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Quality of economic evaluations of drug-coated balloons and drug-eluting stents in peripheral artery disease: a systematic review

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Abstract

Objective. We aimed to perform a systematic review of economic evaluations of drug-coated balloons (DCBs) and drug-eluting stents (DESs) in peripheral artery disease (PAD) and to assess the level of evidence of relevant studies. The purpose was not to present economic findings.

Methods. A systematic review was performed using four electronic databases to identify health economic evaluation studies reporting on the use of DCBs and DESs in PAD. The methodological and reporting quality of the studies was assessed using three different tools, the Drummond, Cooper, and CHEERS (Consolidated Health Economic Evaluation Reporting Standards) checklists.

Results. Six articles were included in this review of the 1,728 publications identified. Four studies were cost-effectiveness analyses and two cost–utility analyses. According to the Cooper hierarchy scale, the studies used good-quality data sources. The level of evidence used for clinical effect sizes, safety data, baseline clinical data, and costs was of high quality in general. In contrast, an evaluation of the reporting quality suggested that essential information was lacking.

Conclusion. The present study demonstrates that clinical data used in economic evaluations of DCBs and DESs in PAD are from clinical studies of high quality in general. However, the quality of reporting represents a concern when interpreting the results provided by these economic studies.

Introduction

Peripheral artery disease (PAD) is a major health problem. In 2010, it was estimated that PAD affected 200 million people worldwide (1). Patients with PAD are at high risk of developing major adverse cardiovascular events (MACEs) and major adverse limb events (MALEs). Among patients with symptomatic PAD, annual rates of MACEs are 4–5 percent and rates of MALEs are 1–2 percent (2). MACEs include myocardial infarction, ischemic stroke, and cardiovascular death, and MALEs include major amputations and acute limb ischemia. PAD is associated with significantly elevated all-cause mortality, cardiovascular disease mortality (CVD), and combined CVD morbidity/mortality at 3 and 6 years after the diagnosis (3).

First-line treatment is based on lifestyle management that improves functional outcomes and reduces MACE (4). Lifestyle management, including smoking cessation and exercise therapy, can modify important risk factors. In addition, several pharmacological interventions can be used, such as antiplatelet agents, anticoagulant agents, and statins (4). For symptomatic patients with PAD with intermittent claudication who have not responded to medical treatment, limb revascularization is recommended. Patients with critical limb ischemia require more urgent revascularization because of an increased risk of tissue loss and amputation, as well as an extremely high risk of cardiovascular events (5). Either of the two strategies can be used: endovascular surgery as the first choice or open surgery (6). For endovascular surgery, plain old balloon angioplasty (POBA), drug-coated balloon (DCB) angioplasty, stent placement (bare-metal stent, drug-eluting stent [DES], or covered stent), and atherectomy may all be reasonable options in specific circumstances and for specific lesion anatomy (7). DCBs and DESs contain medications that inhibit vessel restenosis and have been shown to result in notable improvements in clinical outcomes in several studies (8–10). However, this point is controversial, as a recent study found an increased risk of death following the use of paclitaxel-coated balloons and stents in PAD (11).

In addition, these medical devices are expensive, and the question of their cost-effectiveness —and of the quality of economic studies on this topic—remains. Furthermore, this information is valuable in health technology assessments (HTAs), which, in turn, support decision-

making processes, for instance at a hospital level. Knowing the quality of available economic studies would seem to be essential for making knowledge-based decisions. The purpose of the present study was to perform a systematic review of the literature on economic evaluations of DCBs and DESs in PAD in order to assess the methodological and reporting quality of the currently available publications on the topic. We also aimed to provide valuable information for HTA analysts and policy makers dealing with DCBs and DESs in PAD.

Materials and Methods

In July 2020, we performed a systematic literature review to identify economic evaluation studies relating to DCBs and DESs. To do so, we followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (see Supplementary File 1, PRISMA Checklist).

Search Strategy

The articles have been selected from four electronic databases, namely, PubMed, Embase, the National Health Service Economic Evaluation Database (NHS EED), and the Cost-Effectiveness Analysis (CEA) Registry. To identify all relevant studies published in the last 10 years (from 3 July 2010 to 3 July 2020), the search strategy was first developed in the PubMed database and then was applied to the other databases. This 10-year period was chosen because the technology has remained the same over this time span with no significant evolution (10). The search term combined a descriptor of the device (MeSH or not) and a term related to economics (MeSH or not) (Supplementary File 2, Study Protocol).

