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Original Article

Economic impact of limb-salvage strategies in chronic limb-threatening ischaemia: modelling and budget impact study based on national registry data

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Abstract

Background: Missed opportunities to reduce numbers of primary major lower-limb amputation and increase limb-salvage procedures when treating chronic limb-threatening ischaemia have previously been identified in the literature. However, the potential economic savings for healthcare providers when salvaging a chronic limb-threatening ischaemia-affected limb have not been well documented.

Methods: A model using National Health Service healthcare usage and cost data for 1.6 million individuals and averaged numbers of primary surgical procedures for chronic limb-threatening ischaemia from England and Wales in 2019–2021 was created to perform a budget impact analysis. Two scenarios were tested: the averaged national rates of major lower-limb amputation (above the ankle joint), angioplasty, open bypass surgery or arterial endarterectomy in the National Vascular Registry (current scenario); and revascularization rates adjusted based on the lowest amputation rate reported by the National Vascular Registry at the time of the study (hypothetical scenario). The primary outcome was the net impact on costs to the National Health Service over 12 months after the index procedure.

Results: In the current scenario, the proportions of different index procedures were 10% for lower-limb major amputation, 55% for angioplasty, 25% for open bypass surgery and 10% for arterial endarterectomy. In the hypothetical scenario, the procedure rates were 3% for major lower-limb amputation, 59% for angioplasty, 27% for open bypass surgery and 11% for arterial endarterectomy. For 16 025 index chronic limb-threatening ischaemia procedures, the total care cost in the current scenario was €243 924 927. In the hypothetical scenario, costs would be reduced for index procedures (−€10 013 814), community care (−€633 943) and major cardiovascular events (−€383 407), and increased for primary care (€59 827), outpatient appointments (€120 050) and subsequent chronic limb-threatening ischaemia-related surgery (€1 179 107). The net saving to the National Health Service would be €9 645 259.

Conclusion: A shift away from primary major lower-limb amputation towards revascularization could lead to substantial savings for the National Health Service without major cost increases later in the care pathway, indicating that care decisions taken in hospitals have wider benefits.

Introduction

Steno-occlusive lower-limb peripheral artery disease (PAD) is a major health problem and the main cause of lower-limb amputations worldwide[1]. Estimated prevalence worldwide was 236 million in 2015[2]. In the UK, PAD is estimated to affect 20% of people older than 60 years[3]. Among patients who are symptomatic at presentation around 10% are thought to have progressed to chronic limb-threatening ischaemia (CLTI)[4], a life-threatening condition that typically requires urgent revascularization or possibly primary amputation[5,6]. Strikingly, in the UK in 2021, of 11 426 index procedures performed to treat CLTI, 8358 (74%) were open and endovascular revascularization procedures, but one-quarter (3068 (26%)) were primary major lower-limb amputations[7]. In 2018, the National Health Service (NHS), in its Getting it Right First Time (GIRFT) report, highlighted opportunities for reducing the number of major lower-limb amputations through earlier identification of risk to the limb to allow more index revascularization procedures[8].

In many patients, care costs rise dramatically after a diagnosis of PAD due to the need for multiple hospital follow-up visits, lower-limb procedures and high risk of other cardiovascular events. In Sweden, Hasvold *et al.*[9] estimated that in the first year after a diagnosis of PAD, the average healthcare costs per patient increased by 90%. While some studies have assessed the cost-effectiveness of different surgical techniques in patients with CLTI[10,11], the impact of performing a limb salvage procedure instead of a primary amputation in this group of patients has not been previously modelled in detail.

In this study, national registry data from primary and secondary care were employed to create a model that could estimate the effects of increasing the rate of limb-salvage

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procedures and reducing that of primary lower-limb amputations in patients with CLTI. The performance of the model was assessed through a budget impact analysis.

Methods

Study design

This was a modelling and budget impact analysis study based on national registry data. The model population was patients who underwent primary surgical procedures due to CLTI from 2019 to 2021, as reported in the 2022 UK National Vascular Registry (NVR)[7,12]. The NVR publishes a large amount of data at NHS trust level, which are anonymized and are available in the public domain. Permission to use these does not have to be formally requested. Therefore, in line with current NHS Good Clinical Practice guidelines, Health Research Authority guidance, and in the opinion of the NHS East Midlands (Leicester) NHS Research Ethics Committee, no ethics approval was required to analyse the data in this study.

