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## NATIONAL REGISTRY

# Geographical Variation in the Management of Peripheral Arterial Occlusive Disease: A Nationwide Danish Cohort Study

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## WHAT THIS PAPER ADDS

Small area variation in clinical practice patterns is well known in areas other than vascular surgery. This study demonstrates that costs and amputation rates after first time revascularisation for peripheral arterial occlusive disease vary by factors of up to 1.6 and 1.1, respectively, depending on the geographical region in which the surgery is performed and followed up. This indicates the potential for standardisation of clinical management to improve clinical outcomes without incurring additional costs.

**Objective:** Equal access for equal needs is a key goal for many healthcare systems but geographical variation research has shown that this is often not the case in areas other than vascular surgery. This study assessed the variation across specialised vascular centres of an entire healthcare system in the costs and outcomes for patients having first time revascularisation for peripheral arterial occlusive disease.

**Methods:** This was a national study of all first time revascularisations performed in the Danish healthcare system between 2009 and 2014. Episodes were identified in the Danish Vascular Registry ( $n = 10\ 300$ ) and data on one year follow up in terms of the costs of specialised healthcare (€) and amputation status were acquired from national registers. Generalised gamma and logit regressions were used to predict margins between centres while adjusting for population heterogeneity (age, sex, education, smoking, hypertension, diabetes, use of prophylactic pharmacological therapy, indication and type of revascularisation). Cost effectiveness frontiers were used to identify efficient providers and to illustrate the cost of reducing the system level risk of amputation.

**Results:** For each of the indications of chronic limb threatening and acute limb ischaemia, the one year amputation risks varied from 11% to 16% across centres ( $p = .003$ ,  $p = .006$ ) whereas for intermittent claudication there was no significant difference across centres. The corresponding costs of care varied across centres for all indications ( $p = .027$ ,  $p = .028$ ,  $p = .030$ ). Linking costs and outcomes, three of seven centres were observed to provide poorer quality at higher costs. Exponentially increasing costs to obtain the maximum reduction of the amputation risk were observed.

**Conclusion:** The results suggest that there is substantial variation in the clinical management of peripheral arterial occlusive disease across the Danish healthcare system and that this results in very different levels of efficiency — on top of potentially unequal treatment for equal needs. Further research is warranted.

**Keywords:** Peripheral arterial occlusive disease, Practice patterns, Small area variation, Cost effectiveness

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## INTRODUCTION

Peripheral arterial occlusive disease (PAOD) is a relatively common condition in the elderly with a prevalence of around 10%.<sup>1,2</sup> The disease spectrum ranges from mild intermittent claudication (IC) to severe limb threatening

ischaemia requiring revascularisation or amputation. Around 75% of patients are at the mild end of the spectrum but because of disease progression and the higher risk of coronary artery disease, heart attack, or stroke, early prevention is crucial. The indication for healthy lifestyle support

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and pharmacological preventive therapy is relatively straightforward, whereas patient selection for revascularisation is more controversial.<sup>3,4</sup>

Clinical guidelines refer to chronic limb threatening ischaemia (CLTI) and acute limb ischaemia (ALI) as indications for revascularisation, whereas there is no strict consensus when it comes to IC.<sup>4,5</sup> Local area variation in terms of the indication threshold for revascularisation and related outcomes is thus to be expected. Several studies have already shown that revascularisation rates vary substantially across settings<sup>6,7</sup> and that different patterns of recurring hospitalisations and repeat revascularisation add to this variation.<sup>8</sup> Also the cost consequences to the healthcare system have been shown to vary. But, to the best of the present authors' knowledge, the synthesis of costs and outcomes remains to be informed.<sup>9,10</sup> From a health policy perspective, variation in clinical practice across geographical areas not only threatens equality of access, but also economic efficiency, meaning that the healthcare budget is not spent where it generates the most utility to the patient.<sup>11</sup>

Geographical variation in clinical practice can be warranted if this is because of variation in population needs, patient preferences, or other premises outside the discretion of local clinical management. If it is a result of the provider not being able to comply with good clinical practice guidelines, for example because of capacity issues, staff preferences, or culture, it might be unwarranted. In economic terms, this will often be a case of inefficiency meaning that, overall, better outcomes could have been achieved for the same costs. In that case, the healthcare system level management principally has two options: to redirect patients from inefficient to efficient providers or to force inefficient providers to adopt the operating mode of the efficient providers.

