Cardiovasc Intervent Radiol
https://doi.org/10.1007/s00270-021-03050-6

Cost-Effectiveness of Urea Excipient-Based Drug-Coated Balloons for Chronic Limb-Threatening Ischemia from Femoropopliteal Disease in the Netherlands and Germany

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Received: 16 September 2021 / Accepted: 18 December 2021

Abstract
Purpose Drug-coated balloons (DCBs) for femoropopliteal peripheral artery disease have been shown to be clinically superior and cost-effective compared to conventional percutaneous transluminal angioplasty (PTA). However, few studies enrolled patients with chronic limb-threatening ischemia (CLTI). Our objective was to study the cost-effectiveness of endovascular treatment with versus without DCB in CLTI patient populations in the Netherlands and Germany.
Material and Methods Target lesion revascularization (TLR) and major amputation rates were obtained from the CLTI subgroup of the IN.PACT Global study. Rates for "status quo" treatment involving PTA with primary or bailout stenting were derived from systematic literature search. Costs and cost-effectiveness were calculated using a decision-analytic Markov model considering, in the base case, a 2-year horizon, and strategy-specific quality-adjusted life year (QALY) gains calculated from survival and health state-specific utilities. A willingness-to-pay threshold of €50,000/QALY was assumed, and extensive sensitivity analyses were performed.
Results Model-projected 24-month probabilities of TLR were 26.2% and 32.8% for treatment with and without DCB, and probabilities for amputation were 2.8% and 11.9%, respectively. DCB added 0.017 QALYs while saving €1,030 in the Dutch setting and €513 in the German setting, respectively. DCB was found dominant or cost-effective across a wide range of assumptions.
Conclusion Urea excipient drug-coated balloon therapy for treating CLTI from femoropopliteal artery disease is associated with improved patient outcomes and expected overall cost savings to payers in the Dutch and German healthcare systems, rendering it a cost-effective and likely dominant treatment strategy.

Keywords Peripheral Arterial Disease [MeSH terms] · Economic/cost-effectiveness · Cost–benefit analysis [MeSH terms] · Angioplasty [MeSH terms] · The Netherlands [MeSH Terms] · Germany [MeSH Terms]

Introduction

Chronic limb-threatening ischemia (CLTI) is related to a high risk of lower limb loss, resulting in functional impairment negatively affecting quality of life [4, 6]. A major treatment goal is thus to maximize amputation-free survival and to increase quality of life.

Endovascular strategies, including drug-based technologies, play an increasing role in the treatment of both superficial femoral artery disease and below-the-knee

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Published online: 04 January 2022

lesions [2, 7, 10, 17, 21, 22]. Several studies have assessed clinical outcomes and also health economic implications of drug-coated balloon (DCB) use in femoropopliteal occlusive disease in intermittent claudication (IC) or mixed groups of patients with IC and CLTI [11, 16, 19]. Data from the CLTI subcohort of the IN.PACT Global Study recently provided 1-year clinical data of treatment with urea excipient-based DCB [18].

The objective of this study was to assess the potential cost-effectiveness of a DCB-supported vs. standard-of-care interventional strategy using these data in the context of the Dutch and German healthcare systems.

Materials and Methods

Overview

The cost-effectiveness of DCB was assessed using a decision-analytic Markov model. Two strategies, endovascular treatment with DCB and bailout stenting vs. conventional "status quo" treatment with conventional PTA and primary or bailout stenting (see details below), were compared. The effectiveness of the "status quo" strategy was derived from a systematic literature search. Cost data for both countries were calculated from reimbursement data. The base case analysis evaluated incremental cost-effectiveness in Euro per quality-adjusted life year (QALY) gained, considering a 2-year analysis horizon.

Study Data and Analyses

Clinical data for DCB were obtained from the post hoc analysis of the CLTI subgroup of the IN.PACT Global study ($n = 156$ of the total $n = 1535$ study participants) [18]. In that study, which was limited to Rutherford 4 and 5 patients, the freedom from clinically driven TLR through 12 months was 86.3% in the CLTI group and 93.4% in the IC group ($p < 0.001$), with a freedom from major target limb amputation at 12 months of 98.6% and 99.9% ($p < 0.005$), respectively [18]. In the absence of RCT data, comparator data were identified through a systematic literature search. Inclusion criteria included both controlled and uncontrolled studies of PTA, DCB, or bare metal or drug-eluting stent in cohorts with close to 100% CLTI symptoms (Rutherford category 4 through 6) and a primary lesion in the superficial femoral or the popliteal artery. See supplementary materials for details.

