (Kappa = 0.98), mode of admission (Kappa = 0.80), and procedure type and side (Kappa = 0.92 and 0.87, respectively) was excellent. When all diagnostic fields in HES were explored, substantial agreement was observed for chronic ischaemia with tissue loss (Kappa = 0.63), but it was lower for chronic ischaemia without tissue loss (Kappa = 0.32) and acute limb ischaemia (Kappa = 0.15). Agreement on comorbidities was mixed; excellent for diabetes (Kappa = 0.82), moderate for chronic lung disease (Kappa = 0.56), chronic kidney disease (Kappa = 0.56), and ischaemic heart disease (Kappa = 0.45) and fair for chronic heart failure (Kappa = 0.35).

Interpretation The diagnostic ICD-10 codes currently used in HES cannot accurately differentiate between stages of PAD. Therefore, studies using HES to examine patterns of care and outcomes for patients with PAD are likely to suffer from misclassification bias. Adopting an extended ICD-10 system or the ICD-11 version released to the World Health Organisation member states in 2022, may overcome this problem.

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Keywords: Clinical coding; Electronic health records; Registries; Peripheral arterial disease; Vascular surgical procedures; Hospital episode statistics

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Research in context

Evidence before this study

We searched Medline from inception until August 1, 2022, using search terms ("Hospital Episode Statistics") AND ("Arterial Occlusive Diseases" OR "Peripheral Arterial Disease"), to identify studies that used Hospital Episode Statistics (HES), the national administrative database in England, to evaluate patterns of care for patients with peripheral arterial disease (PAD) who undergo revascularisation. Eight citations were retrieved, but none of the studies explored the accuracy of diagnostic information available in HES for this patient cohort.

Added value of this study

We analysed information on English patients with PAD from the National Vascular Registry linked to HES and found moderate levels of agreement on diagnostic information between the two databases. We found that the same International Classification of Diseases 10th Revision (ICD-10) diagnostic codes were used for the milder and the more severe forms of chronic limb ischaemia, as well as acute limb ischaemia. Therefore, the ICD-10 codes used in the English Hospital Episode Statistics database to capture diagnostic information cannot accurately discriminate the different stages of PAD.

Implications of all the available evidence

Studies using HES to examine patterns of care and outcomes for patients with PAD are likely to suffer from misclassification bias. This might affect the definition of the study cohort as well as the definition of patient subgroups by type of disease. The adoption of an extended ICD-10 system, similar to the German or US version, or rapid introduction of the new ICD-11 and Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT) systems may overcome this problem and similar issues for other diseases. This would enhance the value of this national administrative database for research, commissioning, and public health purposes.

Introduction

Peripheral arterial disease (PAD) is a common progressive condition characterised by reduced blood flow to the lower limbs. Patients may present with varying degrees of severity, from pain during walking (intermittent claudication), to pain at rest. The most severe form of the disease is called chronic limb-threatening ischaemia (CLTI) and is characterised by pain at rest and/or tissue loss on the leg and foot, in the form of ulcers or gangrene.[1] Treatment options for PAD depend upon the stage of the disease, with early forms often responding to medical management. More severe disease typically requires revascularisation, performed with endovascular procedures (angioplasty and stent), open surgical operations (endarterectomy and bypass) or a combination of the two modalities.

Data about the care received by patients with PAD are available within the Hospital Episode Statistics (HES) Admitted Patient Care (APC) database, an administrative database that contains information about all admissions to National Health Service (NHS) hospitals in England.[2] HES has been used by various studies to evaluate patterns of care for patients with PAD who undergo revascularisation, such as time to surgery[3] and postoperative outcomes.[4,5] A benefit of HES is its comprehensive coverage and its linkage with the Office for National Statistics (ONS) death registry.[6] However, the standard version of the International Classification of Diseases, 10th edition (ICD-10)[7] used by HES does not currently have specific diagnostic codes for the various stages of PAD. This raises the possibility of misclassification bias affecting studies that only use HES data, particularly when they focus on particular subgroups like patients with CLTI, because there is a risk that diagnostic codes are being used inconsistently by different hospitals for the same stage of disease.

