

# Real World Practice Deviation from Nationwide Guidelines in Patients with Intermittent Claudication

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## WHAT THIS PAPER ADDS

This paper adds new insights into compliance with and reasons for deviation from guidelines in the initial treatment of patients with intermittent claudication with supervised exercise therapy. Almost three quarters of deviations from the guidelines can be explained by personalised meaningful care and therefore fall under desired practice variation.

**Objective:** Patients with intermittent claudication (IC) are initially treated with supervised exercise therapy (SET), as advised by national and international guidelines. Dutch health insurance companies and the Dutch National Health Care Institute suggested an 87% compliance rate with these guidelines in the Netherlands in 2017 and judged this to be undesirably low. The aim of this study was to evaluate compliance with IC guidelines and to elaborate on the reasons for deviating from them (practice variation) in a large teaching hospital.

**Methods:** A retrospective single centre cohort study was conducted at a large teaching hospital in the Netherlands. In total, 420 patients with newly diagnosed IC between 1 January 2017 and 31 December 2018 were analysed. Data included risk profiles and prescribed therapies.

**Results:** For all 420 included patients, the compliance rate with the guidelines for SET was 80.5%. The rate of adequately motivated and defensible practice variation was 15.7%; the rate of unjustified practice variation was 3.8%. Meaningful care was seen in 96.2% of cases.

**Conclusion:** Deviation from IC guidelines was found in 19.5% of patients. Almost three quarters of this deviation can be explained by the decision to provide personalised, meaningful care.

**Keywords:** Intermittent claudication, Peripheral arterial disease, Personalised care, Practice variation, Supervised exercise therapy

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## INTRODUCTION

The most common manifestation of symptomatic peripheral arterial disease (PAD) is intermittent claudication (IC). Treatment of IC comprises interventions focusing on the improvement of cardiovascular risk factors and supervised exercise therapy (SET). Invasive revascularisations are reserved for patients who do not respond to SET, as implemented in the stepped care model.<sup>1,2</sup> Home based exercise therapy (HBET) is an alternative when supervision is not available or wanted. The effectiveness of SET<sup>3-5</sup> and HBET<sup>6</sup> has been confirmed in recent studies, resulting in

longer pain free walking distances and total walking time, durable for a time period of at least 18 months analysed in a patient group with aorto-iliac PAD.<sup>7</sup> SET and HBET do not only improve walking performance, but also focus on changes in lifestyle, including quitting smoking.<sup>8,9</sup>

In contrast to invasive revascularisation, SET is time consuming and its effectiveness depends on the motivation and compliance of the patient. Therefore, invasive revascularisation provides an attractive first treatment option for both physicians and patients. As a result, treatment of IC is sensitive to practice variation, defined as differences in treatment, which can be traced back to medical decisions of individual healthcare providers. Indefensible practice variation, defined as practice variation without the written support of the patient or proof of medical necessity,<sup>10,11</sup> may negatively influence the quality, cost effectiveness, and efficiency of care.<sup>10</sup> In the Netherlands, health insurance companies and the Dutch National Health Care Institute (ZiN) have reported an adherence rate to the 2017

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European Society of Cardiology's Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases of 87%, based on financial declarations for IC,<sup>1,12</sup> with a side note that Jansen *et al.* excluded more than half of the study population owing to absent treatment codes.<sup>12</sup> Nevertheless, health insurances companies judged a practice variation of 13% as indefensible, although reasons for deviating from the guidelines were not recorded.<sup>12</sup> Therefore, it is not possible to determine if this deviation was adequately motivated and defensible, or unjustified and indefensible. The question is raised whether the observed practice variation is a result of personalised care, based on individual patient needs and preferences. In this study, compliance with IC guidelines and possible reasons for deviation from the guidelines in a large Dutch teaching vascular centre were investigated. Whether observed practice variation was "adequately motivated and defensible" or "unjustified" was analysed.