Study Selection

First, duplicate articles were removed. Then, titles and abstracts were screened by two reviewers (AE and LN) to select relevant articles based on inclusion and exclusion criteria according to the PICOS format (population, intervention, comparators, outcomes, and study design) (Table 1) (12). Articles written in languages other than English or French, studies in which DCBs or DESs were not the sole topic, and other studies such as reviews, editorials, congress communications, letters, and noneconomic studies were excluded. Discrepancies were resolved by a third reviewer (NM).

Quality Assessment

To evaluate the overall quality of articles screened, two reviewers (AE and LN) used three established checklists to appraise the reporting and methodological quality of the economic evaluations. These three tools are all qualitative instruments. If a discordant classification appeared, the two reviewers discussed discrepancies until a consensus was reached.

First, general characteristics were extracted using international guidelines published by Drummond et al. (13). These recommendations provide general guidance about the way in which the results of economic evaluations should be reported. Authors must provide information about the type of evaluation conducted, perspective chosen, and costs considered (direct, indirect, and both). They also need to characterize the time horizon, comparators chosen, incremental cost-effectiveness ratio (ICER), and source of funding.

Table 1. Study eligibility criteria in PICOS format

PICOS	Inclusion criteria
Population	Patient with peripheral artery disease
Intervention	Drug-coated balloons and drug-eluting stents
Comparators	Balloon angioplasty, bare-metal stent, and plain old balloon angioplasty
Outcomes	Cost-effectiveness and/or cost–utility
Study design	Full economic evaluations: Cost-effectiveness Cost–utility

PICOS, population, intervention, comparators, outcomes, and study design.

Next, a checklist developed by Cooper et al. was utilized to assess the quality of the sources of evidence used in the studies (14). This tool, which ranks evidence used in studies on a scale of 1–6, evaluated the quality of sources for the main clinical effect sizes, baseline clinical data, cost data, and utility data. If the information was not clearly stated, the scale awarded a rank of 9. We then joined the rankings into three quality categories defined by Cooper et al. (14). Level A corresponded to the highest level of evidence quality, covering ranks 1 and 2. Level B corresponded to an intermediate level of evidence quality, covering a ranking of 3. Ranks 4, 5, 6, and 9 were grouped together into level C, corresponding to the lowest level of evidence quality.

Finally, we used the CHEERS (Consolidated Health Economic Evaluation Reporting Standards) checklist, which is a tool used for the reporting of economic studies (15). This checklist includes twenty-four items in six categories (title and abstract, introduction, methods, results, discussions, and others). All twenty-four items were checked per article by two reviewers (AE and LN). In the event of disagreement, a consensus was reached through discussion with the third reviewer (NM).

The above-mentioned methodology of combining several checklists was based on previous work on the quality of economic evaluations (16;17). To our knowledge, no single checklist exists that is able to measure both the reporting and the methodological quality of economic evaluations. For this reason, we chose to consolidate these three qualitative instruments that explore different aspects of an economic evaluation: the global methodology assessed by the Drummond guidelines, the quality of the sources of evidence by the Cooper checklist, and the reporting quality by the CHEERS checklist. This strategy enabled us to be more exhaustive in evaluating the screened articles and to offset the inherent weaknesses of a single tool.

Results

Selected Studies

Figure 1 summarizes the details of study identification and reasons for inclusion/exclusion. The initial electronic literature search identified 1,728 studies. A total of 1,498 articles were obtained after the removal of duplicates. After screening titles and abstracts, we excluded 1,488 articles as they did not meet the selection criteria: 1,453 did not report on DCBs or DESs, 13 did not have accepted designs (letters and congress abstracts), and 22 were not economic evaluations. We read the full text of the remaining ten articles and excluded one article because of