The aim of this study was to assess the variation across specialised vascular centres in the costs and outcomes after first time revascularisation resulting from PAOD. In contrast to the literature assessing the patient costs and outcomes to guide the selection of patients for particular surgical techniques, this study takes a system level perspective on clinical management, which can be used to discuss the potential of standardisation of clinical practice.

## MATERIALS AND METHODS

This was a national study of all first time revascularisations performed in the Danish healthcare system. The Danish system is composed of seven highly specialised vascular centres (Copenhagen, Slagelse, Odense, Kolding, Viborg, Aarhus, Aalborg) at publicly financed hospitals, each covering a fixed geographical uptake area. Apart from varicose vein treatment, all vascular procedures are performed in the public healthcare system and clinical details of indication, procedure type, risk factors, complications, etc., are recorded in the Danish Vascular Registry. Consecutive PAOD patients, who had first time revascularisation between 2009 and 2014 ( $n = 10\ 300$ ) were included and followed from the index revascularisation and one year thereafter. This study followed The Strengthening the

Reporting of Observational Studies in Epidemiology (STROBE) guidelines.<sup>12</sup>

### *Study population*

All patients undergoing first time lower limb revascularisation (index procedure) for PAOD were identified in the Danish Vascular Registry. The completeness of the Danish Vascular Registry for the study period of 2009 to 2014 was 99% when cross checking that the person IDs with a procedure code for revascularisation in the National Patient Registry was also included in Danish Vascular Registry. The high coverage for revascularisations corresponds to high overall coverages reported in the annual reports of the registry of between 92% and 100% ([www.karbase.dk](http://www.karbase.dk)). Indications include IC, CLTI caused by ischaemic rest pain, ulceration, or gangrene, and ALI. Patients aged <50 years were excluded because major amputation is rare in these patients.

### *Patient characteristics*

Baseline status on smoking, comorbidity, indication for revascularisation, type of revascularisation and (any) revascularisations, and the geographical area responsible for the treatment were retrieved from the Danish Vascular Registry, while data on age, sex, education, use of prophylactic pharmacological therapy, and death during follow up were retrieved from relevant national administrative health registries.

### *Healthcare use and costs*

PAOD related healthcare was identified by record diagnosis in the National Patient Registry and included the index surgery, outpatient care for vascular follow up, wound follow up, or vascular imaging, and inpatient care for revascularisations, wound debridement, and minor or major amputation. Complete follow up was achieved through the 100% coverage of the National Patient Registry.<sup>13</sup> The healthcare use was valued using the Diagnosis-Related Grouping system and reported as a total cost per patient (€ at 2014 prices). This system is based on standardised, national tariffs for individual procedures.

### *Cost effectiveness*

A cost effectiveness frontier approach<sup>14</sup> was used to illustrate the average cost effectiveness resulting from the clinical practice of each of the seven centres (total cost per patient vs. amputation risk), as well as the incremental cost effectiveness ratios (ICERs) between successive centres, expressing the additional costs associated with reaching the next level of reduced amputation risk. The higher the ICERs, the higher the required willingness to pay to obtain better outcomes. The willingness to pay for additional outcome is principally the responsibility of the policy level, and the actual level – the cost effectiveness threshold – is unknown for the Danish context. Centre practice located above or to the left of the cost effectiveness frontier is inefficient and cannot be cost effective at any cost

**Table 1. Populations and rates of peripheral arterial occlusive disease (PAOD) diagnosis and revascularisation across Danish centres for vascular surgery**

	Geographical area						
	Copenhagen	Slagelse	Odense	Kolding	Viborg	Aarhus	Aalborg
Population aged >50 y	570 177	328 131	187 290	272 908	192 391	254 906	224 857
Diagnosed with PAOD	5 942	3 583	2 093	3 945	2 329	2 612	2 339
Diagnosed with PAOD per 10 000 population	104	109	111	144	121	102	104
Revascularised	3 377	2 084	1 251	2 790	1 429	1 396	1 621
Revascularised per 10 000 population	59	63	66	102	74	54	72
Revascularised per 10 000 diagnosed with PAOD	5 683	5 816	5 977	7 072	6 135	5 344	6 930
First time revascularised	2 604	1 330	944	2 229	1 063	1 012	1 118
First time revascularised per 10 000 population	20	28	21	34	26	18	24
First time revascularised per 10 000 diagnosed with PAOD	4 382	3 711	4 510	5 650	4 564	3 874	4 779
Cost of first time revascularised per population – €	79	69	86	130	90	71	83
Cost of first time revascularised per population diagnosed with PAOD – €	7 615	6 375	7 755	9 058	7 516	6 959	8 023

Data are presented as *n* unless stated otherwise. Values are cumulative period prevalence or incidence from 2009 through 2014 per 10 000 population aged > 50 y unless otherwise stated. Population size is adopted from Londero *et al.* 2019.<sup>6</sup>

effectiveness threshold – because similar or better outcomes can be achieved for lower costs at other centres.