Model data sources

Numbers of primary surgical procedures for CLTI were included from England and Wales[7,12]; owing to low rates of complete data from Scotland and Northern Ireland, these regions were excluded. Model calculations were based on the average numbers of different procedures from the years 2019 to 2021 in the NVR. The revascularization data in the NVR are presented as open bypass surgery and endovascular procedures. It is not possible from the data to disaggregate angioplasty and arterial endarterectomy alone. Data on hybrid procedures are not formally collected. For the purposes of the model, therefore, it was assumed that all endovascular procedures were either angioplasty or arterial endarterectomy. To estimate the proportion split for these procedures, rates of the two techniques were applied from the study of Saratzis *et al.*, which assessed treatment via the Kent Integrated Dataset (KID)[13,14]. KID contains prospectively recorded linked patient-level data for around 1.6 million people obtained from public health services (for example general practices, hospitals, community health services and social care).

Registration of procedures in the NVR is less than 100% and, therefore, it compares numbers submitted to the registry with those recorded in each nation's administrative hospital database to calculate what proportions have been registered (ascertainment rates)[12]. These rates (85% for major lower-limb amputation (above the ankle joint), 42% for angioplasty, 86% for open bypass surgery and 42% for arterial endarterectomy) were included in the model to estimate the total numbers of all procedures.

Costs of resource use were guided by an analysis of healthcare resource use in the KID for adults (age more than 18 years) who presented to secondary care in the NHS with CLTI and required revascularization or major lower-limb amputation between 1 January 2016 and 1 January 2019[13,14]. To establish numbers of procedures, Saratzis *et al.*[14] used ICD-10 codes to identify patients with CLTI. The codes were selected by relevance to baseline characteristics and postoperative events of interest and using Systematized Nomenclature of Medicine Clinical Terms vocabulary (*Table S1*). Costs were calculated for primary care appointments, hospital outpatient appointments, community care appointments (including prosthesis and rehabilitation costs but not home adjustment costs), major cardiovascular event hospital admissions (myocardial infarction, coronary thrombosis not resulting in myocardial infarction, hypertensive heart disease with (congestive) heart failure, hypertensive heart and renal disease with (congestive) heart failure, heart failure, congestive heart failure, left ventricular failure and other conditions) and antithrombotic prescriptions. Average per-patient costs were calculated as the mean total cost multiplied by the mean procedure rate in KID. Calculations took into account factors such as procedure complexity, duration of hospital stay, consultation length, location, staff type, prescription costs and other typical overhead costs (*Table S2*)[14–17].

Scenarios

Two scenarios were assessed in the budget impact analysis. The first, the current scenario, used the ratios of index procedures (major lower-limb amputation, angioplasty, open bypass surgery or arterial endarterectomy) based on the 2022 NVR. The second, the hypothetical scenario, took the lowest major lower-limb amputation rate reported by an NHS Trust, as recorded in the NVR at the time of the study, with redistribution of the difference across the revascularization techniques, weighted by their proportions as in the current scenario.

Outcomes

The primary outcome was the difference in total costs between the two scenarios over 1 year of follow-up after CLTI index procedures (net budget impact). A positive budget impact indicated that the hypothetical scenario would lead to incremental expenditures, whereas negative impact indicated a cost saving.

Sensitivity analysis

A deterministic sensitivity analysis was conducted to test the potential variation in net budget impact that could result from uncertainty in individual model parameters. This involved testing the variation in net budget impact resulting from using plausible lower and upper values for each model input. KID contains data from all acute NHS Trusts, including primary, social and community care providers located in the geographical area. The values for the present sensitivity analysis were the average costs from all Trust providers with standard deviations (*Table S2*). If standard deviations were unavailable, a 20% difference from the base-case value was assumed. The top 10 parameters for which individual parameter uncertainty could impact the net budget impact result were assessed.

Results

In England and Wales during the study interval, the number of CLTI index procedures reported in the NVR for 2019–2021 was 15 456. With the application of ascertainment rates, the estimated total number of index procedures included in the model was 16 025.

