

SYSTEMATIC REVIEW

Quality Indicators in Peripheral Arterial Occlusive Disease Treatment: A Systematic Review

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WHAT THIS PAPER ADDS

A systematic review was conducted to identify evidence based quality indicators for invasive revascularisation of symptomatic peripheral arterial occlusive disease (PAOD). Only three indicators from two publications were identified. A further search involving databases of professional vascular medical organisations revealed an additional 31 indicators to be used for quality improvement programmes. The results of this systematic review could help to improve updates of clinical practice guidelines. Currently available guidelines do not contain specific quality indicators, nor do they state that it would be important to develop suitable and feasible indicators to measure structure, process, and outcome quality in PAOD treatment.

Objectives: This systematic review aimed to identify evidence based quality indicators for invasive revascularisation of symptomatic peripheral arterial occlusive disease (PAOD).

Methods: A systematic search of clinical practice guidelines, consensus statements, systematic reviews, and meta-analyses reporting quality indicators in patients undergoing invasive open and percutaneous revascularisations for symptomatic PAOD (PROSPERO registration number: CRD42019116317) was performed. Furthermore, a grey literature search was conducted involving databases of professional vascular medical organisations. The identified publications were screened independently by two reviewers for possible inclusion and full texts of potentially relevant records were independently evaluated for eligibility. Disagreement was resolved by discussion involving a third reviewer.

Results: From 685 articles initially identified, one systematic review and one consensus statement focusing on quality indicators were selected for inclusion in the review. From these sources, a total of three process quality indicators matched the search criteria: one on pharmacological intervention, another on smoking cessation, and a third on surveillance of lower extremity vein bypass grafts. The grey literature search revealed an additional 31 structure, process, and outcome quality indicators.

Conclusions: This study revealed a lack of published evidence based quality indicators concerning invasive treatment for PAOD in the literature. An additional 31 indicators from the databases of professional societies and organisations have not been incorporated in prior guidelines. Interestingly, no indicator related to patient reported outcomes could be identified from either high quality sources or grey literature. Further research and harmonisation of different quality indicators is needed to enhance their evidence and subsequently improve patient centred decision making on invasive treatment.

Keywords: Systematic review, Quality indicators, Chronic peripheral arterial disease, Intermittent claudication, Chronic limb threatening ischaemia, Outcomes

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INTRODUCTION

Although demographic developments and the widespread adoption of endovascular techniques have led to a considerable increase in the number of revascularisations in patients with peripheral arterial occlusive disease (PAOD),^{1–3}

clinical practice guidelines lack clear recommendations concerning suitable indicators to measure quality of care.^{4–6}

In fact, there are only few quality indicators which are broadly accepted by clinicians, such as amputation rates for treatments of chronic limb threatening ischaemia (CLTI) or quality of life (QoL) for treatment of intermittent claudication (IC). Quality indicators in prospective trials and retrospective studies commonly involve technical measures such as technical success rate, patency, or freedom from re-intervention. Patient related outcomes are often under-represented in these studies. However, it is vital to prescribe and to define suitable and feasible quality indicators to improve clinical effectiveness and efficiency. Furthermore, quality indicators developed and validated by a commonly accepted methodology would help to align patients' preferences to the objectives of care givers in times of patient centred medicine.⁷

Quality of health care is based on a complex interaction of different factors and can be subdivided into structure, process, and outcome quality.⁸ While structural indicators basically describe the resources and overall infrastructure used in the treatment of patients, process indicators typically involve the clinical pathways in patient care. Suitable and valid structure and process indicators can be used to predict outcomes as the third type of quality measures.

The objective of this systematic review was to identify quality indicators for the invasive treatment of patients with PAOD recommended in the available literature.⁹

METHODS

The German language study protocol was developed and published online in June 2017 (www.idomeneo.de). It was registered in the International Prospective Register of Systematic Reviews (PROSPERO CRD42019116317) in December 2018. The reporting of this review conforms to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement standards.¹⁰

Methodological quality was evaluated by Scottish Intercollegiate Guidelines Network (SIGN) criteria for systematic reviews¹¹ and by the Checklist for the Quality Assessment of Guidelines (AGREE II)¹² by three evaluators independently.