### Statistical analysis

Baseline characteristics were compared across the seven geographical areas using classical frequency tables and tests of chi square and ANOVA. Regression models of amputation (yes/no) and cost (continuous), respectively, were specified as functions of geographical area and relevant variables of population heterogeneity to make patients comparable across the geographical areas:

Outcome = *f* (geographical area, age, sex, education, smoking, hypertension, diabetes, use of prophylactic pharmacological therapy, indication and type of revascularisation)

The amputation model was estimated using logit regression and reported as the probability of major amputation during the first year after revascularisation. The cost model was estimated using a generalised gamma regression with a log link and reported as the predicted cost (€) during the first year after revascularisation. For each of the indications, predictive margins (95% CI) were used to illustrate the variation across the seven geographical areas. There were no missing data except for data on education, which were missing for 475 patients (5%). This was coded as informative missingness. Sensitivity analyses where these patients were instead excluded did not substantially alter the results.

The cost effectiveness frontier was defined from the pairs of predictive margins for amputation risk and cost, respectively.<sup>15</sup> The incremental cost effectiveness ratios were calculated as the cost difference/the difference in amputation risk between successive centres.

### Ethics

The study follows the principles of the Helsinki declaration and was approved by the Danish Data Protection Agency. All

data were anonymised, and therefore no patient informed consent was required according to Danish legislation.

## RESULTS

### Geographical areas

Table 1 shows population numbers and unadjusted rates of diagnosis and revascularisation across the seven geographical areas of Danish specialised vascular care. One area stands out with the highest rates of diagnosis, revascularisation and first time revascularisation per population (Kolding), whereas the remainder are closer, yet not similar. Population heterogeneity could explain some of this variation. Table 2 summarises the characteristics of first time revascularised patients. Except for sex and hypertension as comorbidity, all of the patient characteristics are statistically significantly different across geographical areas at a 5% significance level.

### Amputation outcomes

Figure 1 shows the predicted 12 month amputation first time revascularisation risk across geographical areas after adjustment for population heterogeneity. For each of the indications of CLTI and ALI, respectively, the amputation risks varied between 11% and 16% across the geographical areas. These variations are statistically significantly different from zero at  $p = .003$  and  $p = .006$ . For IC, the variation in the amputation risk is between 0.5% and 0.7% across the geographical areas (not statistically significantly different).

### Healthcare costs

Figure 2 shows the adjusted, predicted 12 month total healthcare cost per patient after first time revascularisation. For IC, the cost varies between €11 606 and €12 834, which is statistically significantly different across geographical areas ( $p = .027$ ). For CLTI, the cost varies between €21 595 and €23 879, which is also statistically

**Table 2.** First time revascularised patients with peripheral arterial occlusive disease served by the Danish centres from 2009 through 2014