In the budget impact analysis current scenario, the proportions of different index procedures were 10% for lower-limb major amputation, 55% for angioplasty, 25% for open bypass surgery and 10% for arterial endarterectomy (*Fig. 1*). In the hypothetical scenario, the procedure rates were 3% for major lower-limb amputation, 59% for angioplasty, 27% for open bypass surgery and 11% for arterial endarterectomy.

Costs of care

The mean base treatment unit costs from KID and calculated per-patient costs are shown in *Table 1*. The total 1-year

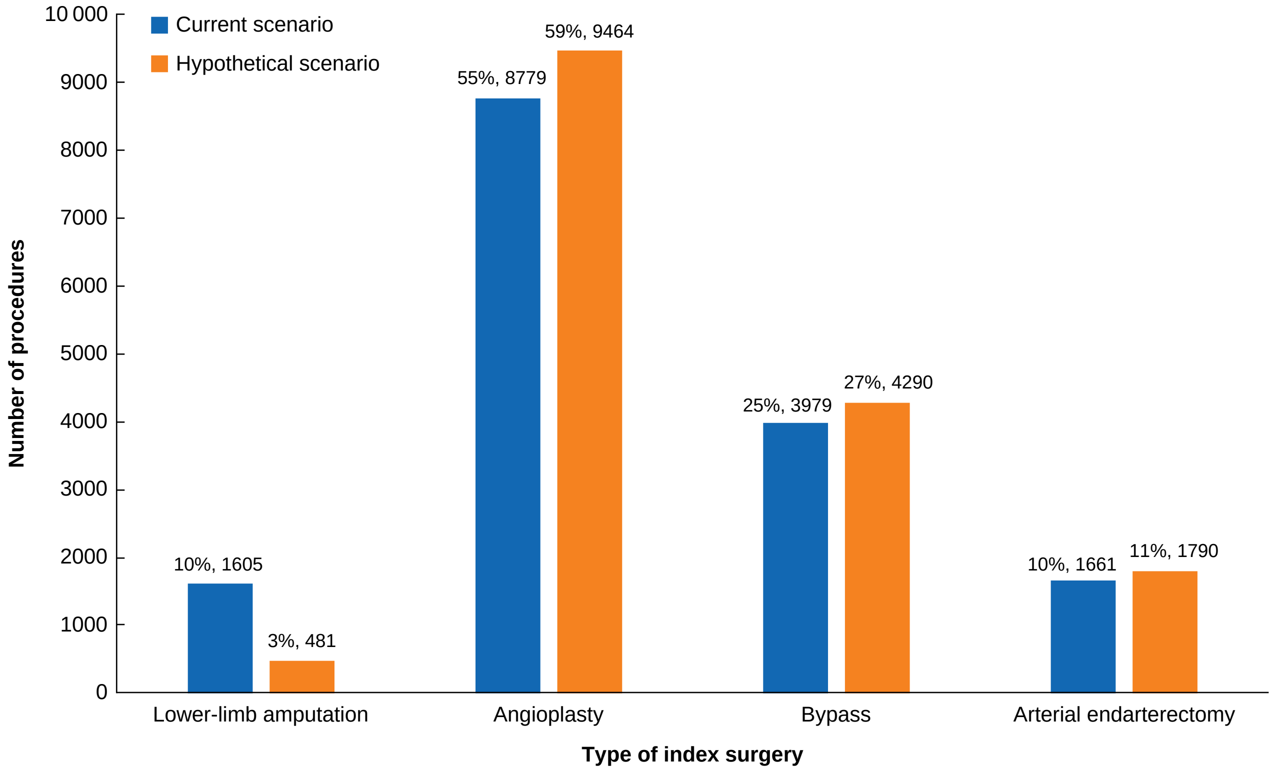

Fig. 1 Numbers and proportions of index procedures by type in the current and hypothetical scenarios
The current scenario uses procedure rates in the 2022 UK National Vascular Registry (NVR) report[7] adjusted with ascertainment rates. In the hypothetical scenario, rates of primary procedures were based on those in an NHS Trust that had achieved the lowest average major lower-limb amputation rate at the time of the NVR report[7,12]. NHS, National Health Service.

per-patient cost was highest after index major lower-limb amputation and lowest after index angioplasty. For all subgroups, key cost drivers were the index procedure, need for subsequent CLTI-related procedures, major cardiovascular events and community care appointments. Although rates of subsequent CLTI-related procedures were notably higher for patients who underwent index revascularization than those who had major amputation, angioplasty was performed most frequently, keeping 1-year costs lower. Total costs for appointments were driven mainly by community care appointments, particularly after major lower-limb amputation. Furthermore, the rate of outpatient appointments was higher after index major lower-limb amputation than after any of the revascularization procedures, which required more primary care involvement. The per-patient costs of major cardiovascular events were similar in all index procedure subgroups. A notably lower frequency after index open bypass surgery, however, did not reduce the cost over 1 year.