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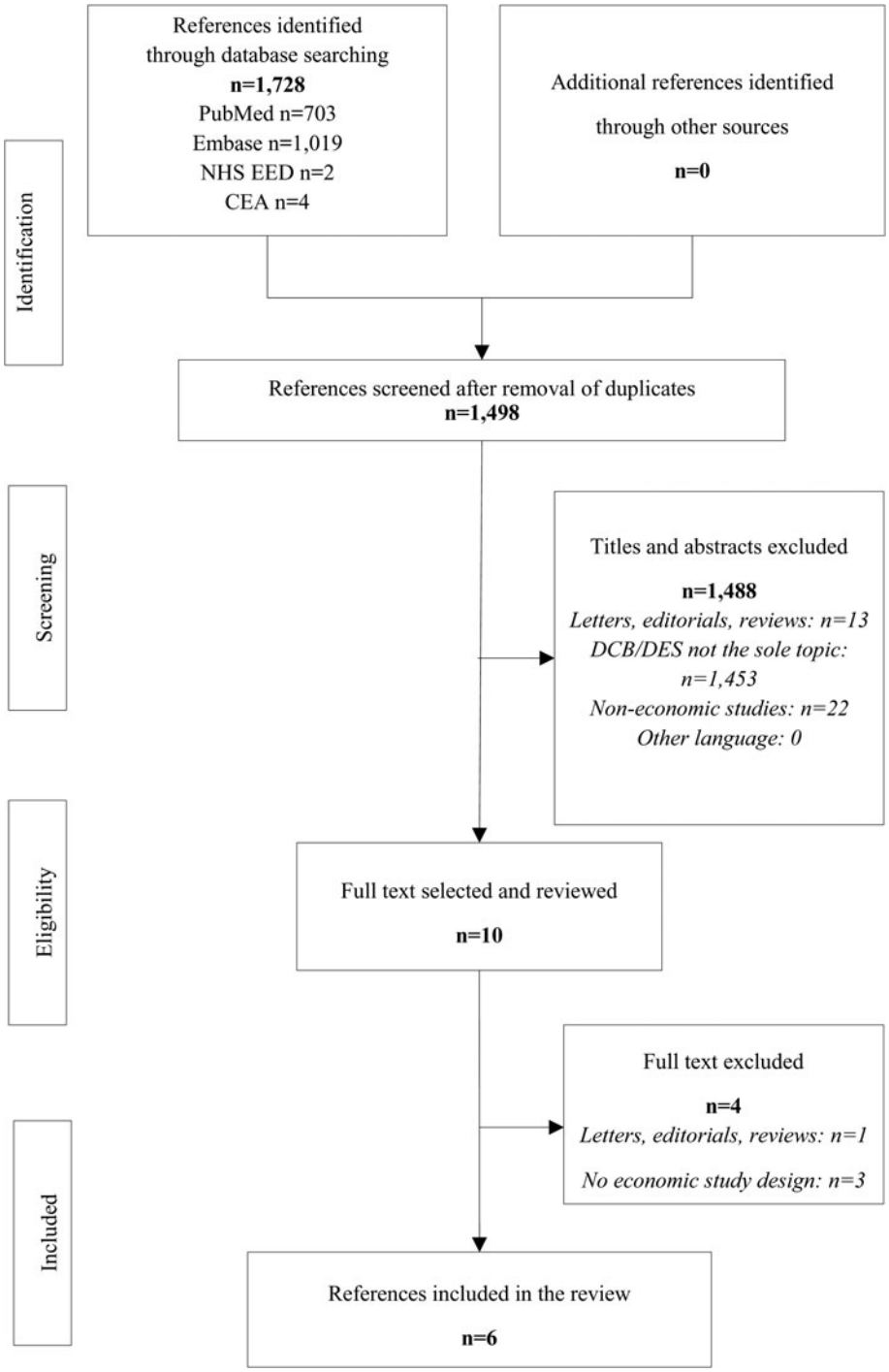

Figure 1. PRISMA flowchart for study selection. CEA, Cost-Effectiveness Analysis; DCB, drug-coated balloon; DES, drug-eluting stent; NHS EED, National Health Service Economic Evaluation Database.

its design and a further three because they were not economic evaluations. Our literature search resulted in six studies that fulfilled inclusion criteria (18–23).

Characteristics of the Studies

The majority of studies were conducted in Europe (66.7 percent); two studies (33.3 percent) were conducted in North America. The selected articles were published between 2012 and 2018. Four studies (66.7 percent) were conducted in the last 5 years. According to the criteria outlined in the Drummond guidelines, three studies (50 percent) were cost-effectiveness analyses and three (50 percent) were cost–utility analyses (Table 2). A payer perspective was retained for five studies (83.3 percent) and one (16.7 percent) did not state a perspective for the analysis. Additionally, direct costs were used for all studies. Authors considered a lifetime horizon in three publications (50 percent) and a two-year horizon in three studies (50 percent).