## MATERIALS AND METHODS

Compliance with IC guidelines and the reasons for deviating from these guidelines was studied in all new patients with IC presenting at the vascular centre of Medisch Spectrum Twente (MST), Enschede, the Netherlands, between 1 January 2017 and 31 December 2018. Patients were identified using the Dutch financial declaration coding system, in which diagnostics and treatments are coded in the same manner throughout the Netherlands. According to Dutch national guidelines, the appropriate declaration code for new patients with IC patients is "DOT 418". Exclusion criteria were an intake consultation conducted outside the study period, acute ischaemia (defined as symptoms that had existed for < 2 weeks), no show at the vascular centre, appointments for follow up instead of intake, or causes of IC other than PAD. Furthermore, patients were excluded when

directives for SET were not applicable (Fig. 1) or when an incorrect DOT 418 was used. The institutional review committee approved this retrospective study, and the need for informed consent was waived.

## Data

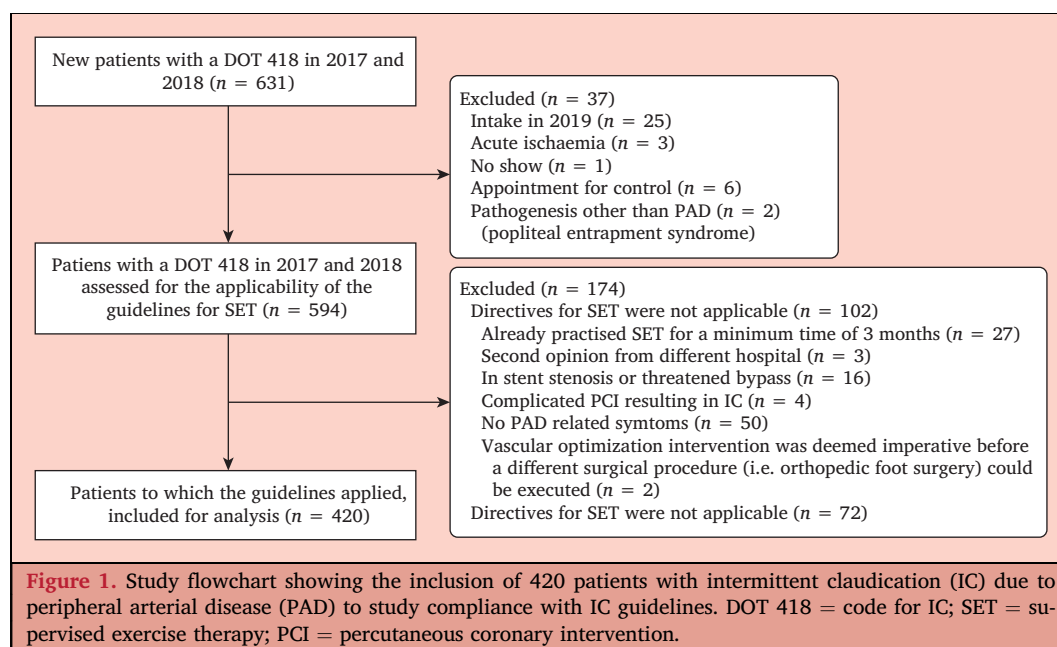
Demographic data and physiological variables, related to IC, were obtained from medical files. Data regarding atherosclerotic risk factors, referral and intake conductors, walking tests, ankle brachial index (ABI) and prescribed treatment were collected, according to the reporting standards of the Society for Vascular Surgery for endovascular treatment of chronic lower extremity PAD.<sup>13</sup>

## Deviation arguments

Arguments for deviating from the guidelines were collected from the medical files of all included patients. Deviation from the guidelines comprised a revascularisation procedure, HBET, or discharge from treatment. Consensus was achieved within the research group, which consisted of vascular surgeons, an epidemiologist, and two researchers for assessment of the defensibility of these arguments (Table 1).