Information about revascularisation procedures performed in NHS hospitals in England is also collected in the National Vascular Registry (NVR), a national clinical audit commissioned by the Healthcare Quality Improvement Partnership (HQIP) on behalf of NHS England.[8] Data include patient demographics, comorbidities, indication for intervention, procedural details and selected postoperative outcomes. Its bespoke dataset includes the Fontaine stage, which is used to distinguish between stages of PAD, with stage III defined as nocturnal/rest pain and IV (necrosis/gangrene) indicating tissue loss.[9]

The aim of this study was to evaluate the agreement of diagnostic details between the National Vascular Registry and Hospital Episode Statistics in records of patients with PAD having revascularisation, and explore which ICD-10 codes are used for the different types of PAD.

Methods

Data sources

This retrospective observational cohort study used a linked dataset that combined information from the NVR and HES on patients with PAD undergoing revascularisation. Linkage was performed at a patient-level by NHS Digital (who supplied the extract of HES data) based on the patients' NHS number, date of birth, gender and postcode. Written consent for patient data collection in the NVR was obtained from patients

undergoing elective procedures, bur for emergency procedures the NVR has approval from the Confidentiality Advisory Group under Section 251 of the Data Protection Act 2018 to collect data without consent. Patient consent was not required for data collection in HES, but patients could opt out of having their data shared, and these were removed prior to linkage. Patient records were supplied for analysis in a pseudonymised format, with each patient given a unique identifier that enabled all their hospital admissions to be tracked. The study involved the secondary analysis of existing pseudonymised data and was therefore exempt from UK National Ethics Committee approval. The study was conducted and reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement.

In HES, a record corresponds to the time a patient is under the care of one consultant and each hospital admission consists of one or more episodes. In each record, clinical conditions can be entered using ICD-10 codes in up to 20 data fields. Records also hold details of procedures performed during the hospital admission, which are coded using the Office of Population, Censuses and Surveys (OPCS)-4 Classification.[10] For revascularisation procedures, the data can describe the date and type of procedure (eg, bypass, angioplasty), the side of the body (right, left, bilateral) and the vessel operated on. In this study, if a patient who had a revascularisation had multiple episodes within an admission, the data relating to diagnoses and procedures in all episodes were merged into a single record.

The NVR is a procedure-based national clinical audit that covers five major vascular procedures undertaken within NHS hospitals in the UK. It captures just over 90 per cent of open and more than 40 per cent of endovascular lower limb revascularisation procedures performed in NHS hospitals.[11] The details for the majority of patients who undergo revascularisation are typically captured in one NVR record. For this study, if the care received during one admission resulted in more than one NVR records, the information was combined into one record.

Study cohort

The study cohort was constructed in a series of steps. First, the records of patients who underwent revascularisation procedures for PAD (presenting problem: acute limb ischemia (ALI), chronic limb ischemia, neuropathy, tissue loss, uncontrolled infection) between 1 January 2017 and 31 December 2019 were extracted in the NVR. Most patients had a single procedure during these three years but a minority were admitted on multiple occasions for revascularisation. Second, the extract of HES data was searched to find the admissions that corresponded to the admission described in the NVR records. This involved finding the HES records containing a revascularisation procedure (see eTable 1 for OPCS code) and selecting as the match the record that (1) had an admission date closest to that in the NVR record (up to 10 days difference in the dates was allowed), and (2) initial revascularisation procedures that were recorded as being performed on the same date or 1 day apart. Only patients with matched NVR-HES records were included in the study.

Key diagnostic variables

The study examined the agreement in various variables of importance to researching patients with PAD. First, variables in the NVR and HES were defined to differentiate types and severity of PAD, distinguishing between: acute limb ischaemia, chronic limb ischaemia without tissue loss (Fontaine stage I, II and III) and chronic limb ischaemia with tissue loss (Fontaine stage IV).[9] In the NVR, ALI was defined from the presenting problem data item, while the other categories corresponded to the respective Fontaine stages. Two HES–derived variables were defined for these categories. A basic version was defined using only the ICD-10 codes in the principal diagnosis field. A refined version was defined using all the diagnosis information available within an admission. The set of ICD-10 diagnostic codes used to differentiate these categories are described in eTable 2. Each patient could only belong in one category. If more than one category's codes were present, the chronic ischaemia with tissue loss codes took precedence over the others, followed by ALI codes and then chronic limb ischaemia without tissue loss.

Another variable was defined for patients with CLTI (Fontaine III – rest pain and IV – tissue loss) being admitted as an emergency. The definition of this variable in the NVR required the emergency mode of admission to be combined with a new variable that included Fontaine stages III and IV. The HES version of this variable was based on the presence of any chronic ischaemia code and the emergency admission mode because it was not possible to identify the Fontaine stage in HES.