Two studies (33.3 percent) provided both deterministic and probabilistic analyses, two (33.3 percent) provided only deterministic analyses, and two studies (33.3 percent) provided only probabilistic analyses.

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Table 2. Details of the Drummond checklist criteria for each included study

References	Year	Country	Economic evaluation	Perspective	Time horizon	Comparator	Study population	Number of patients	States used in the Markov model	ICER	Sensitivity analysis	Sources of funding
Sridharan et al. (21)	2018	USA	CEA	Payer	1 year	POBA versus DCB POBA versus DES POBA versus BMS DCB versus DES BMS versus DCB	Patients for superficial femoral artery or popliteal artery diseases	1,248	No information on the Markov model	– POBA versus DCB: USD 14,136 per additional patent limb at 1 year – POBA versus DES: USD 38,549 per additional patent limb at 1 year – POBA versus BMS: USD 59,748 per additional patent limb at 1 year – DCB versus DES: USD 87,377 per additional patent limb at 1 year – BMS versus DCB: Dominated	Probabilistic/ deterministic	No information
Salisbury et al. (19)	2016	USA	CUA	Payer	2 years	DCB versus standard PTA	Patients undergoing revascularization for symptomatic femoropopliteal PAD	181 (60 vs. 121)	Ten states: nine alive states based on the number of each type of revascularization, and 1 dead health state	USD 54,849 /QALY	Probabilistic/ deterministic	Private
Albrecht et al. (20)	2018	Germany	CEA	Payer	2 years	DCB versus POBA	Symptomatic PAOD patients treated in more than one femoropopliteal lesion	153 (78 vs. 75)	Four states: amputation, TLR, death, no event	EUR 1553.05/free of TLRs in months	Deterministic	Private
Kearns et al. (23)	2017	Germany	CUA	Payer	Lifetime	BioMimics 3D stent versus BMS or PTA with bail-out BMS, DES, DCB, or BMS	Patients with symptomatic infrainguinal PAD suitable for endovascular treatment	Not applicable	Five states: asymptomatic, IC, CLI, dead, amputation	BioMimics 3D stent dominated all of the other interventions by having lower lifetime costs and greater effectiveness (QALY)	Probabilistic	Private
Katsanos et al. (22)	2012	Greece	CEA	No sources	Lifetime	SES versus BMS EES versus POBA and BMS	Patients treated for critical limb ischemia	103 (62 vs. 41); 81 (47 vs. 34)	Not applicable	– SES versus BMS: EUR 6518 per event-free life-years gained (EUR 1,685–10,112) – EES versus POBA and BMS: EUR 11,581 per event-free life-years gained (EUR 4,945–21,428)	Deterministic	No information
Kearns et al. (18)	2013	UK	CUA	Payer	Lifetime	DCB versus DES	Patients with symptomatic infrainguinal PAD suitable for endovascular treatment	Not applicable	Five states: asymptomatic, IC, CLI, dead, amputation	DCB dominated all other options by having both lower lifetime costs and greater effectiveness (QALY)	Probabilistic	Private

BMS, bare-metal stent; CEA, cost-effectiveness analysis; CLI, critical limb ischemia; CUA, cost–utility analysis; DCB, drug-coated balloon; DES, drug-eluting-stent; EES, everolimus-eluting stent; IC, intermittent claudication; PAD, peripheral artery disease; PAOD, peripheral artery occlusive disease; POBA, plain old balloon angioplasty; PTA, percutaneous transluminal balloon angioplasty; QALY, quality-adjusted life-year; SES, sirolimus-eluting stent; TLR, target limb revascularization.

Quality of the Sources

We used the Cooper scale to evaluate the quality of the study sources. The results of the Cooper scale are presented for each study in Table 3. The results of the hierarchy of data sources are given in Supplementary Table 1. The data sources for the clinical effect size and safety were of a high quality (level A, 100 percent). Most studies were based on randomized controlled trials (RCTs) with direct comparison between comparator therapies. For instance, the CONSEQUENT trial, which is a prospective, multicenter, two-armed, randomized controlled trial, was the main source used for documenting the clinical effect size in the study by Albrecht et al. (20). This was also observed for other studies using RCTs such as IN.PACT SFA I and IN.PACT SFA II as a source (19–21).