Budget impact

Over 1 year, the overall care cost for the entire cohort in the current scenario was €243 924 927 (*Table 2*). In the hypothetical scenario, despite the increased costs of revascularization index procedures, the reduction in the proportion of amputations led to a fall of €10 013 814 in the total index procedure cost (*Fig. 2*). Additional incremental savings were €383 407 for major cardiovascular events and €633 943 in community care costs. With little change in any other areas of the care pathway and the increase in subsequent CLTI-related procedures, the net saving was €9 645 259.

Sensitivity analysis

In the deterministic sensitivity analysis, the model was found to be robust in predictions irrespective of individual parameter uncertainty (*Fig. 3*). The top parameters identified confirmed that the net budget impact was influenced most by costs associated with index procedures and subsequent CLTI-related major lower-limb amputation.

Discussion

In this budget impact analysis, a model was tested using NVR data compared with a scenario in which the rate of major lower-limb amputation, as an index procedure for CLTI, was reduced and more limb-salvage procedures were performed. By lowering the rate of major lower-limb amputation from 10% to 3% in the NHS, a net saving of €10 013 814 was estimated to be achievable. While amputation should account for only a small proportion of primary procedures, the per-patient procedure and follow-up costs are considerably higher than for limb-salvaging procedures[14]. Of note, the savings calculated did not lead to expenditure being shifted to later in the care pathway, such as major cardiovascular events, which is one of the key arguments of proponents of primary amputation in this clinical context[8,18]. Savings were also achieved for community appointments while effects on primary care were minimal, indicating that care decisions taken in hospitals have wider benefits.

The 2018 GIRFT NHS report[8] highlighted inconsistencies across all elements of care for CLTI. NHS CLTI care provision was remodelled into a hub-and-spoke structure in line with GIRFT recommendations to pool resources, standardize care and shorten waiting times. However, only a slight reduction in the

Table 1 Mean care rates and costs in the 1 year after index procedure

Healthcare type	Index procedure			
	Major lower-limb amputation	Angioplasty	Bypass	Arterial endarterectomy
Care rates*				
Subsequent CLTI-related procedures				
Lower-limb amputation	0.14	0.11	0.12	0.07
Angioplasty	0.01	0.20	0.15	0.13
Open bypass surgery	0.01	0.09	0.08	0.05
Arterial endarterectomy	0.01	0.02	0	0.05
Appointments				
Primary care	6.46	7.47	8.40	8.46
Community care	32.16	23.46	22.28	19.04
Outpatient care	8.89	6.11	5.12	5.34
Other				
Cardiovascular event admission	0.77	0.80	0.23	0.75
Antithrombotic therapy prescriptions	3.48	6.97	5.91	8.04
Care costs				
Index procedure				
KID mean unit cost*	€15 340.00	€4543.00	€9369.20	€9416.40
Subsequent CLTI-related procedures				
KID mean unit cost*				
Major lower-limb amputation	€15 606.13	€13 108.18	€14 000.31	€14 000.31
Angioplasty	€6133.01	€5822.82	€7796.79	€6133.01
Open bypass surgery	€8649.45	€8649.45	€8649.45	€8649.45
Arterial endarterectomy	€10 366.54	€10 366.54	€10 366.54	€10 366.54
Per-patient cost†	€2433.16	€3590.74	€3508.14	€2784.80
Appointments				
KID mean unit cost*				
Primary care	€33.39	€35.21	€33.09	€32.97
Outpatient care	€80.95	€151.12	€121.54	€151.34
Community care	€53.70	€51.08	€51.31	€53.87
Per-patient cost‡				
Primary care	€215.94	€263.14	€277.30	€279.66
Outpatient care	€719.80	€922.76	€621.86	€808.30
Community care	€1726.34	€1198.88	€1143.42	€1025.42
Total	€2662.08	€2384.78	€2042.58	€2112.20
Major cardiovascular event				
KID mean unit cost*	€3246.68	€3391.78	€3317.79	€3317.79
Per-patient cost‡	€2489	€2715	€753	€2489
Antithrombotic therapy prescriptions				
Antithrombotic therapy prescriptions	€14.16	€49.56	€38.94	€38.94
Per-patient cost‡	€4.07	€7.19	€6.53	€3.48
Total				
KID mean unit cost*	€44 177.98	€41 583.37	€44 343.34	€42 708.75
Per-patient cost	€22 939.20	€13 284.44	€15 711.70	€16 830.34