## Endpoints

This study had multiple main endpoints, namely compliance with the guidelines for SET, shown as percentage prescribed SET as the first treatment modality, and the percentages of defensible and indefensible arguments when SET was not prescribed. Results were compared with the available Dutch national data from 2017, as no national data were available for 2018. Finally, an indication of meaningful care was determined (compliance with the guidelines [%] + defensible practice variation [%]).



**Table 1.** Arguments noted by the vascular surgeons for alternative treatment options that deviate from guidelines for intermittent claudication and the consensus assessment of these arguments

Arguments	Patients – n	Prevalence
<i>Reasons noted for revascularisation</i>		
	33	
“Patient adequately followed walking advice from the general practitioner”		19/33
“Patient lost his job as a result of his complaints”		3/33
“Borderline resting pain; patient is able to justify that SET is not a suitable treatment option for him”		1/33
“Because of osteoarthritis, patient does not wish to participate in SET”		1/33
“No results are expected from SET with a low resting ABI”		2/33
“SET is not useful when complaints are seriously disabling”		2/33
“SET is not considered useful when stenosis is at the level of the iliac arteries”		1/33
“No added value of SET is expected when symptoms abruptly arose in a fit and healthy patient when embolus has been ruled out”		1/33
No reasons were noted		3/33
<i>Reasons noted for HBET</i>		
	19	
“There are no complaints about disability”		4/19
“Symptoms are very non-specific; let us first see how it develops”		1/19
“Because of comorbidities, advice was given to find a type of physical exercise that this patient was capable of”		2/19
“Patient wishes to walk at home without supervision”		6/19
“SET is not considered useful when the patient needs a walking aid”		1/19
“Because of low cardiac reserve, walking advice was given to improve stamina”		2/19
No reasons were noted		3/19
<i>Reasons noted for discharge</i>		
	30	
“SET is not possible or not considered possible for this patient (because of not fitting a lower leg prosthesis, cox arthritis, walking aid, back complains or balance problems)”		5/30
“Patient is able to walk for an unlimited amount of time. Complaints only arise when bicycling. SET is not considered useful”		1/30
“There are no complaints of disability”		4/30
“Patient does not wish to participate in SET”		6/30
“SET is not considered an option because of alcoholism and no expected compliance”		1/30
“SET was not prescribed because there is a greater burden due to comorbidities, dialysis, or carcinoma”		5/30
“Patient requests a second opinion from a different hospital”		1/30
“Patient has already had or is starting to have COPD, or is receiving geriatric physical therapy”		3/30
No reasons were noted		4/30
<i>Consensus assessment of these 82 arguments by the research group*</i>		
	420	
Defensible, green + yellow		66 (15.7)
Well defensible, green		61 (14.5)
Understandable personal opinion of vascular surgeon, yellow		5 (1.2)
Indefensible, orange		16 (3.8)

Data are presented as *n* or *n* (%) if group is > 100 subjects. Green indicates “well defensible”, yellow indicates “understandable personal opinion of vascular surgeon”, and orange indicates “indefensible”. SET = supervised exercise therapy; ABI = ankle brachial index; HBET = home based exercise therapy; COPD = chronic obstructive pulmonary disease.

\* Percentages shown on total patient group of 420 patients.

## Statistics

Continuous normally distributed data were assessed with a two sided *t* test and displayed as mean ± standard deviation. Non-normally distributed data were assessed with the Wilcoxon rank sum test and displayed as median (interquartile range). Categorical data were assessed with Pearson’s chi square test or Fisher’s exact test when the expected cell count was < 5 for at least one cell. *P* values < .05 were assumed to be statistically significant. Statistical analysis was conducted with SPSS Statistics Version 26.0 (IBM, Armonk, NY, USA).

## RESULTS

A total of 420 patients newly diagnosed with PAD with IC who met the inclusion criteria were included. The mean age was 67.7 ± 0.48 and 61.0% of patients were male. The patient characteristics are shown in Table 2.