In most studies (83.3 percent), cost data were based on recently published cost calculations from reliable databases (in the same jurisdiction as the study performed). In the remaining study (16.7 percent), the sources of cost data were of medium quality, and the origin of the source was not clearly stated.

Only one study (16.7 percent) used data from direct utility assessments for the specific study. In this study, health utilities were assessed using the EuroQol questionnaire (19). Two studies (33.3 percent) used utility data that were direct estimates from a previous study on patients with the diseases of interest.

Quality of Reporting

We used the CHEERS checklist to establish the quality of reporting; Table 3 presents the main results of each study. Most studies (83.3 percent) did not state the aspects of the system in which the decision needed to be made or for which the economic evaluation had been designed (18–22). In addition, very few studies (33.3 percent) reported the choice of discount rate used for costs and outcomes and explained why it was appropriate (18;23). We noticed that the authors correctly stated the time horizon over which costs and consequences had been evaluated, but they rarely explained why the time period chosen was appropriate (33.3 percent) (20–23). Finally, very few studies (33.3 percent) provided a figure to illustrate the model structure (19;21–23).

However, all studies (100 percent) reported information properly for the abstract, background, and objectives, measurement of effectiveness, estimation of resources and costs, and characterization of uncertainty.

Discussion

To our knowledge, this study is the first systematic review to analyze the quality of economic studies on drug-eluting medical devices used for treating PAD and to use three formal checklists. Although it is a blossoming field, we did not identify many economic studies on the topic. Indeed, only six studies in 10 years seem a rather small number for a widespread pathology such as PAD. However, the aim of this systematic review was not to analyze these medical devices or their efficiency but to assess the level of evidence used to inform economic evaluations. With the present work, we wish to contribute to the HTA process, which is not only designed to review and summarize outcomes but also to assess the quality of the evidence itself. In addition, we would like to share our experience with this three-tool approach and discuss its strengths and flaws.

Our examination of the studies first revealed that most of the studies retrieved fully complied with the Drummond guidelines. This represents a strength of the included studies, which seemed, in general, to provide the essential information about the economic evaluation performed (type of study, perspective, and evaluated costs). One of the flaws of the studies highlighted with this checklist was a lack of detail about the sources of funding. Studies sponsored by industry are more likely to reach positive conclusions than similar studies funded by not-for-profit organizations (24). Nevertheless, the Drummond guidelines only give a general overview of an economic study because they focus solely on key elements. For example, this tool does not guarantee that the data sources used are of a good quality or that all information needed to understand the study is reported properly. For this reason, the Drummond guidelines must be complemented by the use of the Cooper and CHEERS checklists.

The Cooper checklist is a useful tool for assessing the level of evidence of the sources used to perform an economic evaluation. Here, its use revealed that most studies used good-quality clinical effect size and safety data sources. However, the Cooper checklist does not allow an in-depth analysis of the quality of the clinical data used, especially for retrospective clinical data that are at a high risk of bias. Exploring this point, a recent study suggested using two checklists, the Joanna Briggs Institute (JBI) Checklist for Prevalence Studies and a modified version of Risk Of Bias In Non-randomised Studies of Interventions (ROBINS-I) (25); it would be relevant to combine the Cooper checklist with these two checklists. However, it must also be kept in mind that the more tools used for a single study, the more complicated and longer the assessment is. For information, we found in our study that the average time spent for grading an article with the three tools was reasonable and after a first full reading of the article did not exceed 1 h for a trained scorer.

Finally, we chose to use the CHEERS checklist to assess the quality of reporting. We would like to underline here how poor-quality reporting may raise doubts on the general quality of the economic study itself. In fact, we observed that important information was not clearly stated in most of the studies we retrieved. This could have skewed our perception of the studies and prevented us from concluding on their actual quality.

Additional items could be taken into consideration when evaluating medical devices, such as the learning curve or the organizational impact. As stated by Craig et al., there is a need to adopt new modeling approaches to incorporate and/or assess certain unique characteristics of medical devices that are often unaddressed (26). When new models are developed for the economic evaluation of medical devices, we should keep in mind that verification tools such as the checklists used in the present work will need to be adapted and will need to integrate new items such as the learning curve.

Some limitations of our study need to be highlighted. First, the search was performed in scientific journals only and we did not include economic evaluations from gray literature. In addition, during data collection, we found many articles related to the use of DESs and DCBs in coronary arteries, and this complicated screening for articles only on PAD. For this reason, it is possible that some articles about DES and DCB treatment of PAD may have been discarded in the screening step due to the large number of articles referring to DES/DCB use in coronary arteries.