	Geographical area							
	Copenhagen (n = 2 604; 25%)	Slagelse (n = 1 330; 13%)	Odense (n = 994; 9%)	Kolding (n = 2 229; 22%)	Viborg (n = 1 063; 10%)	Aarhus (n = 1 012; 10%)	Aalborg (n = 1 118; 11%)	All (n = 10 300)
Age – y	70 ± 10	69 ± 9	71 ± 10	71 ± 10	70 ± 10	70 ± 10	71 ± 10	70 ± 10
Male	1 462 (56)	730 (55)	524 (56)	1 227 (55)	570 (54)	522 (52)	579 (52)	5 614 (55)
<b>Education</b>								
≤Lower secondary school	1 044 (40)	616 (46)	468 (50)	1147 (51)	565 (53)	474 (47)	604 (54)	4 918 (48)
Upper secondary or vocational	1 053 (40)	541 (41)	329 (35)	733 (33)	352 (33)	378 (37)	377 (34)	3 763 (37)
Higher	365 (14)	135 (10)	110 (12)	231 (10)	108 (10)	112 (11)	83 (7)	1 144 (11)
No information	142 (6)	38 (3)	37 (4)	118 (5)	38 (4)	48 (5)	54 (5)	475 (5)
Smoking	1 100 (42)	647 (49)	414 (44)	889 (40)	471 (44)	454 (45)	456 (41)	4 431 (43)
Hypertension	1 953 (75)	1 010 (76)	723 (77)	1 750 (79)	815 (77)	764 (76)	880 (79)	7 895 (77)
Diabetes	622 (24)	299 (23)	197 (21)	498 (22)	229 (22)	177 (18)	231 (21)	2 253 (22)
Prophylactic therapy*	2 161 (83)	1 147 (86)	734 (78)	1 980 (89)	917 (86)	901 (89)	964 (86)	8 804 (86)
<b>Indication</b>								
IC	1 114 (43)	687 (52)	356 (38)	1 311 (59)	535 (50)	459 (45)	492 (44)	4 954 (48)
CLTI	1 171 (45)	638 (48)	356 (38)	775 (35)	456 (43)	485 (48)	528 (47)	4 489 (44)
Acute limb ischaemia	319 (12)	5 (0)	152 (16)	143 (6)	72 (7)	68 (7)	98 (9)	858 (8)
<b>Index revascularisation</b>								
Open	1 022 (39)	416 (31)	632 (67)	926 (42)	457 (43)	593 (59)	571 (51)	4 617 (45)
Endovascular	1 582 (61)	914 (69)	312 (33)	1 303 (59)	606 (57)	419 (41)	547 (49)	5 683 (55)
Major amputation within one year	170 (7)	79 (6)	74 (8)	113 (5)	87 (8)	90 (9)	104 (9)	717 (7)
Death within one year	327 (13)	144 (11)	130 (14)	267 (12)	112 (11)	100 (10)	169 (15)	1 249 (12)

Data are presented as n (%) or mean ± standard deviation. All characteristics are significantly different across geographical areas at the 5% significance level. IC = intermittent claudication; CLTI = chronic limb threatening ischaemia.

\* Baseline use of statins or antithrombotic agents.

significantly different across geographical areas ( $p = .028$ ), and, similarly for ALI, statistically significant cost variation ( $p = .030$ ) is observed from €13 349 to €14 761.

Figure 3 shows a breakdown of the total cost for the least costly vs. the costliest geographical areas (among those on the cost effectiveness frontier, see below). For the indication of the highest magnitude, CLTI, Viborg was spending €1 905 (12%) less than the national average on the index revascularisation and any re-operations but then €691 (22%) more on amputations. The opposite is observed for Kolding where the revascularisation costs were €147 (1%) above and amputation related costs €132 (1%) below the national average costs. For IC and ALI, respectively, the pictures were more blurred, yet the general finding was that Kolding spends above and Viborg below the national averages for revascularisations.