Criteria for considering studies

Types of studies. Systematic reviews, meta-analyses, consensus statements, and clinical practice guidelines recommending quality indicators for invasive treatment of chronic PAOD of the lower extremities were reviewed. Furthermore, a grey literature search was conducted to identify quality indicators from databases and websites of professional vascular medical organisations (Tables S1 and S2).

The following criteria were used for exclusion: acute peripheral arterial disease and embolic occlusions of the lower extremities, non-invasive treatment and conservative or pharmacological treatment, primary amputation without revascularisation, and stem cell treatment. Narrative

reviews, case reports, clinical studies, and (controlled) clinical trials were also excluded.

Types of participants. Male and female patients of any age presenting with IC or CLTI that was assumed to have been caused by chronic PAOD and was treated by invasive revascularisation.

Types of interventions. The interventions of interest were any peripheral vascular intervention (PVI), such as percutaneous transluminal angioplasty (PTA), open surgical endarterectomy (EA), or bypass surgery (BS).

Types of outcome measures. The primary outcomes of this systematic review were recommended quality indicators in the care of patients including process, structure, and outcome indicators.

Search strategy

An electronic search was performed using the search engine PubMed (US National Library of Medicine) to access databases from MEDLINE, OLDMEDLINE, and PubMed Central. Additionally, databases of professional societies and organisations were searched for publications and quality indicators in patients with PAOD that fulfilled the inclusion criteria for types of participants and types of interventions, and were available in German or English language (Tables S1 and S2). The search was run in December 2017 and April 2019. Hence, all publications included were published before March 31, 2019 in either English or German. A detailed search strategy using a combination of the following three terms with corresponding synonyms and MESH terms was used: chronic peripheral arterial disease AND quality indicator AND systematic review/guideline (Electronic Supplemental File 1).

Study selection

The identified publications were screened independently by two reviewers (MB and SH) for possible inclusion and full texts of potentially relevant records were independently evaluated for eligibility. Disagreement was resolved by discussion. The selected studies were then sent to a third review author (CAB), who assessed and confirmed their suitability for inclusion and acted as an adjudicator in the event of substantial disagreement.

Included studies and other types of sources were described by providing information on the author(s), title and year of publication, language/country, short description of the context, and number of extracted relevant quality indicators (Table 1).

Data extraction

Suitable quality indicators were collected and described using the following: title, description, indicator type, numerator, denominator, exclusion criteria, indicator variations, target range, risk adjustment, and source (Table 2).

German language quality indicators were translated into English

Table 1. Publications and additional sources included in this systematic review of quality indicators of invasive management of peripheral arterial occlusive disease

Source	Author	Year	Language/ country	Type of publication	Description	Indicators included
Healthcare quality indicators of peripheral artery disease based on systematic reviews ¹³	Bellmunt <i>et al.</i>	2014	English	Systematic review	6 indicators are defined “to evaluate the quality of healthcare provided in PAD”	2
ACCF/AHA/ACR/SCAI/SIR/SVM/SVN/SVS 2010 performance measures for adults with peripheral artery disease ¹⁴	Olin <i>et al.</i>	2010	English	Consensus document	Seven performance measures and two test measures are presented by the ACCF/AHA Task Force on Performance Measures	1
German National Institute for Quality Measurement in Health Care (BQS) ³¹	Federal Office of Quality Assurance (BQS)	2008	Germany	Database	The BQS Institute provides quality assurance in the German health care system up to 2008	13
CMS Measures Inventory ³²	Centres for Medicare and Medicaid Services (CMS)	2017	USA	Database	Centres for Medicare & Medicaid Services (CMS) regularly publishes the CMS Quality Measures Inventory to provide a compilation of measures used by the CMS	12
External Quality Assurance Hamburg (EQS) ³³	Quality indicator database of the External Quality Assurance Hamburg	2015	Germany	Database	The external quality assurance Hamburg is a mandatory quality improvement registry that records and compares the quality of medical services in Hamburg to improve patient care continuously.	10
National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) ³⁴	Quality indicator thesaurus of the Statutory Health Insurance Funds Association (QUINTH)	2017	Germany	Database	Since 2009, the GKV-Spitzenverband provides “QUINTH” a database of quality indicators for health care developed in German-speaking countries by various authors and institutions	20
Quality Positioning System (QPS) ³⁵	National Quality Forum (NQF)	2017	USA	Database	NQF started 2012 the QPS as an interactive searchable database of NQF endorsed quality measures	2
List of 2017 Vascular Quality Initiative (VQI) Qualified Clinical Data Registry (QCDR) Measures and List of 2017 Non-Quality Payment Program (QPP) Measures ^{36,37}	Vascular Quality Initiative (VQI)	2017	USA	Database	The VQI is a patient safety organisation to improve the quality, safety, effectiveness and cost of vascular health care by collecting and exchanging information	8

