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Received: 6 July 2023 | Revised: 6 September 2023 | Accepted: 30 September 2023

DOI: 10.1002/ccd.30878

ORIGINAL ARTICLE - CLINICAL SCIENCE

WILEY

Cost effectiveness analysis of drug coated balloon only angioplasty for de novo coronary artery disease

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Funding information
National Institute for Health Research Capability Fund from Norfolk and Norwich University Hospital; B. Braun Medical

Abstract

Aims: We aimed to perform a cost analysis of drug coated balloon (DCB)-only angioplasty versus drug eluting stent (DES), for de novo disease of all vessel sizes and all clinical indications.

Background: DCB angioplasty is an emergent technology for the treatment of coronary artery disease. There is lack of data regarding the cost-effectiveness of DCB-only angioplasty for treatment of de novo coronary artery disease as compared with second generation DES.

Methods: We compared total costs of patients treated with DCB or DES for first presentation of ST-elevation myocardial infarction, non-ST-elevation myocardial infarction, or stable angina due to de novo disease between January 1, 2018 and November 15, 2019. We defined total cost as the sum of (1) procedural devices-cost, (2) procedural staff-cost, (3) post-percutaneous coronary intervention hospital stay cost, and (4) antiplatelet regime cost. A cost minimization analysis was performed to compare the costs of DCB and DES.

Results: We present 1952 all-comer, consecutive patients; 902 (1064 lesions) treated with DCB and 1050 (1236 lesions) treated with DES for de novo coronary artery disease. The cost per patient was estimated to be £9.02 more expensive in the DCB group (£3153.00 vs. £3143.98). However, the cost per lesion treated was calculated to be £15.51 cheaper in the DCB group (£3007.56 vs. £3023.07). The results were consistent irrespective of duration of long-term antiplatelet medications.

Conclusion: We have compared the cost-effectiveness of DCB-only angioplasty to DES-angioplasty and showed that the per patient and per lesion results were not different and hence cost should not be implicated in the decision to choose DCB or DES.

https://clinicaltrials.gov/ct2/show/NCT04482972 Unique identifier: NCT04482972.

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KEYWORDS
cost analysis, drug coated balloon, drug eluting stent

1 | INTRODUCTION

Drug coated balloon (DCB) is an emergent technology for treatment of coronary artery disease. Its use is supported by guidelines for in-stent restenosis (ISR) while randomized trials have demonstrated its efficacy for small vessel de novo disease.[1,2] Previous work from our group has demonstrated the safety and efficacy in terms of cardiovascular outcomes of DCB-only angioplasty as compared to second generation drug eluting stent (DES) in patients with ST-elevation myocardial infarction (STEMI), left main stem disease as well as stable angina due to de novo coronary artery disease of all vessel sizes.[3–5] Limited data suggest that DCB angioplasty for ISR is cost-effective compared to DES.[6] There is a lack of data regarding the cost-effectiveness of DCB-only angioplasty for de novo coronary artery disease as compared to second generation DES.

Here we report a cost analysis of DCB-only angioplasty versus DES from our institution, for de novo disease of all vessel sizes and all clinical indications.

2 | METHODS

In our institution, patients undergoing percutaneous coronary intervention (PCI) are prospectively entered in a dedicated clinical database. Following institutional approval and approval from the Northwest Haydock (17/NW/0278), UK research ethics committee, we retrospectively surveyed our clinical database to identify all patients whose first entry was either for stable angina, non-ST-elevation myocardial infarction (NSTEMI) or STEMI due to de novo coronary artery disease. We included all consecutive patients from January 1, 2018 to November 15, 2019 with first presentation of STEMI/NSTEMI/Stable angina, treated either with DCB-only angioplasty or DES-only angioplasty. We excluded patients treated with both DCB and DES in the same procedure. Clinical and angiographic data were obtained from our prospectively collated database supplemented with data from electronic hospital records as required. All angiograms were reviewed by an expert operator to confirm accuracy of PCI strategy.