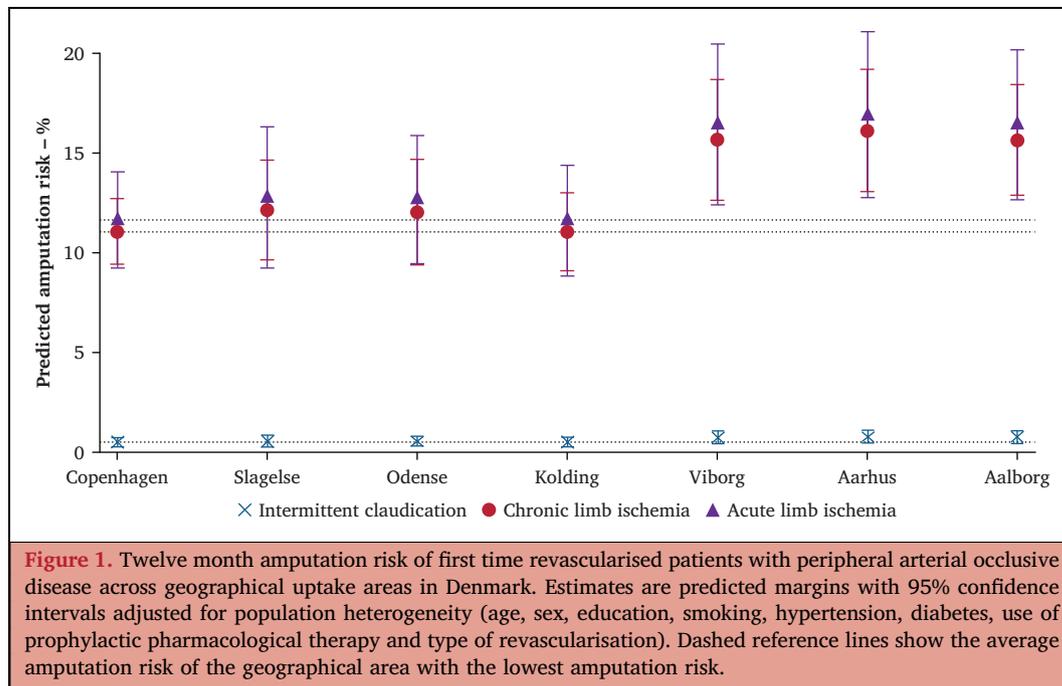
### Cost effectiveness

Figure 4 illustrates the average total cost per patient and the average amputation risk in each of the geographical areas. Three areas are dominated by others (Aarhus, Aalborg, Slagelse) meaning that a similar or lower amputation risk is obtained at a lower cost elsewhere. Non-dominated areas form the cost effectiveness frontier. Whether it is worthwhile standardising practice towards the mode of the centre demonstrating the lowest amputation risks (Kolding)

depends on the cost effectiveness threshold. For IC, reducing the amputation risk from 0.72% (Viborg) to 0.53% (Odense) requires €84 974 per percentage point, whereas additional reductions along the frontier require >€1 million. For CLTI, a reduction from 15.66% (Viborg) to 12.02% (Odense) requires only €8 377 per percentage point, whereas further reductions require €84 346 (down to the 11.05% demonstrated by Copenhagen) and around three quarters of a million (down to the 11.02% demonstrated by Kolding). For ALI, a reduction from 16.44% (Viborg) to 12.65% (Odense) costs only €4 983, whereas reaching the lowest level demonstrated by Kolding requires around half a million per percentage point reduction.

### DISCUSSION

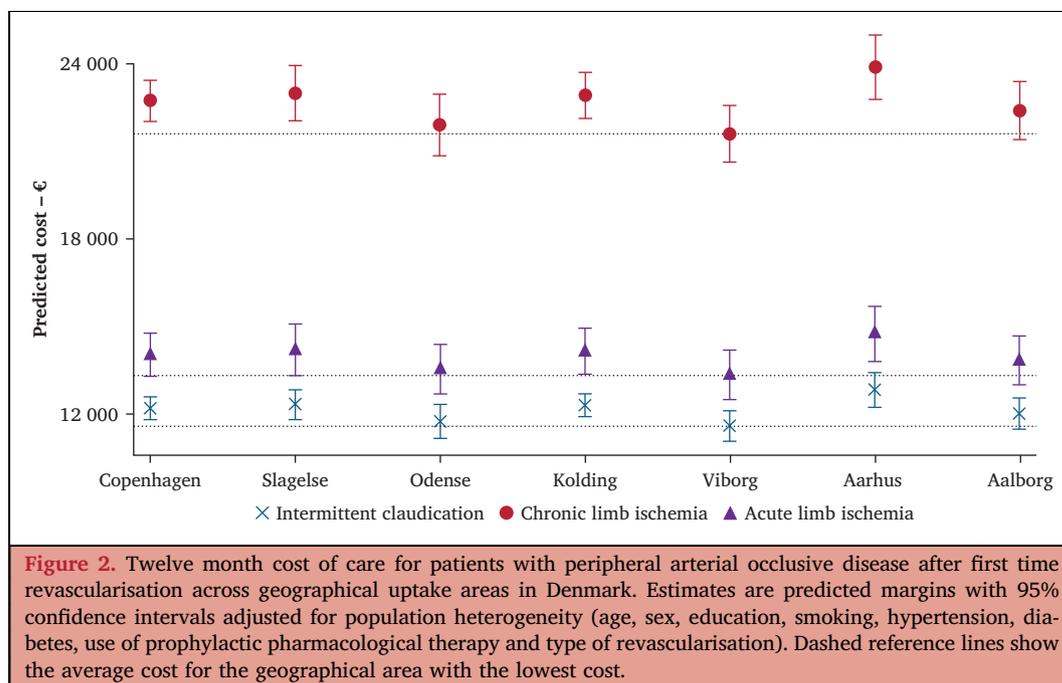
This study of geographical variation in cost and outcomes after first time revascularisation in the Danish healthcare system showed that there is substantial variation. This is relevant for system level management because some centres demonstrate an operating mode resulting in relatively poorer outcomes at relatively higher costs, such that – *ceteris paribus* – both legs and money can be saved only by standardising practice. Studies of geographical variation should, however, always be interpreted with great caution because it is difficult to fully adjust for local premises that are unchangeable.