A second set of HES variables were defined for important comorbidities collected in the NVR. These were: diabetes, ischaemic heart disease, chronic heart failure, chronic lung disease, and chronic renal disease. The ICD-10 codes available in the revascularisation admission were used for this analysis (eTable 2). In both databases, only the presence of the comorbidities is captured, with no definitive statement of absence.

Statistical analysis

Demographic (age, gender), diagnostic and procedural information between NVR and HES was summarised as frequencies and proportions. Overall agreement was measured using the unweighted Cohen's kappa (k)

statistic for categorical variables.[12] This statistic ranges from zero (a level of agreement no greater than would be obtained by chance) to one (perfect agreement). Kappa values above 0.80 are generally considered to indicate excellent agreement.[13] To calculate the agreement for age using Cohen's kappa, age was categorised into 5-year age bands, with upper limit "85 years or more" and lower limit "less than 55 years".

For selected PAD diagnostic categories and comorbidity variables, agreement was also measured in terms of sensitivity and specificity, with the values from the NVR being used as the ''gold standard''. NVR data were used as reference because they were completed by clinicians or under supervision of clinicians with good knowledge of the patient's condition and understanding of clinical nuances, and therefore they were more likely to be accurate. In contrast, HES data are entered by hospital clinical coders, who only have access to the information within inpatient clinical summaries that they receive after the patient's discharge. Sensitivity described the proportion of patients coded with a condition in HES among those coded with the condition in the NVR, and specificity described the proportion of patients coded without a condition in HES among those coded without the condition in the NVR.

We used funnel plots to examine variation among NHS trusts in the consistency of diagnostic information referring to chronic ischaemia with tissue loss.[14] The inner and outer control limits were set at two and three standard deviations above and below the national average, respectively. The limits also took into account a measure of over-dispersion. This was derived using the random-effects method fitted to NHS trust figures and incorporated five per cent Winsorisation at the lower and upper ends of the distribution to prevent the limits being widened excessively by extreme outliers.[14] All analyses were undertaken in STATA 17 (StataCorp, College Station, Texas, USA).

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. All authors confirm that they had full access to all the data in the study and accepted responsibility to submit for publication.

Results

During the study period, 38,083 hospital admissions with revascularisation procedures for PAD were submitted in the NVR for 31,704 patients admitted in English NHS trusts. Of those, 8375 patients had not given consent for collection of identifiable information (NHS number) and therefore their records could not be linked to the HES dataset. Among the 23,329 patients eligible for linkage, records were successfully linked for 21,042 patients, and the HES records corresponding to the admissions described in the NVR were found for 20,603 patients. These 20,603 patients had a total of 24,621 admissions between January 2017 and December 2019 (ie, the study analysed a sample of 24,621 matched records).

Agreement of demographic information and procedure details

Agreement on patient gender (men/women) was excellent (99.3%, n = 24,443; Kappa = 0.98), with high sensitivity (99.2%) and specificity (99.3%). The same age (in years) was recorded in both datasets for 93.4% of patients (n = 22,984), while relaxing "agreement" to allow for a difference of one year increased agreement to 99.5% (n = 24,503). The Kappa statistic for age categorised into 5-year bands was 0.98. Date information was also similar between the databases, with 90.5% of records (n = 22,274) having the same admission date, 89.6% (n = 22,052) the same discharge date, and 90.5% (n = 22,273) the same date of first procedure. Agreement in relation to the mode of admission when limited to elective and emergency categories was 91.9% (n = 21,674; Kappa = 0.80), with sensitivity for emergency admission 84.8% and specificity 94.7%. HES allows for "hospital transfer" as an admission mode but this does not exist in the NVR. We noted that 82.5% of transfers (852 of 1033) were recorded as emergency admissions in the NVR.

Regarding procedure details, the type and side of the first procedure during an admission was the same in the NVR and HES for 95.4% (n = 22,217; Kappa = 0.92) and 92.0% of patients (n = 20,714; Kappa = 0.87) respectively.

Agreement of PAD diagnostic information

Agreement between the basic HES definitions and NVR definitions for ALI was poor (Kappa = 0.08), and marginally improved when all the diagnostic fields were explored (Kappa = 0.15), with sensitivity increasing from 24.1% for the basic definition to 33.7% for the refined definition and specificity remaining approximately the same (86.2% vs 86.4%) (Table 1).