From these studies, the proportion of patients experiencing TLR, major amputation, or death were extracted for the longest reported follow-up. All events were converted to 12-month proportions via rates. If more than one proportion or rate was available for a given endpoint, rates from different studies were pooled by weighing the proportion or rate by the number of patients.

Bailout stenting rates for the balloon index procedure were assumed to be similar for the DCB and status quo strategies and were based on the reported 23.4% bailout rate observed in the IN.PACT Global CLTI subcohort [18]. For reinterventions, the proportion of stent use was assumed to be the same for the DCB and status quo strategies and was informed by the identified comparator studies. The choice of a status quo bailout rate similar to the IN.PACT Global CLTI cohort was made as a conservative choice, as it was assumed that the need for bailout stenting would likely not be driven by the choice of balloon type.

For the Dutch analysis, cost data for 2020 were sourced from the *Diagnose Behandel Combinatie* diagnosis-related group (DRG) information system, with differences in reimbursement between vascular surgery and interventional radiology service considered and equal treatment volumes between services assumed in the base case [25]. For DCB, an add-on reimbursement of €470 per device was assumed in the Dutch analysis, based on device cost reimbursed on top of the DRG amount at the time of analysis.

For the German analysis, year 2020 reimbursement amounts were identified from the G-DRG system, considering the procedure-specific DRGs [9]. Add-on reimbursement for DCB use was taken into account according to the current fee schedule. See Table 1 for details.

In both country analyses, cost-effectiveness was evaluated relative to a willingness-to-pay threshold of €50,000 per QALY gained [12, 13].

Model-Based Projections and Scenarios

The decision-analytic Markov model was implemented separately for each of the two analyzed countries and included three health states as follows: post-endovascular intervention, post-major amputation, and death. Subjects in the modeled cohorts progressed through these states based on strategy-specific event rates, with a modeled cycle length of 3 months. Respective TLR and amputation events were accounted for in each model cycle. In line with the findings of prior studies [19], any TLR was assumed to be associated with a temporary reduction in health-related quality of life, applied as a one-time QALY decrement in the model cycle in which the TLR occurred. For amputation events, a reduced health-related quality of life was assumed for the post-amputation state [5]. Mortality was assumed to be similar for both strategies and was estimated from the country-specific general population life tables and

Table 1 Input parameters for the long-term cost model

Variable	Definition	Source
Clinical parameters		
Age (years)	71.8	[18]
Gender (% male)	55.8	[18]
Mortality HR relative to general population mortality in the Netherlands	3.55	Calibrated based on pooled mortality estimate of 6.1% at 12 months as reported in [3, 8, 14, 18, 23, 24]—see supplementary materials
Mortality HR relative to general population mortality in German	3.15	
Effectiveness: Twelve-month TLR proportions		
PTA with DCB	14.1%	[18]
Status quo PTA	18.0%	Pooled from [24], CLTI subcohort of [18], BMS subcohort of [14], endovascular group of [3]
Effectiveness: Twelve-month major amputation proportions		
PTA with DCB	1.4%	[18]
Status quo PTA with plain balloon	6.1%	Pooled from [24], CLTI subcohort of [18], BMS subcohort of [14], endovascular group of [3], and [20]
Probability of bailout stenting/stent use		
PTA with DCB	23.4%	[18]
Status quo PTA with plain balloon	23.4%	Assumed to be similar to DCB angioplasty [pooled estimate of stent use for included status quo studies [3, 23, 24] is 79.4% stent use—this assumption was tested in sensitivity analysis]
Reinterventions after TLR, either strategy	79.4%	Assumed to be similar to pooled estimate of stent use for included status quo studies [3, 23, 24]
Utilization of devices, per respective procedure		
DCB	1.4	[22]
BMS (for German analysis also for DES, as applicable)	1.5	Krankenberg et al. 2015
Cost parameters		
The Netherlands		
Endovascular intervention (PTA with balloon only, with single stent placement, or with multiple stent placement), surgery tariff	€ 12,355	33,679 – DRG 099,699,099 (2020)
PTA with balloon only, interventional radiology tariff	€ 1,569	DRG 990,062,007 (2020)
PTA with single stent, interventional radiology tariff	€ 2,181	DRG 990,062,004 (2020)
PTA with multiple stents, interventional radiology tariff	€ 5,201	DRG 990,062,005 (2019/20)
Additional reimbursement of DCB cost, per device used	€ 470	Per information provided by Medtronic Inc. for IN.PACT DCB
Percent of endovascular procedures performed under surgery tariff, as opposed to interventional radiology	50.0%	Assumption based on expert input; 0–100% tested in sensitivity analyses
Major amputation	€ 14,839	38,690—Weighted average of DRGs 099,699,016, 099,699,023, 099,699,100 (2020)
Germany		
PTA with balloon only	€ 3,059	G-DRG F59F (2020)
PTA with single stent	€ 3,938	G-DRG F59E (2020)
PTA with multiple stents	€ 4,735	G-DRG F59D (2020)
Additional reimbursement if DCB is used (one DCB)	€ 172	ZE137.01 (2020)
Additional reimbursement if DCB is used (two DCBs)	€ 573	ZE137.02 (2020)
Major amputation	€ 7,535	G-DRG F28C (2020)
Health-related quality of life		
Utility (post-treatment)	0.82	Average of plain balloon and DCB utilities reported for period 1 m–24 m in [19]
Utility (post-amputation, long term)	0.68	[5]
QALY decrement for TLR	0.059	[19]