Of these 420 patients, 338 (80.5%) patients received SET as the first treatment modality. Eighty-two (19.5%) patients received an alternative treatment. Alternative treatment comprised advice on HBET (*n* = 19 [4.5%]), revascularisation (*n* = 33 [7.9%]), or discharge with advice to the general practitioner to optimise the cardiovascular risk profile (*n* = 30 [7.1%]) (Fig. 2 and Table 4).

Significant differences were found between patients who received SET as the first treatment modality and patients who received an alternative treatment. Patients who received alternative treatment were statistically significantly more often male (*p* = .043), practised HBET before intake (*p* < .001), had a history of IC (*p* < .001), had a cardiac comorbidity (*p* = .036), had a lower Rutherford classification (*p* = .015), or no disabling or severe disabling symptoms (subject to the patient’s perception; *p* < .001) (Table 2).

**Table 2.** Baseline characteristics of 420 patients in the Netherlands studied for compliance analysis, in total and divided by whether they received supervised exercise therapy (SET) or an alternative treatment as initial treatment for intermittent claudication (IC)

Variable	Total (n = 420)*	SET according to the guidelines (n = 338)	Alternative treatment (n = 82)†	p
Age – y	67.70 ± 9.873	67.32 ± 9.317	69.30 ± 11.827	.10‡
Male	256 (61.0)	198 (58.6)	58 (70.7)	.043§
Treatment prescribed by GP before intake in the vascular centre				<.001
None	275 (74.7)	237 (79.5)	38 (54.3)	
HBET	69 (18.8)	38 (12.8)	31 (44.3)	
SET < 3 months	24 (6.5)	23 (7.7)	1 (1.4)	
Medical history of IC, > 1 year ago	138 (33.2)	93 (27.8)	45 (54.9)	<.001§
Smoking				.42§
Never	33 (8.0)	27 (8.2)	6 (7.5)	
Quit	194 (47.2)	151 (45.6)	43 (53.8)	
Current smoker	184 (44.8)	153 (46.2)	31 (38.8)	
BMI – kg/m <sup>2</sup>	27.12 ± 4.968	27.25 ± 5.165	26.71 ± 4.373	.51‡
Hypertension	271 (72.3)	218 (70.8)	53 (79.1)	.17§
Diabetes mellitus	102 (25.0)	85 (25.8)	17 (21.8)	.47§
GFR – mL/min/1.73 m <sup>2</sup>	74 (53.5–89.0)	75 (54.0–89.0)	72 (53.3–89.0)	.64‡
LDL – mmol/L	2.6 (1.9–3.3)	2.6 (2.0–3.4)	2.4 (1.7–3.2)	.086‡
Cardiac comorbidity	153 (37.3)	115 (34.8)	38 (47.5)	.036§
Cerebrovascular comorbidity	76 (18.3)	57 (17.1)	19 (23.2)	.20§
Pulmonary comorbidity	50 (13.6)	39 (13.1)	11 (15.5)	.60§
Walking test, median maximum walking distance – m	200 (101–210)	196 (100–210)	200 (117–210)	.55‡
Resting ankle pressure – mmHg	104.89 ± 30.493	104.86 ± 30.028	105.01 ± 32.555	.97‡
Ankle pressure after exercise – mmHg	64.84 ± 36.730	64.78 ± 37.601	65.15 ± 32.013	.94‡
ABI at rest – mmHg	70.11 ± 19.769	69.68 ± 19.651	71.91 ± 20.280	.37‡
ABI after activity – mmHg	37.90 ± 21.058	37.21 ± 20.937	41.56 ± 21.504	.15‡
Rutherford classification				.015§
1	25 (6.6)	16 (5.1)	9 (14.3)	
2	179 (47.2)	148 (46.8)	31 (49.2)	
3	175 (46.2)	152 (48.1)	23 (36.5)	
Disabling symptoms				<.001
None	15 (5.4)	9 (3.9)	6 (11.5)	
Moderate	96 (34.3)	79 (34.6)	17 (32.7)	
Disabling	118 (42.1)	107 (46.9)	11 (21.2)	
Severe	51 (18.2)	33 (14.5)	18 (34.6)	

Data are presented as n (%), mean ± standard deviation, or median (interquartile range). GP = general practitioner; HBET = home based exercise therapy; BMI = body mass index; GFR = glomerular filtration rate; LDL = low density lipoprotein; ABI = ankle/brachial index.