Agreement for patients with chronic ischaemia varied more markedly depending on whether the basic or the refined HES definition was used. Inclusion of all diagnostic information improved the agreement for the chronic ischaemia without tissue loss (Kappa = 0.15 for basic vs. 0.32 for refined HES definition). Similarly, only 30.8% (n = 2897) of the cases with tissue loss in the NVR were also recorded as such in the primary diagnosis field (Kappa = 0.29), but this number increased substantially to 78.3% (n = 7369) when all diagnostic fields were taken into account (Kappa = 0.63).

Compared to the diagnosis of CLTI (Fontaine stage III/IV) and emergency admission in the NVR, the HES

	Patients with diagnosis in NVR		Patients without diagnosis in NVR		Agreement (%)	Kappa
	Number of patients	% patients with diagnosis in HES (sensitivity)	Number of patients	% patients without diagnosis in HES (specificity)		
Basic HES definition (primary diagnosis field)						
Acute limb ischaemia	2232	24.1	22,389	86.2	80.6	0.08
Chronic ischaemia without tissue loss	12,818	44.7	11,803	70.7	57.2	0.15
Chronic ischaemia with tissue loss (Fontaine IV)	9417	30.8	15,204	95.2	70.5	0.29
Refined HES definition (all diagnosis fields in admission)						
Acute limb ischaemia	2232	33.7	22,389	86.4	81.6	0.15
Chronic ischaemia without tissue loss	12,818	47.5	11,803	85.1	65.5	0.32
Chronic ischaemia with tissue loss (Fontaine IV)	9417	78.3	15,204	84.8	82.3	0.63
Patient subgroup (all diagnosis fields in admission)						
Emergency Chronic Limb-Threatening Ischaemia	5741	67.1	18,880	91.7	86.0	0.60

Table 1: **Agreement regarding diagnosis between the National Vascular Registry (NVR) and Hospital Episode Statistics (HES) databases, measured using Cohen's Kappa, and diagnostic accuracy (sensitivity and specificity) using the NVR as the gold standard.**

variable for emergency admissions with any ICD-10 code for chronic ischaemia had low sensitivity (67.1%) but high specificity (91.7%) (Table 1), with overall moderate agreement (86.0%, n = 21,170; Kappa = 0.60).

ICD-10 codes representing "Embolism and Thrombosis" were more frequently related to a diagnosis of chronic ischaemia rather than ALI in the NVR (Table 2). After the HES basic definitions were constructed, 8182 admissions (33.2%) remained uncategorised, as they had a primary diagnosis code other than the ones defined. This figure dropped to 3291 (13.4%) for the refined HES definitions, which had better agreement with the NVR overall (Table 2). The most common ICD-10 codes in the main diagnosis field in HES for these uncategorised records are presented in eTable 3, stratified by the diagnosis recorded in the NVR. The commonest code was I77.1, defined as "Stricture of artery", which is not referring to atherosclerotic disease from a clinical perspective.

Agreement of comorbidity information

Agreement on comorbidities was mixed (Table 3). There was excellent agreement for diabetes (Kappa = 0.82), moderate agreement for chronic lung disease (Kappa = 0.56), chronic kidney disease (Kappa = 0.56), and ischaemic heart disease (Kappa = 0.45) and only fair agreement for chronic heart failure (Kappa = 0.35). The HES comorbidity variables typically had high specificity but low sensitivity with diabetes being the exception, with a sensitivity and specificity of 89.2 and 93.1, respectively.

Coding of chronic limb ischaemia with tissue loss (Fontaine stage IV) across NHS trusts

Fig. 1 shows the variation in coding of chronic limb ischaemia with tissue loss (refined HES definition) among the 72 NHS trusts that had more than ten matched records in the analysis. The national average was 82.4% and five NHS trusts had agreement between

	NVR definition			Kappa
	Acute limb ischaemia	Chronic ischaemia without tissue loss	Chronic ischaemia with tissue loss (Fontaine IV)	
Basic HES definition (primary diagnosis field)				
Acute limb ischaemia	538	1843	1182	0.15
Chronic ischaemia without tissue loss	723	5725	2716	
Chronic ischaemia with tissue loss (Fontaine IV)	234	475	2897	
Uncategorised	737	4775	2622	
Refined HES definition (all diagnosis fields in admission)				
Acute limb ischaemia	751	2520	474	0.37
Chronic ischaemia without tissue loss	579	6082	1161	
Chronic ischaemia with tissue loss (Fontaine IV)	633	1627	7369	
Uncategorised	269	2589	413	