Table 1 continued

Variable	Definition	Source
Discounting		
Discount rate on costs, p.a. (NL)	4.0%	[1]
Discount rate on costs, p.a. (Germany)	3.0%	[1]
Discount rate on outcomes, p.a. (NL)	1.5%	[1]
Discount rate on outcomes, p.a. (Germany)	3.0%	[1]

BMS, bare metal stent; CLI, critical limb ischemia; DCB, drug-coated balloon; HR, hazard ratio; p.a., per annum; NL, The Netherlands; PTA, percutaneous transluminal angioplasty; QALY, quality-adjusted life year; TLR, target lesion revascularization. Note: German DRG amounts apply independent of specialty performing the respective procedure

calibration factors derived from six of the included studies that reported all-cause mortality [3, 8, 14, 18, 23, 24].

The primary study outcome was the incremental cost-effectiveness ratio (ICER), defined as the ratio of incremental costs and incremental effectiveness in QALYs. Total costs were further stratified by index procedure cost vs. follow-up treatment cost. The base case analysis considered a 2-year time horizon. Costs and outcomes, per country-specific requirements, were discounted by 4.0% and 1.5% per annum for the Netherlands and by 3.0% for Germany [1].

Various sensitivity and scenario analyses were conducted to evaluate the effect of variations in clinical input parameters (PAD cohort mortality, strategy-specific TLR, and amputation rates), number of DCB devices used per procedure, proportion of bailout stenting, analysis time horizon, health-related quality of life (utility) assumptions, and—for the Dutch model—evaluation of the effect of surgery versus interventional radiology reimbursement.

Results

The systematic literature search conducted to identify comparator performance yielded five papers that met the inclusion criteria [3, 14, 20, 23, 24]. In addition, it identified two additional DCB studies that were used for additional scenario analysis [8, 15].

See supplementary materials for details on search strategy and identified studies, including cohort and lesion characteristics.

The resulting 12-month TLR and major amputation proportions pooled from the comparator studies (resembling the "status quo" strategy in this analysis) were 18.0% and 6.1%, respectively, compared to 14.1% and 1.4% reported for DCB in the IN.PACT Global CLTI subcohort at 12-month follow-up. This TLR rate closely resembled the 12.4% and 14.3% reported in Goksel et al. and Phair et al. [8, 15]. One-year all-cause mortality, calculated from the identified studies, was 6.1%, leading to hazard ratios of 3.55 and 3.15 relative to general population mortality in the Dutch and German country settings, respectively.

Calculated 24-month event proportions for the status quo and DCB strategies were 32.8% and 26.2% (risk difference 6.6%) for TLR and 11.9% and 2.8% (9.1%) for major amputation (see supplementary materials Table S.1). This resulted in total projected 24-month costs of €10,791 and €9761 (incremental costs €1030) for the status quo and DCB strategy in the Dutch analysis, and in corresponding total costs of €5175 and €4662 (− €513) in the German analysis. DCB index treatment cost was €615 and €332 higher than status quo index treatment cost in the Dutch and German analysis, respectively. These higher index costs were more than amortized by 24-month follow-on costs that were €1645 and €846 lower than those of the status quo strategy in the Dutch and German setting, respectively (Fig. 1).