The primary endpoint was total cost. We defined total cost as the sum of (1) procedural devices-cost, (2) procedural staff-cost, (3) post-PCI hospital stay cost, and (4) antiplatelet regime cost. Previous work from our group demonstrated no difference between DCB-only angioplasty and second generation DES in terms of all-cause mortality and net cardiac events including unplanned TLR.[3,4] Therefore, for this work we did not estimate costs from subsequent cardiovascular-related hospital admissions. Every effort was made to identify how many devices were used for patients with multiple lesions. Such devices included guide extensions, intravascular ultrasound, optical computed tomography, pressure wire, pre/post-dilatation balloons, microcatheters, thrombectomy devices, and if felt that the same device was used in more than one lesion it was only counted once.

Statistical analysis was undertaken in SPSS version 25. Continuous variables were compared with independent *t*-test and categorical variables were compared with χ^2 test. A health economics analysis was performed to compare the cost of DCB against DES method in accordance with NICE standards for economic evaluation. As both approaches proved to have an equivalent clinical effect, we adopted a cost-minimization analysis (CMA) which is a method of comparing the costs of alternative interventions.

2.1 | Health economics analysis

To characterize uncertainty (variance) in the CMA, we conducted probabilistic sensitivity analyses (PSA) using 1000 iterations of a Monte Carlo simulation.[7] PSA is a technique used in economic modeling that allows the characterization of the level of confidence in the output parameters of the analysis regarding the uncertainty in the model inputs. In the probabilistic analysis, the parameters' value from clinical trials, observational studies or, in some cases, expert opinion is represented as distributions around their deterministic value.[7] This process is repeated in many iterations of the model, resulting in a distribution of outputs that can be graphed and analyzed.

2.2 | Input variables

The health economics analysis was undertaken from the National Health Service (NHS) perspective, using the national annually published resource, the Personal Social Services Research Unit and Unit Costs of Health and Social Care 2022.[8,9] Briefly, the analysis only accounts for direct medical costs. Non-health-related costs due to lost productivity and informal care are not included.

Table 1 presents the analysis input parameters and their sensitivity analysis distribution and confidence intervals (CI). As the variables were mainly monetary units in the PSA a gamma distribution was used to represented the probabilistic around the deterministic value, the gamma distribution is more appropriate for modeling positive skewed data such as treatment and consumables costs.[10] Following the gamma distribution we have calculated the 95% CI for each parameter (95% CI: lower CI to upper CI).

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TABLE 1 Analysis input parameters.

Parameter	Deterministic value	LCI	UCI	Distribution
Model parameters				
DCB cohort size	902.00			
DCB lesions	1064.00			
DES cohort size	1050.00			
DES lesions	1236.00			
Monthly prescription tablets	28.00			
Life expectancy (in years)	15.00	8.40	23.49	Gamma
Staff compensation and time parameters				
Average time per patient (DCB)	1.06	0.03	3.81	Gamma
Average time per lesion (DCB)	0.90	0.02	3.47	Gamma
Average time per patient (DES)	1.20	0.05	4.10	Gamma
Average time per lesion (DES)	1.06	0.03	3.82	Gamma
Consultant (hourly compensation)	81.80	65.04	100.45	Gamma
Band 6 physiologist (hourly compensation)	30.69	20.81	42.46	Gamma
Band 6 radiographer (hourly compensation)	30.69	20.81	42.46	Gamma
Band 5 nurse (hourly compensation)	24.69	15.93	35.34	Gamma
80% SpR (hourly compensation)	41.70	30.02	55.28	Gamma
Medication parameters (DCB)				
Aspirin <lifelong # of patients	37.00	26.05	49.84	Gamma
Aspirin lifelong # of patients	818.00	762.90	875.00	Gamma
Clopidogrel <lifelong # of patients	235.00	205.91	265.98	Gamma
Clopidogrel lifelong # of patients	54.00	40.57	69.33	Gamma
Ticagrelor <lifelong # of patients	576.00	529.92	623.98	Gamma
Ticagrelor lifelong # of patients	34.00	23.55	46.34	Gamma
Prasugrel <lifelong # of patients	1.00	0.03	3.69	Gamma
Prasugrel lifelong # of patients	1.00	0.03	3.69	Gamma
Medication parameters (DES)				
Aspirin <lifelong # of patients	51.00	37.97	65.92	Gamma
Aspirin lifelong # of patients	981.00	920.56	1043.33	Gamma
Clopidogrel <lifelong # of patients	277.00	245.34	310.56	Gamma
Clopidogrel lifelong # of patients	36.00	25.21	48.68	Gamma
Ticagrelor <lifelong # of patients	692.00	641.39	744.50	Gamma
Ticagrelor lifelong # of patients	41.00	29.42	54.47	Gamma
Prasugrel <lifelong # of patients	1.00	0.03	3.69	Gamma
Prasugrel lifelong # of patients	0.00	0.00	0.00	Gamma
Medication monthly cost				
Aspirin	0.75	0.01	3.14	Gamma
Clopidogrel	1.23	0.06	4.16	Gamma
Ticagrelor	54.60	41.09	70.01	Gamma