Table 2: **Agreement regarding different types of peripheral arterial disease between the National Vascular Registry (NVR) and Hospital Episode Statistics (HES) databases among patients undergoing revascularisation.**

	Patients with comorbidity in NVR		Patients without comorbidity in NVR		Agreement (%)	Kappa
	Number of patients	% patients with comorbidity in HES (**sensitivity**)	Number of patients	% patients without comorbidity in HES (**specificity**)		
Diabetes	10,283	89.2	14,190	93.1	91.5	0.82
Ischaemic heart disease	8394	51.4	16,079	90.7	77.2	0.45
Chronic lung disease	5022	71.5	19,451	88.0	84.6	0.56
Chronic kidney disease	3242	63.0	21,231	93.8	89.7	0.56
Chronic heart failure	1820	44.5	22,653	93.8	90.2	0.35

Table 3: **Agreement between selected comorbidity variables in the National Vascular Registry (NVR) and Hospital Episode Statistics (HES) databases for patients undergoing lower limb revascularisation for peripheral arterial disease, measured using Cohen's Kappa, and diagnostic accuracy (sensitivity and specificity) using the NVR as the gold standard.**

67.8% and 76.9%, which was lower than three standard deviations from the national average.

Discussion

This study demonstrates that there is good agreement between the National Vascular Registry and the Hospital Episode Statistics database regarding patient, admission and procedure characteristics. However, it is not possible to accurately define the severity of chronic limb ischaemia based on the available diagnostic codes in HES, as the same diagnostic codes are used for the milder and the more severe forms of the disease, as well as ALI. Notably, it was not possible to identify the patient cohort with CLTI in HES, as there were no ICD-10 codes referring to rest pain. This is an important limitation of HES and therefore of any study using HES to report risk-adjusted postoperative outcomes or studies aiming to develop risk prediction models. It also indicates that it is impossible to estimate the incidence of CLTI in the population for service planning and commissioning purposes.

Data captured in the NVR contain important clinical information not collected in HES, such as haematological and biochemical results, and are considered more accurate due to their completion by healthcare staff often involved in patients' care. However, the case ascertainment is variable and not all eligible cases are being captured.[15] On the other hand, HES, as an administrative database, provides a more complete coverage of the population, but suffers from coding issues due to the limitations of the current ICD-10 classification and the variable coding practices in different hospitals in England, demonstrated in this and other studies.[16]

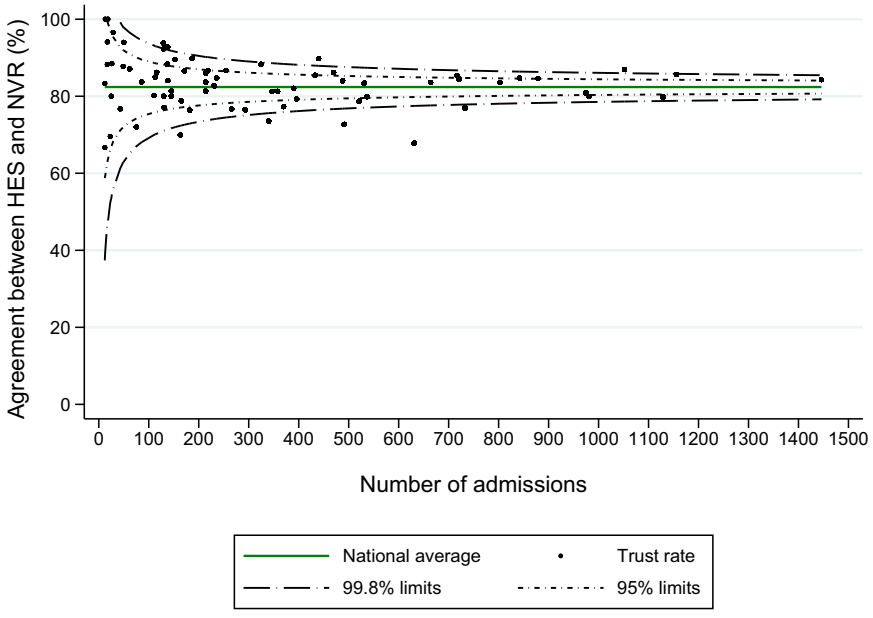

Fig. 1: **Funnel plot showing variation in the coding consistency of chronic limb ischaemia with tissue loss in the Hospital Episode Statistics (HES) and the National Vascular Registry (NVR) databases (refined HES definition) among the 72 English National Health Service Trusts that had more than ten matched records.**