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Table 3. Summary of the main results of the Cooper and CHEERS checklists

		Sridharan et al. (21)	Katsanos et al. (22)	Kearns et al. (18)	Salisbury et al. (19)	Kearns et al. (23)	Albrecht et al. (20)
Cooper checklist	Clinical effect sizes/adverse events and complications	Single RCT with direct comparison between comparator therapies, measuring the surrogate outcomes	Single placebo-controlled RCT with similar trial populations, measuring the final outcomes for each individual therapy	Single RCT with direct comparison between comparator therapies, measuring the surrogate outcomes	Single RCT with direct comparison between comparator therapies, measuring the surrogate outcomes	Meta-analysis of RCTs with direct comparison between comparator therapies, measuring surrogate outcomes	Single RCT with direct comparison between comparator therapies, measuring the surrogate outcomes
	Baseline clinical data	Recent case series or analysis of reliable administrative databases covering patients solely from the jurisdiction of interest	Old case series or analysis of reliable administrative databases. Estimates from RCTs	Recent case series or analysis of reliable administrative databases covering patients solely from the jurisdiction of interest	Recent case series or analysis of reliable administrative databases covering patients solely from another jurisdiction	Old case series or analysis of reliable administrative databases. Estimates from RCTs	Recent case series or analysis of reliable administrative databases covering patients solely from the jurisdiction of interest
	Costs	Recently published cost calculations based on reliable databases or data course: same jurisdiction	Data source not known: same jurisdiction	Recently published cost calculations based on reliable databases or data course: same jurisdiction	Recently published cost calculations based on reliable databases or data course: same jurisdiction	Recently published cost calculations based on reliable databases or data course: same jurisdiction	Recently published cost calculations based on reliable databases or data course: same jurisdiction
	Utility	NA	Direct utility assessment from a previous study	NA	Direct utility assessment for the specific study	Direct utility assessment from a previous study	NA
CHEERS checklist	Main flaws in reporting	No description of the interventions compared in the title No description of the characteristics of the base case population and subgroups analyzed, including why they were chosen No statement on the relevant aspects of the system(s) in which the decision(s) need(s) to be made No report of the choice of discount rate(s) used for costs and outcomes or why it is appropriate	No description of the interventions compared in the title No statement on the relevant aspects of the system(s) in which the decision(s) need(s) to be made No report of the choice of discount rate(s) used for costs and outcomes or why it is appropriate No details on the assumptions underpinning the decision-analytical model No information about the source of funding	No description of the interventions compared in the title No description of methods for adjusting estimated unit costs to the year of reported costs	No statement on the relevant aspects of the system(s) in which the decision(s) need (s) to be made No report of the choice of discount rate(s) used for costs and outcomes or why it is appropriate No description of methods for adjusting estimated unit costs to the year of reported costs No description of any potential for conflict of interest of study contributors in accordance with journal policy	No description of the interventions compared in the title No statement on the relevant aspects of the system(s) in which the decision(s) need(s) to be made No report of the values, ranges, references, and, if used, probability distributions for all parameters.	No description of the interventions compared in the title No statement on the relevant aspects of the system(s) in which the decision(s) need(s) to be made No report of the choice of discount rate (s) used for costs and outcomes or why it is appropriate

NA, not applicable; RCT, randomized controlled trial.

Conclusion

All identified studies relied on the high-quality level of clinical evidence to inform the respective economic evaluations of DCBs and DESs in PAD, but the quality of reporting in these economic evaluation studies was low. Nevertheless, it is worth mentioning the argument that currently exists about the safety of these devices: the divergent analyses conducted by Katsanos et al. and Nordanstig et al. merit consideration (11;27). It could be that the apparent increased mortality associated with these devices is actually connected to confounding factors unrelated to paclitaxel. Finally, our evaluation of the reporting quality suggests that essential information was not present in these studies. Without well-reported data, readers are not able to critically assess whether the results provide reliable information or whether the conclusions are valid. This is of concern in the interpretation of economic studies, especially in an HTA process.

Supplementary material. The supplementary material for this article can be found at https://doi.org/10.1017/S0266462321000532.

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Conflict of Interest. The authors declare no conflict of interest.

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