(Continues)

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TABLE 1 (Continued)

Parameter	Deterministic value	LCI	UCI	Distribution
Prasugrel	4.59	1.40	9.64	Gamma
Consumables cost				
Predilatation balloons (excluding scoreflex/cutting)	38.00	26.89	51.00	Gamma
Postdilatation balloons (excluding OPN)	38.00	26.89	51.00	Gamma
OPN	0.00	0.00	0.00	Gamma
DCBs (SeQuent please NEO)	450.00	409.38	492.52	Gamma
Onyx stent	293.00	260.41	327.49	Gamma
Synergy stent	325.00	290.62	361.27	Gamma
Xience stent	293.00	260.41	327.49	Gamma
Ultimaster stent	285.00	252.87	319.02	Gamma
Pressure wire	320.00	285.90	356.00	Gamma
IVUS	415.00	376.03	455.87	Gamma
OCT	546.00	501.16	592.74	Gamma
Pronto	115.00	94.94	136.95	Gamma
Angiojet	1235.00	1167.07	1304.82	Gamma
Guideliner	350.00	314.29	387.61	Gamma
Cutting balloon	250.00	219.97	281.93	Gamma
Scoreflex	250.00	219.97	281.93	Gamma
Finecross	250.00	219.97	281.93	Gamma
Shockwave	1200.00	1133.06	1268.84	Gamma
Rotablation	1198.00	1131.11	1266.78	Gamma
Hospitalization parameters				
Hospitalization duration DCB (in days)	1.85	0.20	5.31	Gamma
Hospitalization duration DES (in days)	2.02	0.25	5.61	Gamma
Hospitalization costs	586.00	539.51	634.39	Gamma

Note: Table 1 shows analysis input parameters and their sensitivity analysis distribution and confidence intervals.
Abbreviations: DCB, drug coated balloon; DES, drug eluting stent.

3 | RESULTS

We identified 1952 patients treated for de novo coronary artery disease between January 1, 2018 and November 15, 2019. Of these, 902 patients (1064 lesions) were treated with DCB and 1050 patients (1236 lesions) were treated with DES. The mean age was 67.3 (11.6) years old in the DCB group and 67.2 (11.2) years old in the DES group. Table 2 summarizes the baseline clinical characteristics. There were no significant differences in terms of clinical indication. The DCB group had significantly more patients with previous stroke and history of heart failure while the DES group had significantly more patients with history of COPD and smoking.

Table 3 summarizes the procedural, post-PCI hospital costs as well as the antiplatelet regime costs. More scoreflex and NSE Alpha balloons were used in the DCB group while more IVUS and OCT were used in the DES group. However, the average procedural duration and the average post-PCI hospital stay was slightly shortened in the DCB group (1.06 vs. 1.20 h; $p < 0.001$) and (1.85 vs. 2.02 days; $p = 0.26$), respectively. Given the average age of our groups, the lifelong antiplatelets were estimated to be continued for 15 years. However, it is important to mention that the general trend of our results did not change even when lifelong antiplatelet medications were assumed to be continued for as short as 1 year.

As shown in Table 3, the cost per patient was estimated to be £9.02 more expensive in the DCB group (£3153.00 vs. £3143.98). However, the cost per lesion treated was calculated to be £15.51 cheaper in the DCB group (£3007.56 vs. £3023.07) (Figure 1). Assuming only 1 year for lifelong antiplatelet medications did not change the general trend of the results; DCB was £19.58 more

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TABLE 2 Baseline clinical characteristics.