ACCF = American College of Cardiology Foundation; ACR = American College of Radiology; AHA = American Heart Association; BQS = Federal Office of Quality Assurance; CMS = Centers for Medicare and Medicaid Services; SCAI = Society for Cardiac Angiography and Intervention; SIR = Society for Interventional Radiology; SVM = Society for Vascular Medicine; SVN = Society for Vascular Nursing; SVS = Society for Vascular Surgery; PAD = peripheral arterial disease.

RESULTS

A literature search via the database PubMed and a search of additional online sources identified 729 articles. After 44 duplicates were removed, the titles and abstracts of 685 articles were screened. Of these, 601 articles did not fulfil the inclusion criteria and were excluded leaving 84 articles shortlisted for full text review, of which 82 were excluded for the following reasons: unsuitable outcome ($n = 49$), unsuitable study design ($n = 28$), unsuitable patient population ($n = 3$), and unsuitable intervention ($n = 2$). Ultimately, two studies were selected for inclusion in the

qualitative synthesis: Bellmunt *et al.*¹³ and Olin *et al.*¹⁴ as shown in the flow diagram (Fig. 1).

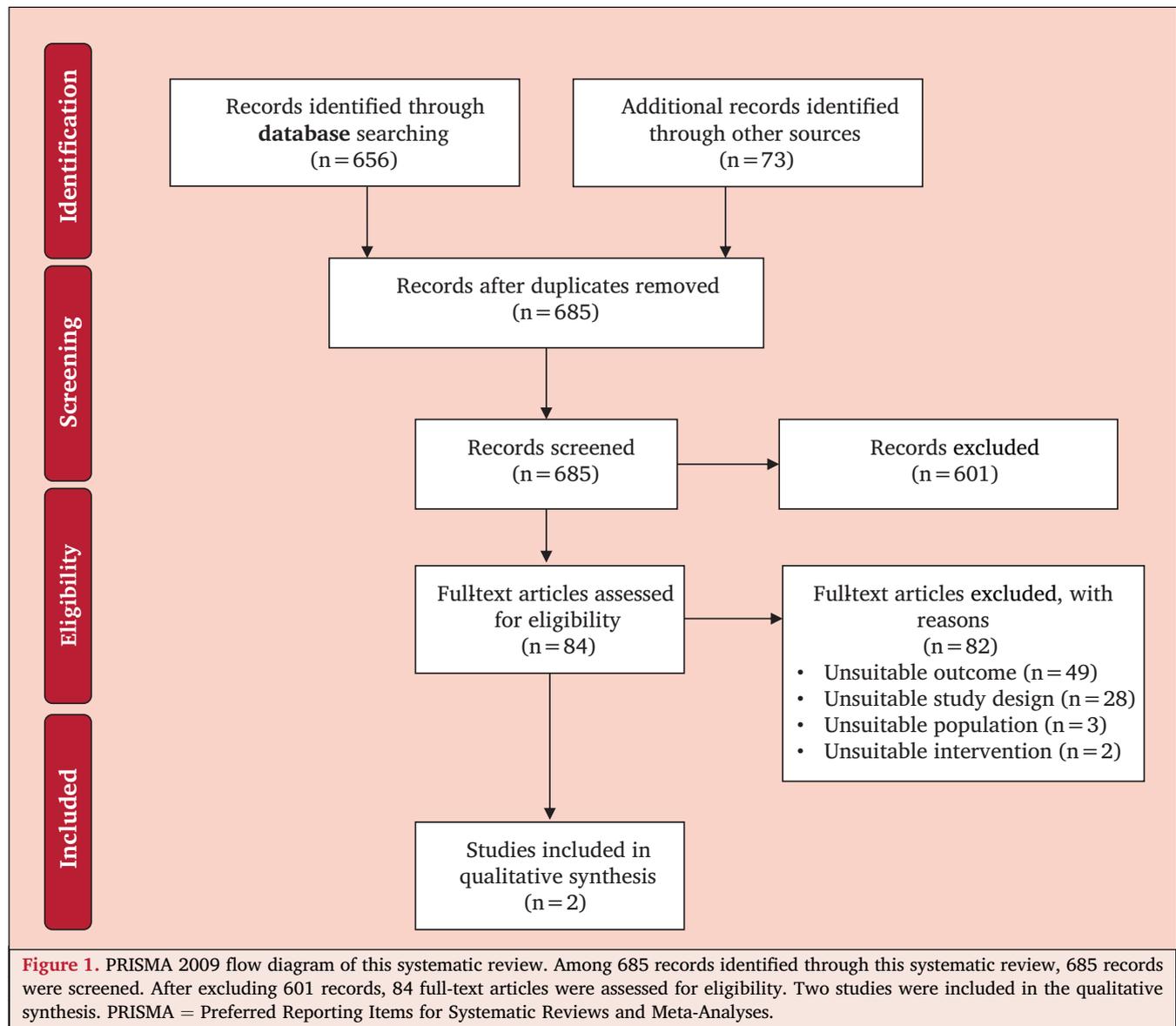
Quality indicators identified by this systematic review