*Obtained from KID analysis (*Table S1*). †Calculated as the sum of all subsequent procedure types × all respective 1-year rates for the given index procedure. ‡KID unit cost × annual rate. CLTI, chronic limb-threatening ischaemia; KID, Kent Integrated Dataset.

Table 2 Annual total cohort costs in the current and hypothetical scenarios

Surgical treatment type	Index procedure	Subsequent CLTI-related procedures	Primary care appts	Community appts	Outpatient appts	Major cardio-vascular events	Anti-thrombotic therapy	Total
Current scenario costs								
Major lower-limb amputation	€24 627 019	€3 906 417	€346 385	€2 772 327	€1 155 779	€3 995 316	€22 697	€36 825 939
Angioplasty	€39 884 199	€31 527 468	€2 308 888	€10 520 560	€8 102 217	€23 841 979	€439 866	€116 625 178
Open bypass surgery	€37 281 856	€13 959 231	€1 105 749	€4 548 717	€2 475 611	€2 994 248	€153 411	€62 518 821
Arterial endarterectomy	€15 640 094	€4 626 325	€463 558	€1 703 252	€1 342 245	€4 133 000	€46 514	€27 954 988
All patients	€117 433 167	€54 019 441	€4 224 582	€19 544 858	€13 075 853	€34 964 541	€662 489	€243 924 927
Hypothetical scenario costs								
Major lower-limb amputation	€7 374 618	€1 169 786	€103 726	€830 180	€346 101	€1 196 407	€6 797	€11 027 613
Angioplasty	€42 995 041	€33 986 511	€2 488 975	€11 341 131	€8 734 165	€25 701 578	€474 175	€125 721 574
Open bypass surgery	€40 189 723	€15 048 007	€1 191 994	€4 903 503	€2 668 701	€3 227 789	€165 376	€67 395 091
Arterial endarterectomy	€16 859 972	€4 987 164	€499 715	€1 836 101	€1 446 936	€4 455 360	€50 142	€30 135 389
All patients	€107 419 352	€55 191 466	€4 284 409	€18 910 915	€13 195 902	€34 581 133	€696 489	€234 279 667

CLTI, chronic limb-threatening ischaemia; appts, appointments.