	DCB	(%)	DES	(%)	*p* Value
Patients	902		1050		
Lesions	1064		1236		
STEMI	319	(35.4)	413	(39.3)	0.11
NSTEMI	360	(39.9)	374	(35.6)	
Elective	223	(24.7)	263	(25.0)	
Arrest/shock/intubation	64	(7.1)	112	(10.7)	**0.006**
Age (years)	67.3 (11.6)		67.2 (11.2)		0.74
Hypercholesterolemia	182	(20.2)	246	(23.4)	0.08
Hypertension	416	(46.1)	468	(44.6)	0.49
Peripheral vascular disease	32	(3.5)	26	(2.5)	0.16
Stroke	49	(5.4)	33	(3.1)	**0.01**
Previous myocardial infarction	104	(11.5)	103	(9.8)	0.22
Previous PCI	74	(8.2)	67	(6.4)	0.12
Coronary artery bypass graft	39	(4.3)	34	(3.2)	0.21
Heart failure	21	(2.3)	11	(1)	**0.03**
family history of CAD	104	(11.5)	96	(9.1)	0.08
Chronic obstructive pulmonary disease	41	(4.5)	78	(7.4)	**0.008**
Diabetes	178	(19.7)	189	(18)	0.34
Ever smoker	515	(57.1)	669	(63.7)	**<0.001**
Creatinine (μmol/L)		84.3 (37.9)		86.6 (34.5)	0.17
Vessel treated					
LMS	20	(1.9)	39	(3.2)	**0.054**
LAD	514	(48.3)	544	(44.0)	**0.039**
LCx	235	(22.1)	233	(18.9)	
RCA	287	(27.0)	410	(33.2)	
Graft	8	(0.8)	10	(0.8)	
Bifurcation	259	(24.3)	206	(16.6)	**<0.001**
Heavy calcification	240	(22.6)	237	(19.2)	**0.046**
Diffuse disease	275	(25.8)	215	(17.4)	**<0.001**

Note: Bold values indicate statistically significant values at $p < 0.05$. Table 2: Baseline clinical characteristics in DCB and DES groups.

Abbreviations: CAD, coronary artery disease; DCB, drug coated balloon; DES, drug eluting stent; LAD, left anterior descending; LCx, left circumflex; LMS, left main stem; NSTEMI, non-ST-elevation myocardial infarction; PCI, percutaneous coronary intervention; RCA, right coronary artery; STEMI, ST-elevation myocardial infarction.

expensive per patient but £4.94 cheaper per lesion (Figure 2). It is important to mention that medications fees, post-PCI hospitalization costs, and the following devices (pressure wire, IVUS, OCT, pronto, angiojet, finecross, rotablation) were calculated "per patient," even in the "per lesion" calculations, as it is likely that a single device would be used for all lesions on the same patient. In the supplement, we have provided the model we built to undertake this cost-effectiveness analysis. This can allow the parameters and prices for each variable (device, equipment, hospital stay, antiplatelet therapy) to be easily modified so that our model can be applied to different institutions in various countries.

4 | DISCUSSION

This study describes the cost-effectiveness of DCB-only angioplasty for de novo disease compared to DES in an unselected, real-world population from a single, large PCI center. The main finding

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TABLE 3 Shows the costs calculated for DCB and DES groups.