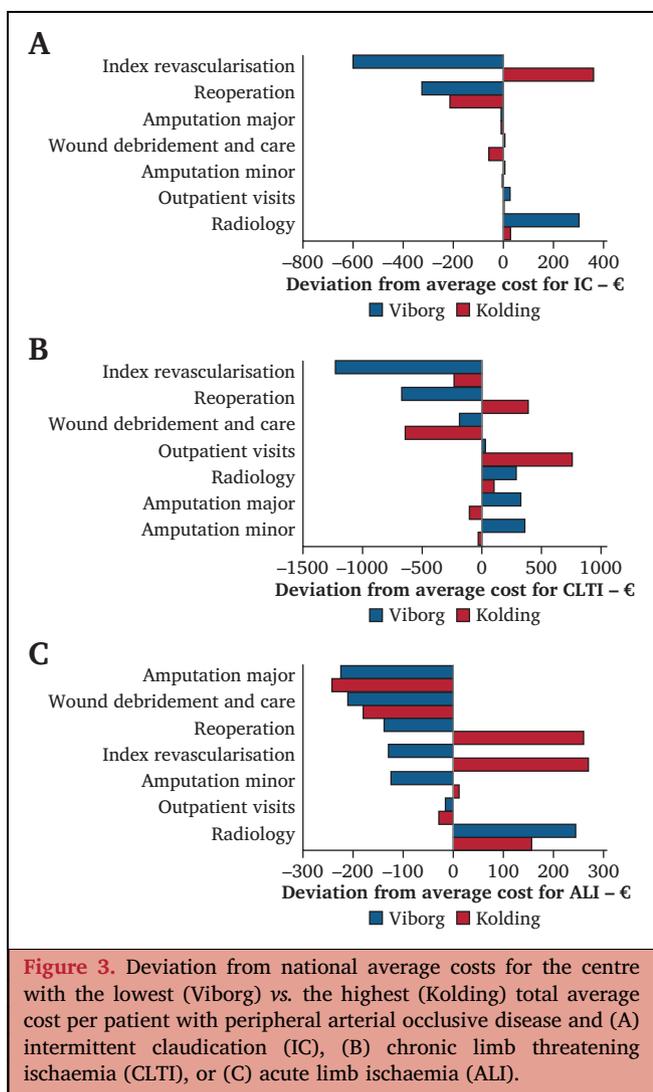


Only few studies in PAOD appear to link costs and outcomes at the system level and, to the best of the present authors' knowledge, this is the first to assess the variation across centres and to analyse the costs of system level performance improvement. A study from the Medicare context assessed the care pattern in a cohort of amputated patients and found no clear link between regional spending and amputation outcomes.<sup>16</sup> A few other studies have assessed variation in single measures of either costs or outcomes. In a recent study of US patients, who had lower extremity bypass, the investigators observed cost variations

across regions, which were at similar levels in relative terms to the present results.<sup>17</sup> In another recent study among asymptomatic patients with coronary artery disease, revascularisation rates were observed to vary two fold between hospitals.<sup>18</sup>

The present analytical strategy relied on patients being comparable. Adjustments were made for index technique (open or endovascular) to take into account that the choice between these techniques could reflect (unobserved) patient characteristics. It is, however, equally possible that this choice is purely preference based on the part of the





surgeon or the centre, in which case variation across the centres could have been overlooked.<sup>19</sup> Sensitivity analysis with no adjustments for index technique did not markedly affect the results.

Although very few patients in this age group and in areas with limited waiting time take advantage of the free choice of hospital, minor misclassification cannot be ruled out. Further, the cohort does not include the most recent years because of delays in source register updates, and also the time demanding process of validation of costs in particular. The present authors are not aware of any major changes to Danish practice that have occurred in recent years and thus consider the actuality reasonable.