\* Due to missing data, not all variables have a total of 420 (see Table 3).

† Alternative treatment comprised revascularisation, HBET or discharge.

‡ Two sided t test.

§ Chi square test.

|| Fisher's exact test.

¶ Wilcoxon's rank sum test.

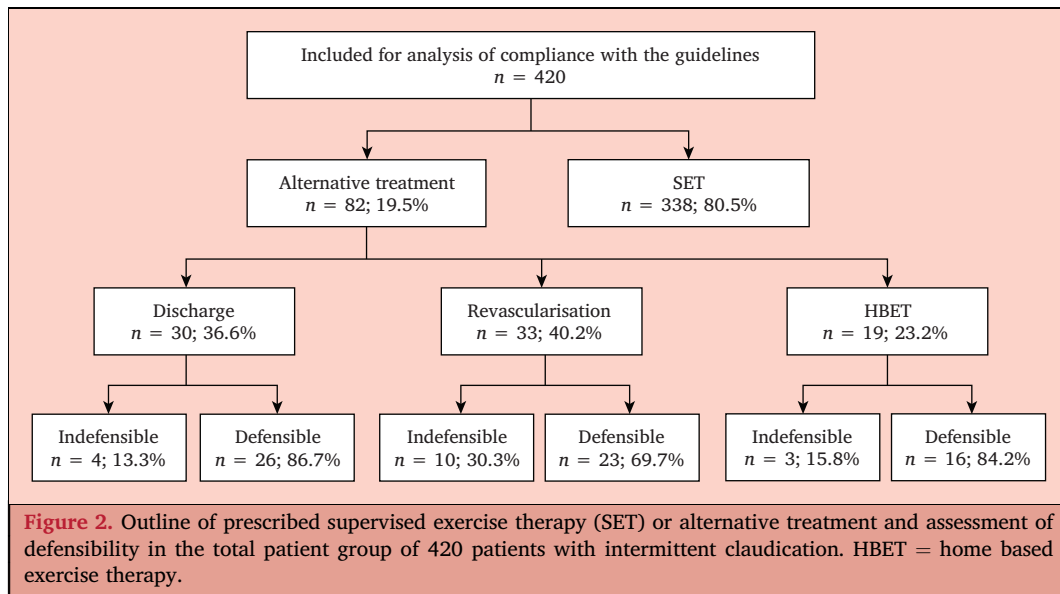
Of the 19.5% of patients who had an alternative treatment prescribed, the decision was assessed as defensible in 15.7% and indefensible in 3.8% (Table 1). The different arguments behind the vascular surgeons' decisions to prescribe an alternative treatment are presented in Table 1. Ninety-six per cent received meaningful care: in 80.5% there was adherence to the guidelines and in 15.7% there was a well reasoned deviation from the IC guidelines.

In newly diagnosed patients with IC in 2017 in the Netherlands, SET was prescribed as the first treatment modality in 87.0% of cases. Alternative treatment was prescribed in 13.0% of cases, which consisted of revascularisation procedures. Of all the revascularisation procedures, 10.0% were minimally invasive revascularisations and

3.0% were invasive (Table 4). No data were available for alternative treatments such as HBET or discharge (Table 4). When comparing the Dutch national data to MST data, equivalent compliance to the guidelines is shown, where MST performed fewer revascularisations not preceded by SET.