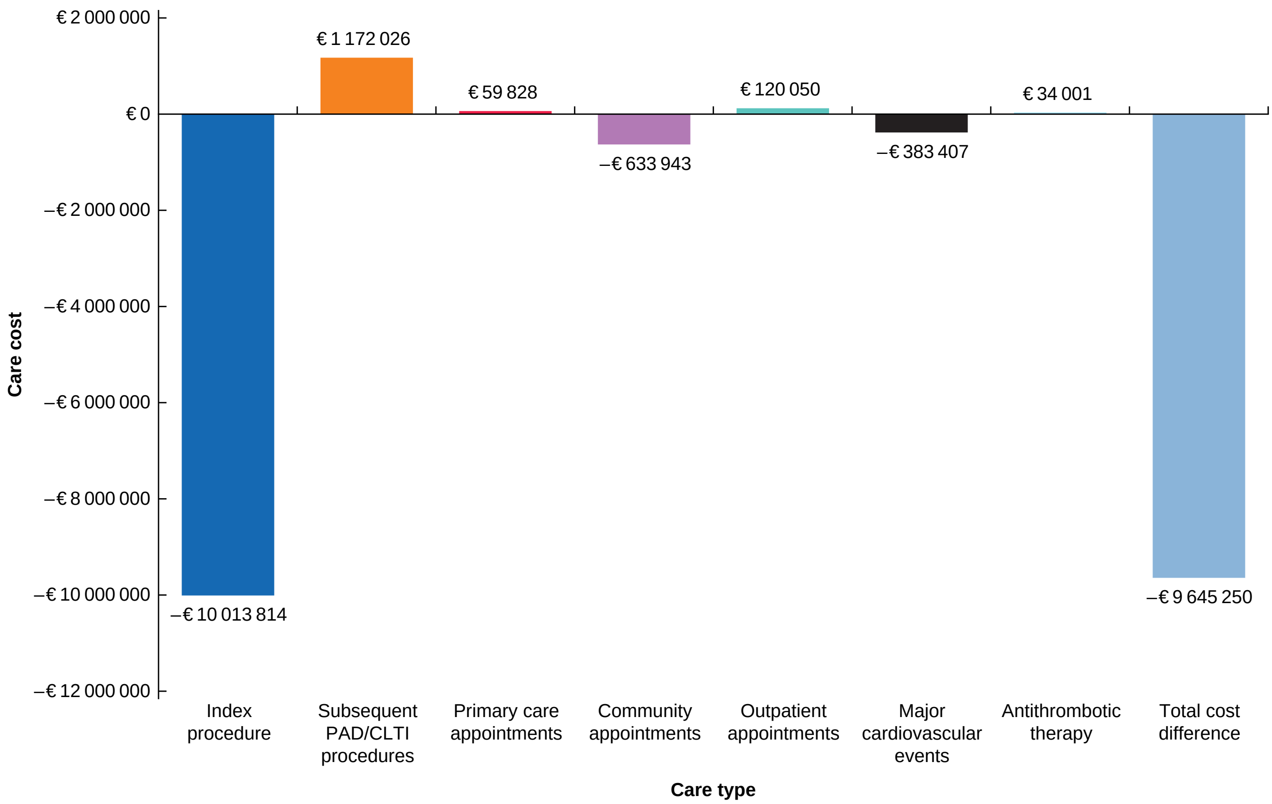

Fig. 2 Annual incremental changes in cost in the hypothetical scenario
CLTI, chronic limb-threatening ischaemia; PAD, peripheral artery disease.