24-month-calculated QALYs for the DCB and status quo strategies were 1.496 and 1.479 (+ 0.017) and 1.473 and 1.456 (+ 0.017) QALYs in the Dutch and German analyses, respectively, based on lower reintervention and amputation rates in the DCB strategy. The combination of lower total costs and improved outcomes over 24 months rendered DCB the dominant treatment strategy in both country settings.

Sensitivity analyses found the DCB strategy to remain cost saving across the majority of tested scenarios (Fig. 2) and thus dominant on the basis of reduced cost at concurrent gain in QALYs (Suppl. Table S.2). The DCB strategy was found to be associated with higher cost in only three scenarios as follows: (1) higher DCB amputation rate of 6.0% based on the pooled DCB study evidence, (2) no amputation benefit of DCB compared to the status quo strategy, and (3) a hypothetical extreme scenario in which DCB incurred only 25% of the TLR and amputation benefits compared to status quo. For these three scenarios, the DCB strategy remained cost-effective despite higher cost (see supplementary materials Table S.2). Limiting the analysis horizon to only 12 months, the reported clinical follow-up time in the IN.PACT Global CLTI subcohort

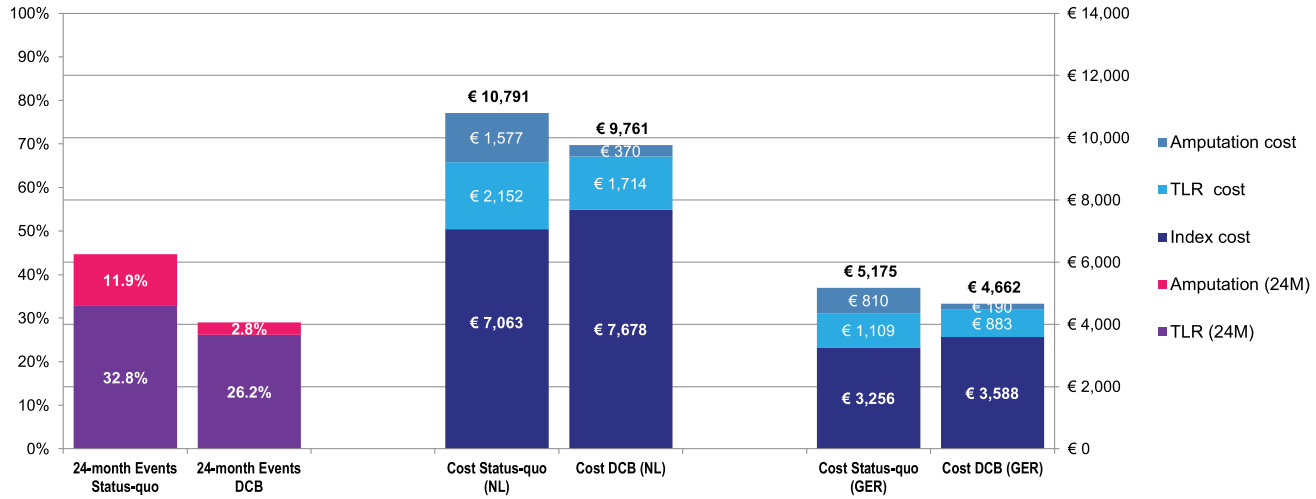

Fig. 1 24-month-projected TLR and amputation events, and costs for status quo and DCB treatment (by country). Abbreviations: TLR: target lesion revascularization; DCB: PTA with drug-coated balloon; Status quo: status quo PTA with plain balloon

[18] rendered the DCB strategy still dominant in both country settings. Extending the analysis horizon to 36 months made findings more favorable than at 24-month follow-up. Under the assumption of two DCB devices used per procedure, DCB remained the dominant strategy in both the Dutch and German analyses. DCB remained cost-effective at ICERs of €7848 and €32,132 per QALY in explored hypothetical scenarios of three or four DCB devices used in the German context, where incremental device reimbursement is available for up to four devices. Only considering the TLR reduction effect, and no effect on amputation rates, still rendered DCB cost-effective, albeit at higher overall cost. Conversely, for a scenario where no TLR reduction effect of DCB was considered, but the base case assumption about reduction in amputation rates was maintained, DCB remained dominant—associated with improved outcomes at overall cost savings.