## DISCUSSION

The main outcome of the present study is that the rate of compliance to IC guidelines at MST was 80.5%. Within the study period, the rate of adequately motivated practice variation was 15.7% and that of unjustified, indefensible practice variation was 3.8%. Differences found between the



two patient groups (SET vs. alternative treatment) can be explained by the patient characteristics (e.g., severe comorbidities and HBET before intake). Practising HBET before intake was considered to be a sufficient alternative to SET and therefore resulted in revascularisation as the first treatment modality.<sup>14</sup> The second explanation for practice variation was the absence of disabling symptoms. In close collaboration with their physician, these patients chose HBET or discharge as the first treatment modality. However, patients with severe symptoms more often received invasive revascularisation as the first treatment modality. The alternative treatment group was too small to perform logistic regression analyses with sufficient power.

Owing to the absence of treatment codes, the study by Jansen *et al.*,<sup>12</sup> which was based on 2017 national data from the Netherlands, excluded a large population. The results of this study showed that 87% of treatment comprised SET, and the only alternative treatment was revascularisation. In the present study, 11.6% of patients received an alternative treatment not consisting of a revascularisation. It is possible that, in the study by Jansen *et al.*,<sup>12</sup> details of an alternative treatment not consisting of a revascularisation were excluded owing to the absence of treatment codes. Furthermore, by excluding such a large population, adherence to the guidelines could be overestimated and be more in line with the results of the present study (i.e., adherence rate of 80.5%).

According to national and international guidelines, all patients with symptomatic PAD presenting with IC are candidates for SET.<sup>1,15,16</sup> In the absence of evidence in the literature or support from IC guidelines, the arguments of “No results are expected from SET with low resting ABI”, “No added value of SET is expected when an embolus was ruled out but symptoms abruptly arose in a fit and healthy patient”, “SET is not useful when complaints are seriously disabling”, and “SET is not considered useful when stenosis is at the level of the iliac arteries” were all assessed to be indefensible by the authors.

As shown by Murphy *et al.*,<sup>15</sup> at the 18 month follow up, SET has a comparable maximum walking time and quality of life improvement as revascularisation for iliac artery lesions. Furthermore, SET is more cost effective and influences overall condition and (cardiopulmonary) health.<sup>8,9</sup> Therefore, SET is, independent of the level of the lesion, the first treatment modality for IC.<sup>1</sup> In most studies, patients walking with a walking aid, or with back, hip, or knee comorbidities besides IC, are excluded from analyses of the effectiveness of SET. Therefore, the effectiveness of SET is unknown in these

**Table 3.** Numbers of missing data per baseline characteristic in Table 2

Variable	Missing – n
Age	0
Male	0
Treatment prescribed by GP before intake in the vascular centre	52
Medical history of IC, > one year ago	4
Smoking	9
BMI	229
Hypertension	45
Diabetes mellitus	12
GFR	103
LDL	176
Cardiac comorbidity	10
Cerebrovascular comorbidity	4
Pulmonary comorbidity	52
Walking test, median maximum walking distance	70
Resting ankle pressure	7
Ankle pressure after exercise	49
ABI at rest	5
ABI after activity	46
Rutherford classification	41
Disabling symptoms	140

GP = general practitioner; IC = intermittent claudication; BMI = body mass index; GFR = glomerular filtration rate; LDL = low density lipoprotein; ABI = ankle/brachial index.

**Table 4. National percentages, newly diagnosed patients with intermittent claudication in 2017 and their initial treatment, compared with the Medisch Spectrum Twente (MST) vascular centre**

Treatment	The Netherlands	MST (n = 420)
Supervised exercise therapy	87.0	80.5
Home based exercise therapy, discharge, other	NA	11.6
Revascularisation	13.0	7.9
Minimal invasive	10.0	4.1
Invasive	3.0	3.8

Data are presented in %. NA = not available

patient groups.<sup>17–19</sup> With the pre-supposition that SET might be less effective, these arguments are assessed to be “understandable personal opinion of vascular surgeon” and therefore defensible.