In the included studies, three process quality indicators were identified that met the inclusion criteria: 1) proportion of patients with history of bypass grafting to whom anti-platelet agents are prescribed,¹³ 2) proportion of current smokers with history of bypass grafting to whom a smoking cessation intervention is prescribed,¹³ and 3) lower extremity vein bypass graft surveillance.¹⁴

Table 2. List of 34 identified quality indicators by different categories

Quality indicator for invasive therapy	Type of indicator	Source	Reference	
<i>Indicators concerning quality of diagnostic work up</i>				
1	Determination of the Fontaine stage	Process	BQS, GKV	31,34
2	Indication for PTA according to Fontaine stage	Process	BQS, EQS, GKV	31,33,34
3	Multidisciplinary team decision prior to invasive therapy	Process	BQS, EQS, GKV	31,33,34
4	Treadmill testing	Process	BQS	31
5	Pre-interventional ankle brachial index	Process	BQS, EQS, GKV	31,33,34
6	Primary stenting of the pelvic region	Process	BQS, EQS, GKV	31,33,34
<i>Indicators concerning quality of concomitant medical therapy and lifestyle modification</i>				
7	Statin therapy at discharge after lower extremity bypass	Process	CMS, NQF, VQI,	32,35–37
8	Procedures with statin and antiplatelet agents prescribed at discharge	Process	VQI	36,37
9	Proportion of patients with history of bypass grafting to whom antiplatelet agents are prescribed	Process	Bellmont	13
10	Anticoagulant medication during PTA	Process	BQS, GKV	31,34
11	Proportion of current smokers, with history of bypass grafting, to whom a tobacco cessation intervention is prescribed	Process	Bellmont	13
<i>Indicators concerning quality of follow up after invasive therapy</i>				
12	Lower extremity vein bypass graft surveillance	Process	Olin	14
13	Rate of surgical conversion from lower extremity endovascular revascularisation procedure	Outcome	CMS	32
14	Amputation free survival assessed at least nine months following infra-inguinal bypass for intermittent claudication	Outcome	VQI	36,37
15	Amputation free survival assessed at least nine months following supra-inguinal bypass for claudication	Outcome	VQI	36,37
16	Amputation free survival assessed at least nine months following peripheral vascular intervention for intermittent claudication	Outcome	VQI	36,37
17	Infra-inguinal bypass for claudication patency assessed at least nine months following surgery	Process	VQI	36,37
18	Peripheral vascular intervention patency assessed at least nine months following infra-inguinal peripheral vascular intervention for claudication	Process	VQI	36,37
19	Post-interventional angiography after PTA	Process	BQS, EQS, GKV	31,33,34
20	Post-interventional ankle brachial index after PTA	Process	BQS, EQS, GKV	31,33,34
21	Improvement of the ankle brachial index following PTA	Outcome	BQS, EQS, GKV	31,33,34
22	Post-interventional residual stenosis following PTA	Outcome	BQS, EQS, GKV	31,33,34
23	Post-interventional complications following PTA	Outcome	BQS, EQS, GKV	31,33,34
<i>Indicators concerning quality of invasive therapy (adverse events)</i>				
24	Absence of serious technical complications during peripheral arterial intervention	Outcome	VQI	36,37
25	Wound infection rate (total) after arterial reconstruction of the lower extremity	Outcome	GKV	34
26	Wound infection rate (in hospital) after arterial reconstruction of the lower extremity	Outcome	GKV	34