Under assumption that all index procedures and endovascular reinterventions in the Dutch analysis were conducted in the surgery setting which is associated with higher specialty-specific procedure reimbursement, DCB remained dominant, at overall higher total savings over 24 months. Dominance was also maintained under assumption that all index procedures and endovascular reinterventions were performed in the interventional radiology setting which is associated with lower procedure reimbursement. For both countries, variation in status quo major amputation rate had the highest impact on the cost difference between the two strategies, followed by variation in status quo TLR performance (see Fig. 2 and supplementary materials Table S.2).

Discussion

This study, based on recently reported DCB performance data in patients suffering from CLTI caused by femoropopliteal artery disease, found DCB to be associated with favorable health economic value profile in two European country contexts. To the authors' knowledge, this is the first study that has evaluated the cost-effectiveness of DCB in this more diseased cohort with a higher risk of amputation. As such, it complements findings of prior studies reporting on the cost-effectiveness of DCB in intermittent claudication populations [11, 16, 19].

Compared to QALY gains reported in IC studies, the projected gain suggests a higher effect (+ 0.017 QALYs over 24 months) in the CLTI cohort when compared to the 0.011 QALYs reported by Katsanos et al. [11] in a similar model-based projection and to the 0.01 QALYs reported in an analysis of the IN.PACT SFA trial [19]. This higher QALY gain can primarily be explained by the additional consideration of major amputation events, which were not relevant in the IC studies.

The study's findings about cost difference associated with DCB treatment are, directionally, in line with the findings of the earlier studies on patients with IC, which suggested that higher index procedure costs in the DCB strategy are partly or fully amortized over 24-month follow-up on the basis of reduced reintervention rates [11, 16, 19]. However, these follow-on savings seem more pronounced in the CLTI cohort, mainly driven by the additional consideration of avoided amputation events.

An interesting observation in the Dutch analysis is the pronounced difference between specialty-specific cost to payers for endovascular procedures. The same procedure, if conducted by the surgical as opposed to interventional