Cost	Total in DCB group	Total in DES group	Price per item (£)	Total price in DCB group (£)	Total price in DES group (£)
Devices					
Predilatation balloons (excluding scoreflex/cutting balloons)	1567	1573	38	59,546	59,774
Postdilatation balloons		1024	38		38,912
DCBs	1149		450		
Stents					
Onyx		429	293		125,697
Synergy		991	325		322,075
Xience		8	293		2344
Ultimaster		13	285		3705
Pressure wire	62	63	320	19,840	20,160
IVUS	24	71	415	9960	29,465
OCT	10	25	546	5460	13,650
Pronto	90	81	115	10,350	9315
Angiojet	1		1235	1235	
Guideliner	85	83	350	29,750	29,050
NSE Alpha	139	27	250	34,750	6750
Scoreflex	217	85	250	54,250	21,250
Finecross	3	5	250	750	1250
Shockwave	3	8	1200	3600	9600
Rotablation	14	17	1198	16,772	20,366
Procedural staff cost					
Consultant	956.12	1260	81.8	78,210.62	103,068
Band 6 physiologist	956.12	1260	30.69	29,343.32	38,669.4
Band 6	956.12	1260	30.69	29,343.32	38,669.4
Band 5 nurse	956.12	1260	24.69	23,606.6	31,109.4
80% SpR	956.12	1260	41.7	31,896.16	42,033.6
Average duration (h)	1.06	1.20			
Post-PCI hospital cost					
Post-PCI hospital stay	1668.7	2121	586	977,858.2	1,242,906
Average hospital stay after PCI (days)	1.85	2.02			
Antiplatelets			Price/month (£)		
Aspirin <lifelong	37 (1.39 months average)	51 (3.46 months average)	0.75	38.65	132.51
Aspirin lifelong[a]	818	981	0.75	119,961.16	143,865.4
Clopidogrel <lifelong	235 (4.6 months average)	277 (12.75 months average)	1.23	1331.69	4344.05
Clopidogrel lifelong[a]	54	36	1.23	12,987.48	8658.32
Ticagrelor <lifelong	576 (13.1 months average)	692 (13.1 months average)	54.6	412,214.4	496,579.2

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TABLE 3 (Continued)

Cost	Total in DCB group	Total in DES group	Price per item (£)	Total price in DCB group (£)	Total price in DES group (£)
Ticagrelor lifelong[a]	34	41	54.6	362,992.5	437,726.25
Prasugrel <lifelong	12.1 months average)	1	4.59	9.67	59.67
Prasugrel lifelong[a]	1		4.59	897.51	
Sum				2,844,004.3	3,301,184.2
Price/patient (£)				3153.0	3143.98
Price/lesion (£)[b]				3007.56	3023.07

Note: Table 3 shows the cost per DCB and DES group.

Abbreviations: DCB, drug coated balloon; DES, drug eluting stent; PCI, percutaneous coronary intervention.

[a]Lifelong duration was estimated at 15 years on this table.

[b]In the price/lesion calculation, medications costs, post-PCI hospitalization costs, and the following devices (pressure wire, IVUS, OCT, pronto, angiojet, finecross, rotablation) were calculated per patient as it is likely that a single device would be used for all lesions on the same patient.

is that the cost of DCB-only angioplasty was not different to DES-angioplasty per patient and per lesion (DCB to DES was 9£ more expensive per patient but 16& cheaper per lesion). The results were consistent irrespective of duration of long-term antiplatelet medications. The finding that more scoreflex and NSE Alpha balloons were used in the DCB group while more IVUS and OCT were used in the DES group, is consistent with our practice over the last few years. In our institution, we aim for optimal lesion preparation with low threshold for use of scoring balloons. The indications for intravascular imaging in DCB PCI are currently less clear than for DES. The finding that the DCB group had significantly more patients with bifurcation disease, diffuse disease or heavy calcification is also consistent with our practice over the last few years.

According to BCIS national audit, approximately 98,000 PCI procedures were undertaken in the United Kingdom in 2021–2022 with substantial financial burden to the NHS.[11,12] A recent cost-effectiveness analysis from ORBITA trial showed that PCI compared to placebo, in patients with stable angina and single-vessel coronary artery disease surpasses the threshold of £30,000 used by the National Institute of Health and Clinical Excellence.[13] However, in patients with acute myocardial infarction PCI has been shown to be cost effective compared to medical therapy.[14] Given the financial constraints of the NHS, it is imperative for any new PCI technology to undergo a cost-effectiveness analysis.

In this report, we have demonstrated for the first time that the cost of DCB-only angioplasty is not different when compared to the cost of DES-angioplasty. In the context of multivessel PCI, it was recently demonstrated that a DCB-based treatment approach was associated with significantly lower major adverse cardiovascular events compared to a DES-only treatment.[15] These findings support, from a cost-effectiveness perspective, that cost should not be implicated in the decision to choose DCB or DES for de novo coronary artery disease.