27	Risk adjusted in hospital measure of mortality and major complications following lower extremity bypass grafting.	Outcome	NQF	35
<i>Indicators concerning quality of invasive therapy (re-interventions)</i>				
28	Re-intervention within 12 months after PTA	Process	BQS, GKV	31,34
<i>Interventional radiology indicators</i>				
29	Professional qualification in interventional radiology	Structure	GKV	34
30	Technical prerequisites for interventional radiology	Structure	GKV	34
31	Structural requirements for interventional radiology	Structure	GKV	34
32	Structural requirements for follow up care in interventional radiology	Structure	GKV	34
33	Maintaining professional qualification in interventional radiology	Structure	GKV	34
34	Documentation of diagnostic catheter angiography or therapeutic interventions	Process	GKV	34

BQS = Federal Office of Quality Assurance; CMS = Centers for Medicare and Medicaid Services; GKV = German statutory health insurance; NQF = The National Quality Forum; EQS = External Quality Assurance Hamburg; PTA = percutaneous transluminal angioplasty; VQI = Vascular Quality Initiative.



Furthermore, 54 indicators were identified from the databases of various professional societies. After 23 duplicates were removed, 31 indicators were left. The characteristics of the sources of the extracted indicators are shown in Table 1.

The sources and types of the 34 identified quality indicators are listed in Table 2. Of these, 18 are process indicators, five structure indicators, and 11 outcome indicators. Their characteristics are described in detail in Table S3.

Most indicators concern the follow up period or adverse events following the index revascularisation. No patient reported outcome (PRO) was recommended as a quality indicator (Table 2).

The methodological quality of both studies was assessed with SIGN (for systematic reviews) and AGREE II (for practice guidelines) criteria. All three authors (SH, MB, CAB) independently assessed high quality (++) of the systematic review by Bellmunt *et al.*¹³ and a mean score of 4.5/7 of the guideline by Olin *et al.*¹⁴

DISCUSSION

In this systematic review on quality indicators in invasive treatment of PAOD, only two of 685 publications containing three quality indicators were of high methodological quality and could be included in the qualitative synthesis. An additional 31 quality indicators could be identified through other sources including structure, process, and outcome quality. These results emphasise the need for further research and reflection to find a consensus on suitable and feasible quality indicators in the medical care of PAOD.

Measuring the performance of vascular health care is important for national quality improvement programmes, statutory pay per quality initiatives, or research projects. However, because of the paucity of high quality evidence in clinical practice guidelines, vascular specialists often face the task pondering achievable patient benefit and the underlying risks of treatment. They should be capable of reflecting and improving their own treatment quality by comparative methods using evidence based quality

indicators. The term “quality of health care” is often described non-homogeneously making quality improvement projects challenging.^{15–18}