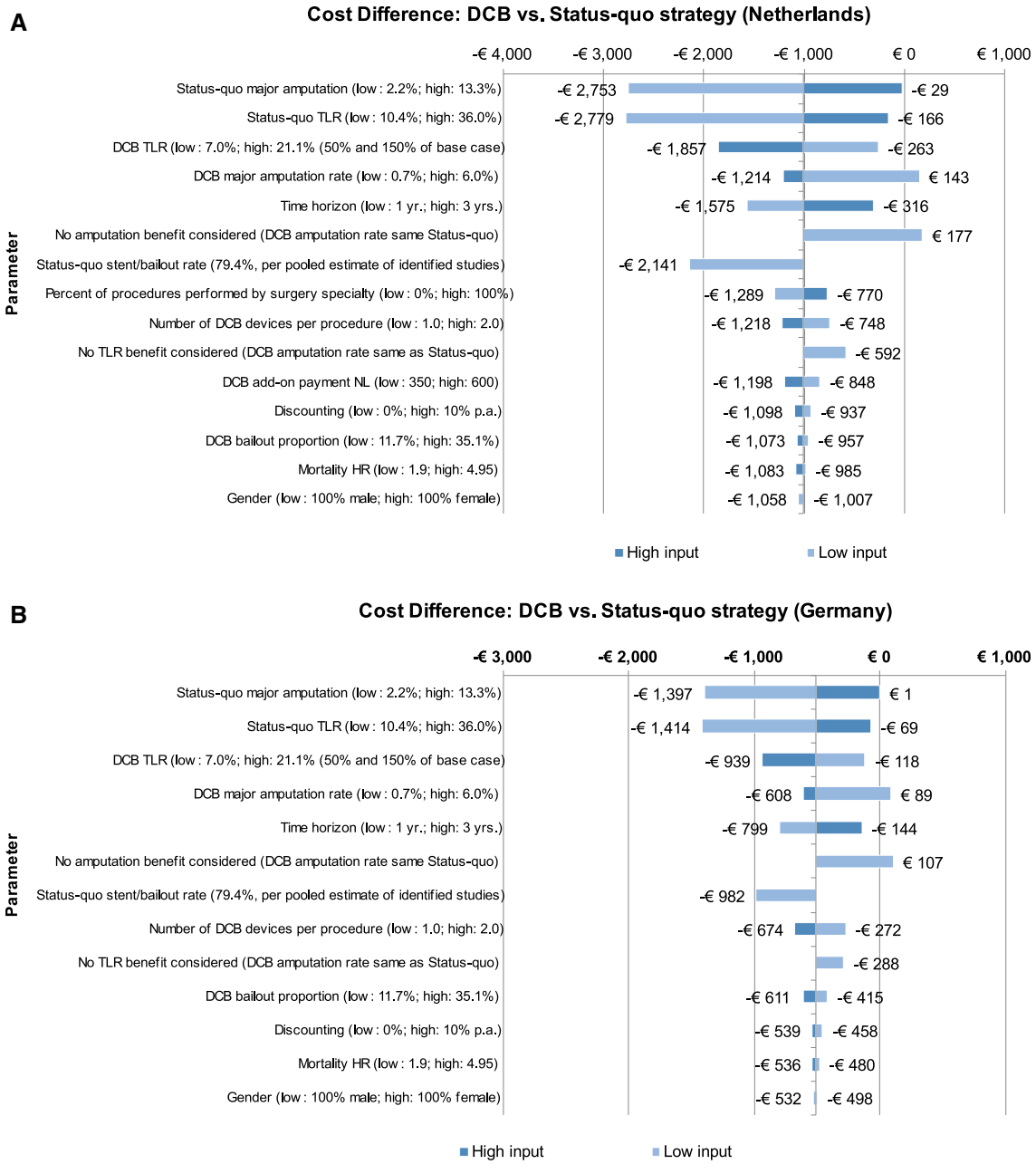

Fig. 2 Tornado diagram showing cost difference between DCB and status quo strategies for The Netherlands (**A**) and Germany (**B**). Abbreviations: TLR: target lesion revascularization; DCB: PTA with drug-coated balloon; Status quo: status quo PTA with plain balloon and primary or bailout stenting, if applicable. Tornado diagrams reflect the uncertainty of the result depending on variation in input parameters. Diagrams are ranked to show parameter with the highest impact on analysis result first. Negative values reflect an overall cost saving of the DCB versus the status quo strategy. The centerline reflects the base case cost difference (− €1,030 in The Netherlands, − €513 in Germany). For all scenarios where cost difference was ≤ €0, DCB was found dominant; for all scenarios where cost difference was > €0, DCB was found to be cost-effective in light of projected QALY gains (see supplementary materials for details)

radiology specialty, drives starkly different reimbursement, with corresponding effects also on the cost-effectiveness of DCB therapy. Dutch reimbursement amounts in the interventional radiology setting are approximately comparable to the reimbursement amounts in Germany, while surgery specialty reimbursement is around three times higher, driving the higher total procedure costs in the Dutch analysis compared to the German analysis. The reason for the higher surgery reimbursement is based on the reimbursement grouping in the surgical field, where a multitude of procedures are linked to the same DRG code, which is associated with a comparably high payment for the procedures investigated in this study. This is different from the German setting, where a designated DRG reimbursement is

defined that applies independent of the specialty performing the procedure. This is the primary reason for the higher payer cost of both the status quo and DCB strategies in the Dutch setting.

The current study is subject to limitations. First, because the IN.PACT Global study was a single-arm study, any incremental comparison could only be made based on evidence from other endovascular treatment studies in CLTI patients. While the performed systematic literature search provided a rigorous approach to evidence identification, it yielded only five studies that could be used for reference, contributing a total of 192 patients that provided TLR data, with no further sub-assessment of drug-eluting vs. plain technology outcome possible. However, the limitations of available comparator data were addressed by performing extensive sensitivity analyses, which showed that cost-effectiveness findings were robust, even for the extreme instance where conventional therapy was assumed to be associated with a lower TLR rate than the DCB strategy. Because of the inclusion criteria of the IN.PACT Global study, the CLTI subcohort encompasses a higher proportion of Rutherford 4 patients compared to the identified controls. While this introduces an inherent limitation, this concern was addressed by exploring extensive sensitivity analyses, specifically around the amputation rate. Second, based on the uncontrolled trial data and reliance on reimbursement cost and literature-based utility estimates as opposed to data collected along-the-trial, the study does not meet the stricter criteria of a formal cost-effectiveness evaluation. However, the study's objective was to evaluate cost-effectiveness from a payer perspective, reflecting current real-world cost implications to healthcare payers based on amounts they need to spend with one vs. the other interventional strategy. Third, the analysis did not assume a potential mortality difference between the DCB and status quo strategies. It could be argued that elevated risk for amputation in the status quo group might also be associated with increased mortality in that group. The mortality data reported in the comparator studies might support this conjecture, as shown in the mortality data tabulated in the supplementary materials [23, 24]. However, any such difference cannot be proven. Finally, the results of the current study are based on the IN.PACT Global clinical study, which used a urea excipient DCB. The findings therefore do not translate to other DCB devices, unless their clinical outcomes are comparable.