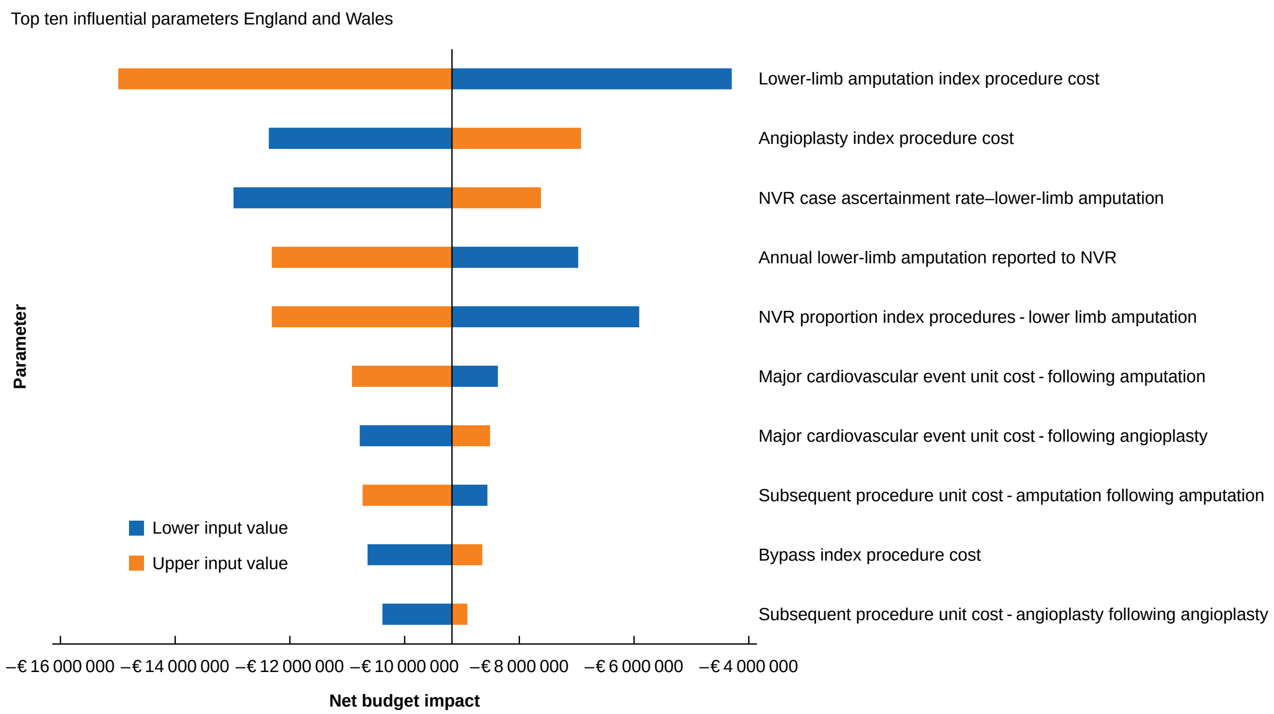

Fig. 3 Ten strongest causes of variable uncertainty in the deterministic sensitivity analysis
NVR, UK National Vascular Registry

number of major lower-limb amputations performed as index procedures for CLTI was seen between 2019 and 2021 (from 3260 to 3068, 6%)[12].

In response, and based on recommendations by The National Confidential Enquiry into Patient Outcome and Death[19], the Vascular Society for Great Britain and Ireland has published a best practice clinical care pathway for PAD, setting targets of inpatient treatment within 5 days and outpatient treatment 14 days for patients with CLTI[20]. The NHS Commissioning for Quality and Innovation scheme from 2022 onwards has recommended that arterial care networks in the NHS follow this guideline to improve revascularization standards for lower-limb ischaemia[21]. It estimates that by reducing delays in assessment, investigation and revascularization for patients with CLTI, annual savings of €14.13 million could be achievable through shortened hospital duration of stay, mortality rates, readmissions and amputation rates. The finding in the present study of a saving of more than €9.42 million supports incremental savings being possible. The Commissioning for Quality and Innovation does not set a clear threshold for reductions. However, the 3% threshold applied for index major lower-limb amputation procedures in this model was chosen because it is a level that has been reached by an NHS Trust already. With replication of these outcomes in more NHS Trusts, the savings potential could become reality.

Early identification of patients with PAD can help to maintain or improve blood flow, reduce tissue loss, delay or prevent the need for major surgical intervention, and reduce other cardiovascular morbidity and mortality rates[5]. However, opportunities for timely recognition and referral are being missed. Nickinson *et al.* showed that in primary care, patients with CLTI who had undergone lower-limb amputation had attended a median of 19 primary care consultations (range 9–32) in the year before the operation[22]. Of 3260 patients, 2073 (64%) had not had a cardiovascular assessment for more than 3 months. Of 2175 patients who had a primary care visit in the month before amputation, only 416 (13%) underwent a cardiovascular assessment in that interval despite 68% of all patients having hypertension and significant proportions having cardiovascular co-morbidities and/or diabetes. Furthermore, secondary preventive medications had been prescribed in primary care to less than half of the 3260 participants (antiplatelets 49.7% and lipid-lowering agents 40.7%). Even within the established diabetes foot care pathway[23], preventable lower-limb complications remain common, particularly among white men older than 65 years from the most deprived areas[24].

Patients' understanding of the causes and progression patterns of PAD is poor, which affects care-seeking and compliance. Qualitative data highlight patients' ignorance and trivialization of symptoms and attempted self-management rather than consulting health professionals[25]. Among those who do seek a diagnosis, they report frustration due to substantial delays of months to years and lack of follow-up and information. Lack of understanding of treatment leads to poor uptake of exercise therapies and unrealistic expectations of surgical treatment[26].

The Vascular Society for Great Britain and Ireland best practice pathway advises arterial care networks to provide education to patients, general practitioners, doctors from other specialties, community nurses, and podiatrists in the diagnosis and treatment of PAD. Furthermore, it ensures patient access to appropriate treatments and lifestyle advice[20]. Additional risk assessments in primary care (for example cardiovascular risks and lifestyle modifications, and measurement of the ankle brachial index or toe pressure)[27] and structural changes in secondary care to increase the number of hub-and-spoke networks and build multidisciplinary teams would enhance practice further[28]. Initiatives in primary care can help to target relevant patients[29].

The present study showed that changing treatment policy to consider more revascularizations than primary major lower-limb amputations is not only valuable to the patients and how they receive care but can result in substantial healthcare savings for the NHS.