In 2010, the American College of Cardiology Foundation (ACCF) and American Heart Association (AHA) Performance Measure Sets were extended by the Performance Measures for Adults with Peripheral Artery Disease published by Olin *et al.*¹⁴ The authors identified a total of seven process and outcome quality indicators involving not only PAOD of the lower extremities, but also other cardiovascular diseases and abdominal aortic aneurysms. Four of the recommended indicators concern pharmacological (e.g., cholesterol lowering medication or antiplatelet therapy) or lifestyle factors (e.g., smoking cessation, supervised exercise). Bellmunt *et al.* identified 1809 reviews, including 29 high quality systematic reviews to ultimately generate six quality indicators for PAOD focussing on pharmacological and lifestyle issues.¹³ Ultimately, three quality indicators from these two publications were identified and subsequently included into the qualitative synthesis of the current review. Among them, no indicator concerns outcome quality.

Interestingly, no patient reported quality indicators such as QoL could be identified by this review, although these are often recommended as a primary treatment aim especially for IC.^{19,20} PROs and patient centred treatment are key aspects of modern evidence based care because PAOD is known to decrease the disease related QoL and might lead to social isolation or even depression.^{21–23} However, prior Delphi studies involving vascular specialists and real world evidence experts demonstrate that limited practicability in collecting data on PROs might counteract their clinical relevance.^{7,24} Furthermore, heterogeneous use of variables and often comprehensive QoL assessing instruments complicate their comparability and validation.^{25,26}

Conte *et al.* suggested objective performance goals (OPG) for catheter based treatment of CLTI including nine measures of outcome quality.¹⁵ The authors used various retrospective cohort studies to suggest OPGs primarily for market access studies complementing randomised and controlled trials (RCT). However, there are important differences between OPGs and traditional quality indicators. Quality indicators are developed from clinical practice guidelines, consensus statements, or systematic reviews. Subsequently, their practicability, reliability, and validity will be evaluated by expert consensus.²⁷

Recently, the Global Vascular Guidelines (GVG) on CLTI were published by the Society for Vascular Surgery (SVS) and the European Society for Vascular Surgery (ESVS).²⁸ Although not specifically containing quality indicators per se, these guidelines involve an entire chapter concerning trial endpoints and outcome measures for studies including patients with CLTI. These valuable recommendations may help specialists in vascular care and they will probably aid future study projects focusing on the development of evidence based quality indicators for the treatment of PAOD.

This study demonstrates a lack of quality indicators published in the literature to be used for revascularisations of PAOD. Although databases of professional vascular medical

organisations contain an additional 31 quality indicators, these indicators have not been incorporated in prior clinical practice guidelines. Meanwhile, there is a growing global community such as the VASCUNET committee or the International Consortium of Vascular Registries (ICVR) active in comparative health services research and quality improvement using real world evidence.^{24,29} The existing data standards for real world evidence research on patients with PAOD need to be followed, to have the possibility of developing indicators in the future.³⁰ That allows international comparison of the quality of health care. Patients with symptomatic PAOD remain the central target population of vascular specialists emphasizing the need of future research and reflection. This review will help to develop evidence based structure, process, and outcome quality indicators to be used for quality improvement in the future.

This study has limitations. Firstly, although quality improvement is a key task in medical care, the methodology and terminology are used non-homogeneously in the literature. Publications and quality indicators were only included if the development and terminology followed commonly accepted standards. Secondly, although an extensive review of the grey literature such as societal websites, databases, and additional sources was performed to identify quality indicators, there might be sources it was not possible to identify. Lastly, searches were only performed in English and German, and the search was limited to the PubMed search engine accessing the largest databases MEDLINE, OLDMEDLINE, and PubMed Central. However, there may be quality indicators available through other databases such as the EMBASE. A multilingual approach and a more inclusive search term could have identified a broader picture.

CONCLUSIONS

Only three quality indicators for invasive treatment and medical care of patients with PAOD are available in the published literature and an additional 31 quality indicators from databases of professional societies and organisations have not been incorporated in prior clinical practice guidelines. Non-homogeneous definitions and methodological discrepancies emphasise the need for further reflection and actions to develop commonly accepted process, structure, and outcome quality indicators in PAOD treatment.

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CONFLICTS OF INTEREST

None.

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ejvs.2019.06.029>.