In conclusion, urea excipient drug-coated balloon therapy for treating CLTI from femoropopliteal artery disease is associated with improved patient outcomes at overall cost savings to payers in the Dutch and German healthcare systems, rendering it a cost-effective and likely dominant treatment strategy.

Authors' Contributions JBP, BPG, and MMPJR contributed to conception, design, analysis, and interpretation and wrote the article. SH, IPSW, MMPJR, ARI, BPG, and JBP collected the data. JBP and BPG helped in model development. JBP, BPG, ARI, SH, IPSW, and MMPJR critically revised the article and provided final approval of the article. JBP and MMPJR had overall responsibility.

Funding This research was—in part—funded by Medtronic, Inc. The authors retained the right to publish without approval of the funding source.

Declarations

Conflict of interest Jan B. Pietzsch, Ph.D.: Dr. Pietzsch is the president, CEO, and a shareholder of Wing Tech Inc., an independent research firm conducting health economic analyses. Wing Tech Inc. received consulting fees from Medtronic, Inc. to conduct the analyses underlying this study. Benjamin P. Geisler, M.D., M.P.H.: Dr. Geisler is a senior consultant for Wing Tech Inc., an independent research firm conducting health economic analyses. Wing Tech Inc. received consulting fees from Medtronic, Inc. to conduct the analyses underlying this study. Annabelle R. Iken, M.Sc.: Mrs. Iken is a research associate for Wing Tech Inc., an independent research firm conducting health economic analyses. Wing Tech Inc. received consulting fees from Medtronic, Inc. to conduct the analyses underlying this study. Iris van Wijck, BSc: No conflict of interest. Suzanne Holewijn, MSc, PhD: No conflict of interest. Michel M. P. J. Reijnen, MD, PhD: Dr. Reijnen received consulting fees and research funding from Medtronic, Inc.

References

1. Attema AE, Brouwer WBF, Claxton K. Discounting in economic evaluations. Pharmacoeconomics. 2018;36(7):745–58.
2. Bausback Y, Willfort-Ehringer A, Sievert H, et al. Six-month results from the initial randomized study of the ranger paclitaxel-coated balloon in the femoropopliteal segment. J Endovasc Ther. 2017;24(4):459–67.
3. Biagioni RB, Nasser F, Matielo MF, et al. Comparison of bypass and endovascular intervention for popliteal occlusion with the involvement of trifurcation for critical limb ischemia. Ann Vasc Surg. 2020;63:218–26.
4. Bosma J, Vahl A, Wisselink W. Systematic review on health-related quality of life after revascularization and primary amputation in patients with critical limb ischemia. Ann Vasc Surg. 2013;27(8):1105–14.
5. Bruhn D, Martin AA, Tavares R, Hunt B, Pollock RF. Cost-utility of albiglutide versus insulin lispro, insulin glargine, and sitagliptin for the treatment of type 2 diabetes in the US. J Med Econ. 2016;19(7):672–83.
6. Dua A, Lee CJ. Epidemiology of Peripheral Arterial Disease and critical limb ischemia. Tech Vasc Interv Radiol. 2016;19(2):91–5.
7. Farber A, Rosenfield K, Siami FS, Strong M, Menard M. The BEST-CLI trial is nearing the finish line and promises to be worth the wait. J Vasc Surg. 2019;69(2):470–81.
8. Goksel OS, Karpuzoğlu E, Işsever H, Çinar B. Midterm results with drug-coated balloons for SFA lesions in patientswith CLI: comparison with conventional bypass surgery. Int Angiol. 2018;37(5):365–9.
9. InEK (2020) Fallpauschalen-Katalog 2020 (German-Diagnosis Related Groups-System). Institut für das Entgeltsystem im Krankenhaus (InEK GmbH), https://www.g-drg.de/aG-DRG-