The interpretation of the cost per percentage point reduction in the system level amputation rate can be seen as an analogue to the cost per quality adjusted life year (QALY), which expresses the return on investment of the healthcare budget. In this case, where the outcome is narrower than quality of life, the results can only guide (re-) allocation of budget within therapy for limb preservation. It would be interesting to map the observed cost per percentage point reduction in the amputation rate to a cost per

QALY but evidence on the relationship between amputation status and quality of life is limited and without clear direction.<sup>20–22</sup>

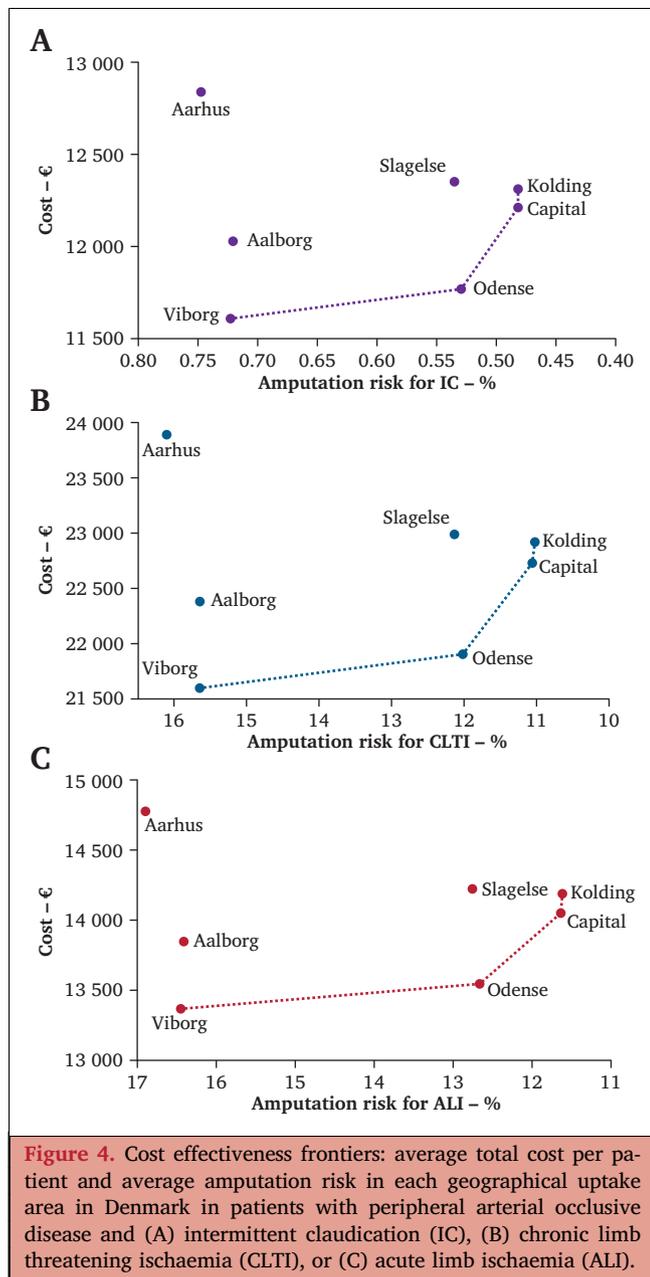
From a centralisation perspective, the minimum number of procedures to ensure high quality is often balanced against patient disutility from travel and/or insecurity being far from their local area.<sup>23</sup> There is evidence that patients are willing to travel far<sup>24</sup> but also that great distance could be associated with worse outcomes.<sup>25</sup> Danish healthcare is characterised by a rather small scale, as the total population of <6 million is governed by five local healthcare governments, with the reality being that structural planning is often a matter of politics rather than effective centralisation. Some degree of variation could therefore be attributable to the regional policies rather than the local clinical practices. The results of two regions might help shed light on the extent of this, as these two regions are each served by two vascular centres. Interestingly, the two pairs of centres (Kolding vs. Odense; Viborg vs. Aarhus) differ by up to around 1 percentage point in amputation rates and up to €1 000 in costs, which indicates that at least some of the variation is the result of factors at the discretion of the local clinical management and thus is unwarranted.

This study is not intended to inform the rationale for centralisation but rather standardisation. Patients should be offered the same care for the same needs irrespective of geographical area. From an evidence based medicine perspective, the only legitimate reason for the observed variation is patient preferences, not personal surgeon preferences or local clinical managements, which would instead represent over or under use of care.<sup>26</sup> The reasons for the observed variation thus warrant further investigation.