To overcome the lack of specific diagnostic codes for CLTI, studies using HES data to evaluate outcomes after revascularisation procedures have used a combination of the urgency of admission variable and codes relating to PAD overall or signs of the disease, such as ulcers and gangrene, as a proxy for the severity of the disease in risk-adjustment models.[3] Our study found that using the emergency mode of admission and ICD-10 codes corresponding to PAD had high specificity but low sensitivity of diagnosing chronic limb-threatening ischaemia. This approach has two important limitations. Firstly, a proportion of the patients that were included had ALI, as the diagnostic codes used are similar and present as emergencies, but this condition often has an entirely different pathology. Secondly, it is not possible to identify the cohort of patients with CLTI who are treated on an outpatient basis and are admitted electively for their procedure, as there are no diagnostic codes to differentiate them from patients with intermittent claudication treated electively. On the other hand, codes that are clinically related to ALI, such as "embolism and thrombosis", were frequently used for chronic ischaemia. Therefore, it is very difficult to discriminate between presentations and severity of PAD using ICD-10 codes in HES.

Other countries have addressed the deficiencies of the ICD-10 classification by using modified versions of ICD-10, such as the ICD-10 Clinical Modification (ICD-10-CM) in the United States[17] and the German Modification of the ICD-10 (ICD-10-GM) in Germany[18] (Table 4). These extended ICD-10 classifications include subcodes which provide more details about the diagnosis. For example, in the German ICD-10-GM, the I70.2 diagnostic code (Atherosclerosis of the arteries of the extremities) includes seven sub-codes corresponding to the stages of the Fontaine classification, an established classification system for peripheral arterial disease.[9] This information has been used in the development of a risk prediction model for amputations in the PAD patient cohort.[19] The ICD-10-CM classification system used in the US also has subcodes of the I70.2 diagnostic code, which capture the patients' clinical presentation (intermittent claudication, rest pain, ulceration, gangrene). Clinicians in the US recently led an update to the inclusion terms of the existing codes in ICD-10-CM to specifically mention CLTI, making it easier for hospital coders and coding software to allocate the most appropriate code and reduce inconsistencies across healthcare providers.[17] Adding the term "Acute Limb Ischaemia" to the description or inclusion criteria for the ICD-10 code I.74 (Embolism and Thrombosis) may provide clarity for clinical coders.

However, increasing the granularity of the coding system may not adequately address the coding issues highlighted in this study. Detailed clinical data should be available in the clinical records used by hospital coders. A way to improve the recording of clinical information would be the adoption of the Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT). SNOMED CT is a collection of clinical terms used in electronic health records to capture patient information such as conditions, procedures, and medications at the point of care, which can then be aggregated in the ICD-10 and OPCS classifications and transferred between IT systems.[20] Its use has recently become mandatory for all NHS healthcare providers in England, and it has the potential to reduce the duplication of data entry and increase data quality. However, the mapping of SNOMED-CT terms to the established classification systems used in HES

United Kingdom	United States	Germany
I70.2 Atherosclerosis of arteries of extremities	**I70.2 Atherosclerosis of native arteries of the extremities**	**I70.2 Atherosclerosis of arteries of extremities**
I70.20 Atherosclerosis of arteries of extremities without gangrene	**I70.20** Unspecified atherosclerosis of native arteries of extremities	**I70.20** Lower limb type, without discomfort. Fontaine stage I
I70.21 Atherosclerosis of arteries of extremities with gangrene	**I70.21** Atherosclerosis of native arteries of extremities with intermittent claudication	**I70.21** Lower limb type, with exercise-induced ischemic pain, walking distance ≥200 m. Fontaine stage IIa
	I70.22 Atherosclerosis of native arteries of extremities with rest pain	**I70.22** Lower limb type, with exercise-induced ischemic pain, walking distance <200 m. Fontaine stage IIb
	I70.23 Atherosclerosis of native arteries of right leg with ulceration	**I70.23** Lower limb type, with pain at rest. Fontaine stage III
	I70.24 Atherosclerosis of native arteries of left leg with ulceration	**I70.24** Lower limb type, with ulceration. Fontaine stage IV with ulceration (limited to the skin/subcutaneous tissues)
	I70.25 Atherosclerosis of native arteries of other extremities with ulceration	**I70.25** Lower limb type, with gangrene. Fontaine stage IV with gangrene. Dry gangrene (Fontaine stage IVa). Wet gangrene (Fontaine stage IVb)
	I70.26 Atherosclerosis of native arteries of extremities with gangrene	**I70.26** Upper limb type, all stages
	I70.29 Other atherosclerosis of native arteries of extremities	**I70.29** Other and unspecified atherosclerosis of the extremity arteries. PAD without a Fontaine stage