Lauret *et al.* surveyed Dutch vascular surgeons and fellows opinions on SET as a treatment option for PAD.<sup>20</sup> The respondents referred 75.4% of patients with IC for SET and considered SET to be less useful in patients with major (cardiopulmonary) comorbidity or a significant iliac artery stenosis.<sup>20</sup> Compared with this study, MST demonstrated better compliance with the guidelines, but outdated misconceptions described in the 2012 study from Lauret *et al.*,<sup>20</sup> were still present in current practice.

In other studies, the limited availability of SET is mentioned as a reason to deviate from the guidelines.<sup>19</sup> In the Netherlands, there is nationwide coverage of SET certified physiotherapists.<sup>21</sup> The argument that SET was unavailable to patients was therefore not found in this study and would otherwise have been noted as indefensible practice variation.

In this study, 19.5% of the patients were prescribed an alternative treatment. In almost one in five patients, this was because the patient did not wish to participate in SET. No reasons were provided to explain why patients, after receiving an explanation of the pros and cons, refrained from SET. Harwood *et al.* showed in 23 studies that 50% of patients with IC were not interested in SET or did not want to participate in the study.<sup>22</sup> Nineteen per cent dropped out of the study, mainly because of a lack of motivation, comorbidities, pain during treatment, or lack of results from SET.<sup>21,22</sup> This shows the burden of SET regarding time, motivation, and compliance. There is a need to inform the patient of the effectiveness of SET and to keep the patient motivated. Moreover, surgeons might increase compliance with IC guidelines if they are well informed about recent developments in SET research.

In MST, the aim is to set up a treatment plan based on shared decision making.<sup>23</sup> There is an open forum for discussion and a weekly multidisciplinary consultation where patients, for whom the treatment plan has not yet

been established, are discussed, after which consensus is reached. Shared decision making comprises the sharing of the advantages and disadvantages of available treatment options based on scientific evidence, and in addition, the personal wishes, norms, and values of the patient.<sup>24</sup> For each patient, a personalised treatment plan will be formed. Therefore, well reasoned deviation from the guidelines is, in the majority of cases, a result of personalised care. Guidelines are applicable to a complete (well defined) patient population but do not necessarily meet the individual characteristics of each patient. Moreover, even the guidelines advise coming up with a treatment plan obtained through shared decision making, with the footnote that SET should be the first treatment modality for patients with IC.<sup>1,21</sup> Therefore, the reasoning behind a deviation from the guidelines should always be noted. Shared decision making is always the first choice, but it must be well reasoned and described. In the present study, shared decision making resulted in meaningful care in 96.2% of patients with a first presentation of IC. National data, based solely on financial registrations, do not provide sufficient insight into the optimal approach for the individual patient and are not a sufficient representative of quality of care. The statement from health insurances companies that adherence to the guidelines should be enforced based on these financial declarations is therefore indefensible.

### Strengths and limitations

A strength of this study was the complete DOT 418 research in the study period. This ensured that the data were representative of the national ZiN data. Next to this, an independent team based assessment of the arguments for defensible and indefensible practice variation, which is based on current literature, was performed.

A limitation of this study was its retrospective nature. Retrospective studies are prone to information and confounding bias. Furthermore, not all patient files contained all the necessary data, which resulted in missing patient characteristic data (Table 3).

### Conclusion

In a large vascular teaching centre, the rate of compliance to SET guidelines was 80.5%. In 15.7% there was defensible practice variation, which was the result of personalised care. This resulted in a total of 96.2% patients receiving correct, patient centred care. The indefensible practice variation rate of 3.8% could be improved with the correct education of both patients and surgeons about the effectiveness of SET, so that misconceptions are prevented. National data, based solely on financial registrations, do not provide sufficient insight into the optimal approach for the individual patient and are not a sufficient representative of the quality of care.

**CONFLICTS OF INTEREST**

None.

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None.

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