System_2020/Fallpauschalen-Katalog/Fallpauschalen-Katalog_2020.
10. Jia X, Zhang J, Zhuang B, et al. Acotec drug-coated balloon catheter: randomized, multicenter, controlled clinical study in femoropopliteal arteries: evidence from the AcoArt I trial. JACC Cardiovasc Interv. 2016;9(18):1941–9.
11. Katsanos K, Geisler BP, Garner AM, Zayed H, Cleveland T, Pietzsch JB. Economic analysis of endovascular drug-eluting treatments for femoropopliteal artery disease in the UK. BMJ Open. 2016;6(5):e011245.
12. Leon MB, Piazza N, Nikolsky E, et al. Standardized endpoint definitions for transcatheter aortic valve implantation clinical trials: a consensus report from the valve academic research consortium. Eur Heart J. 2011;32(2):205–17.
13. Marseille E, Larson B, Kazi DS, Kahn JG, Rosen S. Thresholds for the cost-effectiveness of interventions: alternative approaches. Bull World Health Organ. 2015;93(2):118–24.
14. Meng FC, Chen PL, Lee CY, Shih CC, Chen IM. Real-world comparison of drug-eluting and bare-metal stents in superficial femoral artery occlusive disease with trans-atlantic intersociety consensus B lesions: a 2-year. Single-Inst Study Acta Cardiol Sin. 2018;34(2):130–6.
15. Phair J, Carnevale M, Lipsitz EC, Shariff S, Scher L, Garg K. Amputation-free survival in patients with critical limb ischemia treated with paclitaxel-eluting stents and paclitaxel-coated balloons. Ann Vasc Surg. 2020;62:8–14.
16. Pietzsch JB, Geisler BP, Garner AM, Zeller T, Jaff MR. Economic analysis of endovascular interventions for femoropopliteal arterial disease: a systematic review and budget impact model for the United States and Germany. Catheter Cardiovasc Interv. 2014;84(4):546–54.
17. Popplewell MA, Davies HOB, Narayanswami J, et al. A comparison of outcomes in patients with infrapopliteal disease randomised to vein bypass or plain balloon angioplasty in the bypass versus angioplasty in severe ischaemia of the leg (BASIL) trial. Eur J Vasc Endovasc Surg. 2017;54(2):195–201.
18. Reijnen M, van Wijck I, Zeller T, et al. Outcomes after drug-coated balloon treatment of femoropopliteal lesions in patients with critical limb ischemia: a post hoc analysis from the IN.PACT global study. J Endovasc Ther. 2019;26(3):305–15.
19. Salisbury AC, Li H, Vilain KR, et al. Cost-effectiveness of endovascular femoropopliteal intervention using drug-coated balloons versus standard percutaneous transluminal angioplasty: results from the IN.PACT SFA II trial. JACC Cardiovasc Interv. 2016;9(22):2343–52.
20. Santos Á, Valdivia A, Alguacil S, Sanus E, Guaita J, Zúñiga C. One year results in the endovascular treatment of the femoropopliteal segment with the Tigris® stent in patients with critical limb ischemia. Eur J Vasc Endovasc Surg. 2019;58:e466.
21. Scheinert D, Schmidt A, Zeller T, et al. German center subanalysis of the LEVANT 2 global randomized study of the lutonix drug-coated balloon in the treatment of femoropopliteal occlusive disease. J Endovasc Ther. 2016;23(3):409–16.
22. Tepe G, Laird J, Schneider P, et al. Drug-coated balloon versus standard percutaneous transluminal angioplasty for the treatment of superficial femoral and popliteal peripheral artery disease: 12-month results from the INPACT SFA randomized trial. Circulation. 2015;131(5):495–502.
23. Todoran TM, Connors G, Engelson BA, Sobieszczyk PS, Eisenhauer AC, Kinlay S. Femoral artery percutaneous revascularization for patients with critical limb ischemia: outcomes compared to patients with claudication over 2.5 years. Vasc Med. 2012;17(3):138–44.
24. Torres-Blanco A, Edo-Fleta G, Gomez-Palones F, Molina-Nacher V, Ortiz-Monzon E. Mid-term outcomes of endovascular treatment for TASC-II D femoropopliteal occlusive disease with critical limb ischemia. Cardiovasc Intervent Radiol. 2016;39(3):344–52.
25. Nederlandse Zorgautoriteit. dbc-informatiesysteem (DIS); https://www.opendisdata.nl/dis/over, 2020.