This study fills a gap by mapping, to our knowledge for the first time, total treatment costs across the entire care pathway for CLTI. The use of data from KID ensured that the model reflects the costs and healthcare resource utilization associated with current standards of care. The inclusion of primary, secondary and community care data allowed a system-wide view of resource use. Use of data from the latest NVR Annual Report to supplement modelling provided the fullest picture available of the number of patients requiring index procedures for CLTI. Incorporating the deterministic sensitivity analysis allowed quantification of potential uncertainty in individual model parameters and showed that the inferences were robust. Use of the cost inputs established in KID meant that many also had standard deviations available, particularly for unit costs, and could act as indicators for the low and high plausible costs in this analysis.

This model has some limitations. First, the NVR is commissioned by the Healthcare Quality Improvement Partnership, which generally audits healthcare in England and Wales. By contrast, although hospitals in Scotland and Northern Ireland are encouraged to provide data, reporting is not mandatory, and they are submitted to a much lesser degree. The study findings, therefore, cannot be taken as representative of the whole of the UK. Furthermore, the registry does not provide detailed data on some relevant factors, such as minor lower-limb amputations and hybrid revascularization. Inclusion of such data would provide a clearer picture of potential savings but might need to be achieved through prospective collection of datapoints. Finally, the NVR does not disaggregate arterial endarterectomy from angioplasty procedures. Therefore, calculating separate values for these treatments relied on some assumptions: the distribution proportions were based on those in KID, and the ascertainment and index procedure rates (that is, those used for the overall endovascular category in the NVR) were the same for both.

Second, the model does not consider the impact of differences between vascular centres and regions in factors such as infrastructure investment and patient populations. In the reported analysis, the intention was to assess the performance of the model to calculate costs and, therefore, investigating the causality of potential differences in costs was deemed to be outside of the study scope.

Third, in some areas, data on healthcare resource utilization are low, as not all centres or hospitals perform more than 10 procedures per year. In these cases, the unit cost was assumed equal to the average unit cost for patients regardless of which index procedure they received, which might have reduced the reliability of the point estimates for those costs. However, the deterministic sensitivity analysis was supported by plausible upper and lower values and standard deviations and suggested that uncertainty did not impact this study's findings.

Fourth, the costs in KID are based on identification of patients with CLTI by use of ICD-10 codes. While it is known that use of these codes has limitations and increases the risk of misclassification bias[29], attempts were made to select ICD-10 that restricted the population to patients with CLTI based on baseline characteristics and postoperative events of interest[14].

Finally, data from KID were based on the interval January 2016 to December 2019, and those used to determine the cohort size for England and Wales were from 2021. More recent data were not available at the time of the study, but the model can be updated with future releases of the NVR Annual Report. Using hospital episode statistics could be an alternative data source for future refinement of the analysis.

The model applied in this study used national registry data and estimated potential annual savings of more than €10 million in the NHS budget if the average rate of major lower-limb amputations as the index procedure for CLTI is reduced to 3% across England and Wales. A reduction to at least this level seems feasible through early identification of patients when they are still eligible for limb-salvage procedures in a timely fashion.

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Disclosure

A.S. has received honoraria and lecture and/or consulting fees from Shockwave, Abbott and Cook Medical, educational grant support from Cook Medical, and research funding from Shockwave, Abbott, Boston Scientific and Angiodroid. H.Z. has received payment to perform as a speaker, trainer and/or proctor from Abbott, Gore Medical, Bentley, Boston Scientific, Cordis, Cook Medical and Limflow. Institutional research grant from Abbott. A.S. and H.Z. did not receive payment for authorship on this study. G.V. and M.S. are employees of Abbott. The authors declare no other conflict of interest.

Supplementary material

Supplementary material is available at *BJS Open* online.

Data availability

All relevant data for this study are presented.

Author contributions

Athanasios Saratzis (Validation, Visualization, Writing—review & editing), Hany Zayed (Validation, Visualization, Writing—review & editing), Anna Buylova (Formal analysis, Methodology, Project administration, Software), William Rawlinson (Formal analysis, Methodology, Software), Giota Veliu (Conceptualization, Supervision, Validation, Visualization, Writing—review & editing) and Markus Siebert (Conceptualization, Supervision, Validation, Visualization, Writing—review & editing).

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