Table 4: **International Classification of Diseases 10th edition (ICD-10) codes relating to peripheral arterial disease (PAD) in the United Kingdom, United States, and Germany.**

and other large national databases in not yet complete, and without improvements in the ICD classification, this richer information cannot be used by researchers and commissioners. On that front, the International Classification of Diseases 11th revision (ICD-11) was released by the World Health Organisation in June 2018 and was approved by all member states at the World Health Assembly in 2019. This latest version allows the documentation of the severity of disease with codes relating to the Fontaine and the Rutherford classifications, but has not been implemented within the UK yet.[21]

This is the first study that compares agreement between a national vascular clinical database and a national administrative database, and provides information about the coding of peripheral arterial disease in HES. However, the study has some limitations. Firstly, records pertaining to the same admission episode in the two databases were identified using the admission date, which is occasionally subject to error. Some records may have failed to link for this reason, even though a ten-day difference in admission dates was allowed. The fact that all linked records contained at least one procedure performed on the same date offered some reassurance about the linkage. Secondly, case ascertainment in the NVR is moderate for lower limb procedures, but there is no indication that the non-submitted cases would differ systematically from the submitted ones. Thirdly, it was not possible to validate the accuracy of the data in either database against hospital records and there is a risk of human error during data entry in both databases. Finally, the study could not estimate the sensitivity and specificity of ICD-10 codes related to PAD in the overall population because the NVR only includes records for patients who have a revascularisation procedure.

In conclusion, this study suggests that there is good agreement between the main national administrative and clinical vascular databases, which indicate accuracy of the available information. However, the severity of peripheral arterial disease cannot be assessed using HES data, which limits their suitability for research studies and has commissioning, policy and public health implications. Therefore, there is a strong need to adopt an extended ICD-10 classification system based on a recognised PAD disease classification system, or to expedite the introduction of the new ICD-11 and SNOMED-CT, which will capture the severity of PAD and increase the utility of this large administrative dataset.

Contributors

PB and DAC conceived and designed this study, and performed the statistical analyses. PB and DAC assessed and verified all the data included in the study. PB, DAC and ADP led the drafting of the manuscript. PB, EA, QL, ASJ, SW, RW, ADP and DAC contributed to the interpretation of the data and critical revision of the manuscript, and approved the final version.

Data sharing statement

This study uses data from the National Vascular Registry and Hospital Episode Statistics. The data governance arrangements do not allow the authors to redistribute or provide access to the data to other parties. Researchers can apply for access to NVR data through HQIP's Data Access Request facility (https://www.hqip.org.uk) and access to HES data through NHS Digital.

Declaration of interests

PB and EA have received a joint Royal College of Surgeons of England/Circulation Foundation research fellowship. PB is also funded by the Vascular Society of Great Britain and Ireland and the British Society of Interventional Radiology (BSIR). PB is member of the Vascular Endovascular Research Network executive committee and Associate Surgical Specialty Lead for Vascular Surgery for the Royal College of Surgeons of England. RW is Clinical Lead for Interventional Radiology in the National Vascular Registry and past chair of the research and audit committee of the BSIR. ADP is chair of the Audit and Quality Improvement committee of the VSGBI, Clinical Lead for Vascular Surgery in the National Vascular Registry, member of the Vascular Clinical Reference Group of NHS England, chair of the High-cost tariff-excluded devices (HCTED) of NHS England, and member of the VASCUNET and ICVR representing the UK. DAC is member of the editorial committee of the Journal of Health Services Research and Policy. All other authors have no potential conflicts of interest to declare.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.eclinm.2022.101738.

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