The observed variation points to a potential dilemma in that the centre standing out with the highest revascularisation rates and the highest proportion of IC as indication also generates the lowest amputation risks. Yet, revascularisation is not indicated for IC according to good clinical practice guidelines<sup>4,5</sup> and the required cost effectiveness threshold seems unrealistic. There are at least two ways to progress from that: further studies on the optimal timing of first time revascularisation, including long time follow up, might nuance the indication threshold, and qualitative studies on when and why clinical guidelines are not adhered to could inform opportunities for impact.

In terms of generalisability, cost levels are rarely identical across healthcare systems. For these results, the main threat is if the cost differences between cost categories are different, such that what are observed as high costs are a result of repeated revascularisation vs. repeated admission for wound care and ultimately amputation. Further, amputation rates could be nationally linked to, for example, population characteristics and size, educational and staff structures etc., such that the international contribution is considered a matter of hypothesis generation and motivation of awareness rather than magnitude-wise finding.

In conclusion, there appears to be substantial potential for improving the major amputation risk of first time



revascularised PAOD patients if clinical management were standardised in accordance with the practice demonstrated by efficient centres. Among the departments that already operate in a cost effective manner, relatively minor additional budget allocation appears to have the potential to substantially reduce the amputation risk at one end of the spectrum (Viborg), while at the other end of the spectrum (Odense and Copenhagen), major budget increases appear to be required.

#### CONFLICT OF INTEREST STATEMENT AND FUNDING

None.

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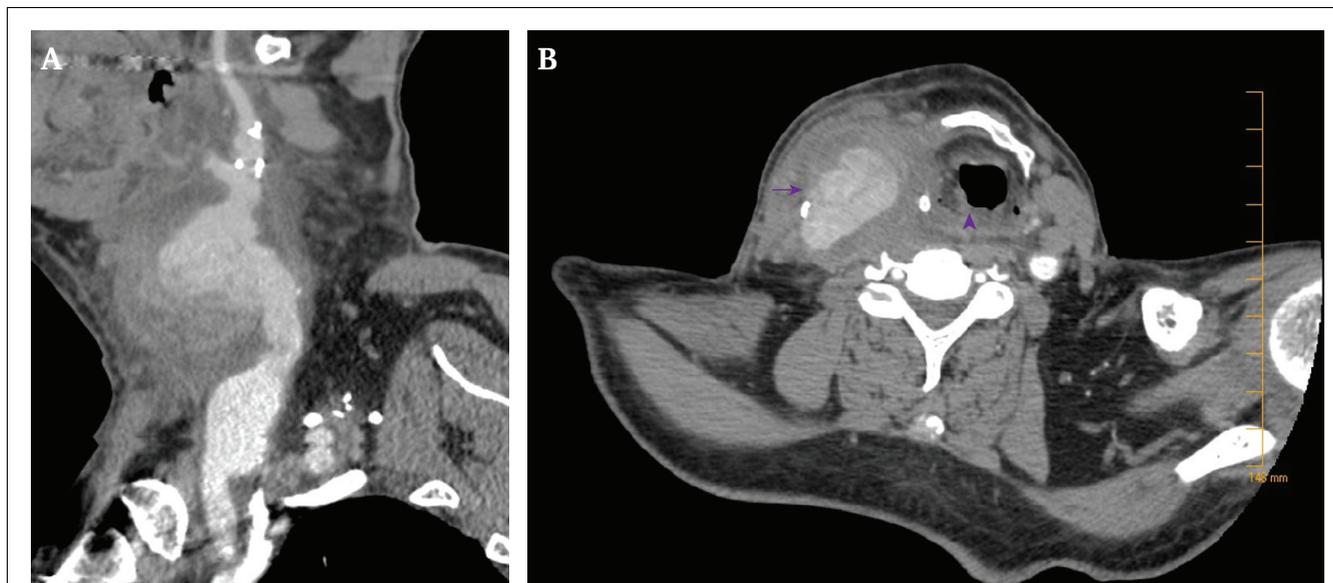
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## COUP D'OEIL

### Rupture of a Common Carotid Artery Aneurysm

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A 72 year old man presented to the emergency department with sudden onset of pulsatile mass in the right neck. The neurological examination noted decreased strength of the left upper and lower extremities. (A, B) Computerised tomography angiography showed contained rupture of a right common carotid artery aneurysm with a large right neck haematoma (arrow) and associated tracheal deviation (arrowhead). The patient was taken to the operating room urgently to repair the aneurysm with an interposition femoral vein graft. Post-operatively, his neurological examination was similar, and the patient was discharged to a rehabilitation facility.

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