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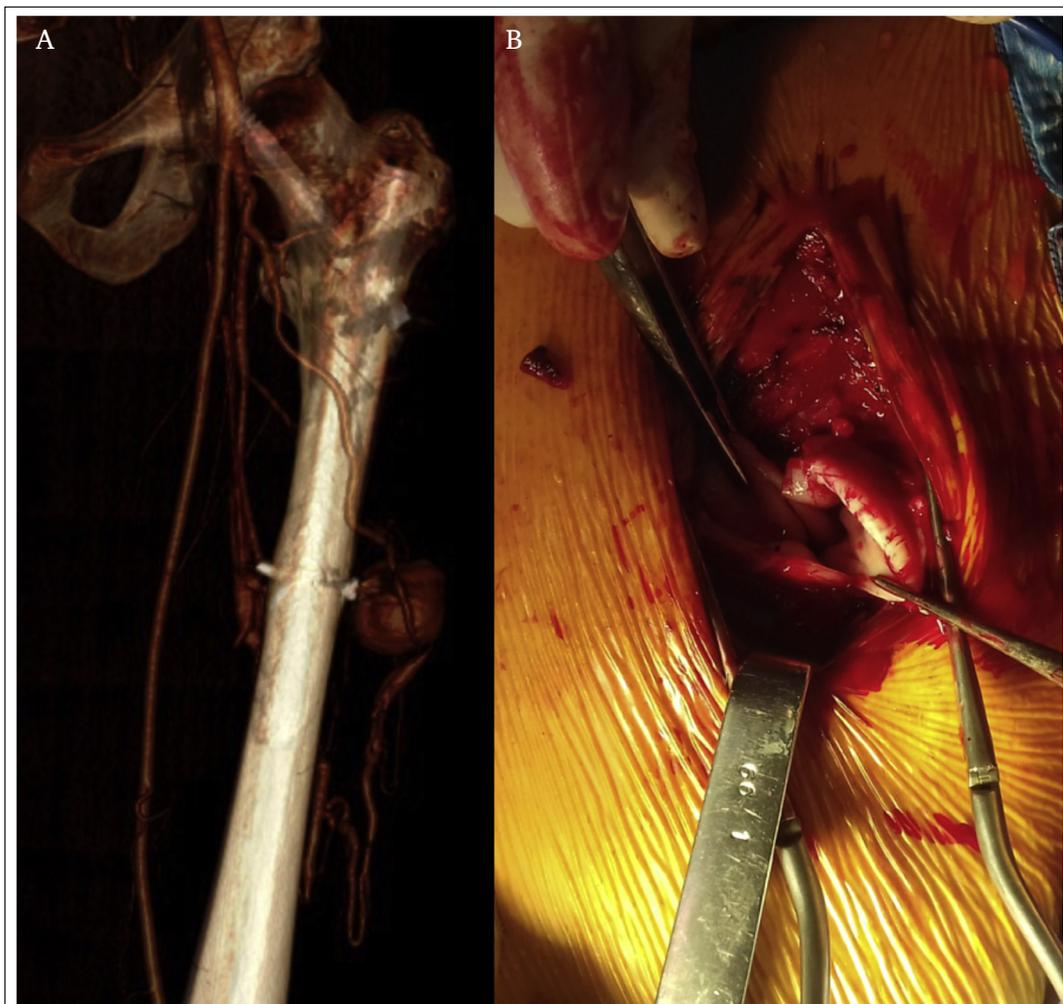
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False Aneurysm After Gamma-nail Surgery: A Rare Complication

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The case of a 29 year old patient who underwent a gamma nail (Stryker, Portage, MI, USA) procedure is reported. Four months after surgery, he presented with a pulsatile mass in the left thigh. Computed tomography angiography showed a 44 mm false aneurysm of a muscular branch of the profunda femoris artery supplying the vastus lateralis, probably due to traumatic injury by the distal screw (A). Open surgical repair was carried out (rather than embolisation, based on patient choice) with proximal and distal ligation to control the false aneurysm which was evacuated (B), and the damaged arterial segment oversewn. The patient was discharged on Day 1.

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