4.1 | Limitations

Whilst the patients were prospectively enrolled in our database, this is a retrospective analysis with potential for selection bias. We included a large number of all-comer, consecutive patients, recruited over a short duration of time. However, there were a few differences in the baseline clinical characteristics and also the angiographic lesion characteristics which limits the generalizability of our analysis. This analysis is specific to our own institution. It can have differences in other institutions depending on the cost of equipment, cost of hospitalization and subsequently choice and cost of antiplatelet agents used. However, one major advantage is the clarity we have presented the data, and the interactive excel document in the supplement, which provides a method and model with which every other institution can calculate their own institution-specific cost-effectiveness analysis by utilizing their own costs for the procedures and consumables. For this analysis, we have only considered the index procedure as we believe that this is the only important one to consider for cost-effectiveness. This is because of previous work from our group which demonstrated no difference between DCB and DES in terms of mortality or any of the major cardiovascular outcomes including subsequent target lesion revascularisati. An important limitation of our study is that we have excluded patients requiring bailout stenting after DCB. However, the percentage of these patients is small (<5% in our center) and unlikely to change significantly the results of the study.

5 | CONCLUSION

In conclusion, we have compared for the first time the cost-effectiveness of DCB-only angioplasty to DES-angioplasty and showed that the per patient and per lesion results were not different. Therefore, cost should not be implicated in the decision between DCB and DES for de novo coronary artery disease.

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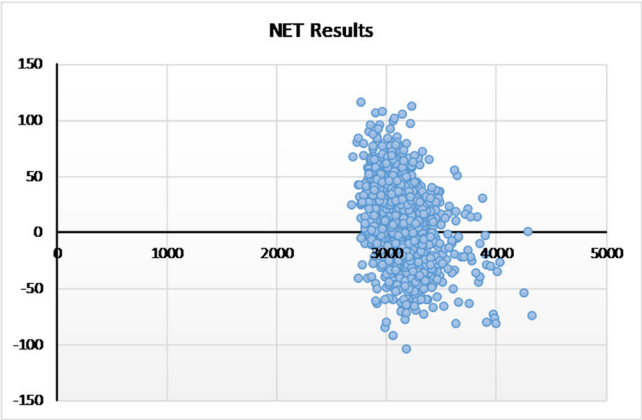
Results

DCB Vs DES Costs per Patient

	DCB	DES	NET	Cost Saving Probability
Deterministic	£ 3153.00	£ 3143.98	£ 9.01	41.3%
Probabilistic	£ 3152.61	£ 3144.59	£ 0.43	
95% LCI	£ 2834.25	£ 2816.81	£ 0.00	
95% UCI	£ 3694.70	£ 3712.18	£ 10.33	



Results

DCB Vs DES Costs per Lesion

	DCB	DES	NET	Cost Saving Probability
Deterministic	£ 3007.56	£ 3023.07	-£ 15.51	69.4%
Probabilistic	£ 3005.48	£ 3020.69	-£ 0.81	
95% LCI	£ 2698.76	£ 2700.87	-£ 17.22	
95% UCI	£ 3453.68	£ 3484.94	£ 0.00	

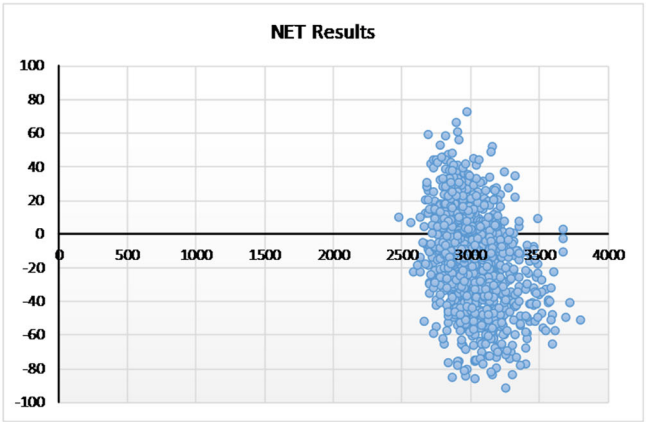


FIGURE 1 Per patient and per lesion costs for 15 years duration of antiplatelet medications. Cost-effectiveness analysis showing per patient and per lesion costs for DCB versus DES for 15 years duration of antiplatelet medications. DCB, drug coated balloon; DES, drug eluting stent. [Color figure can be viewed at wileyonlinelibrary.com]

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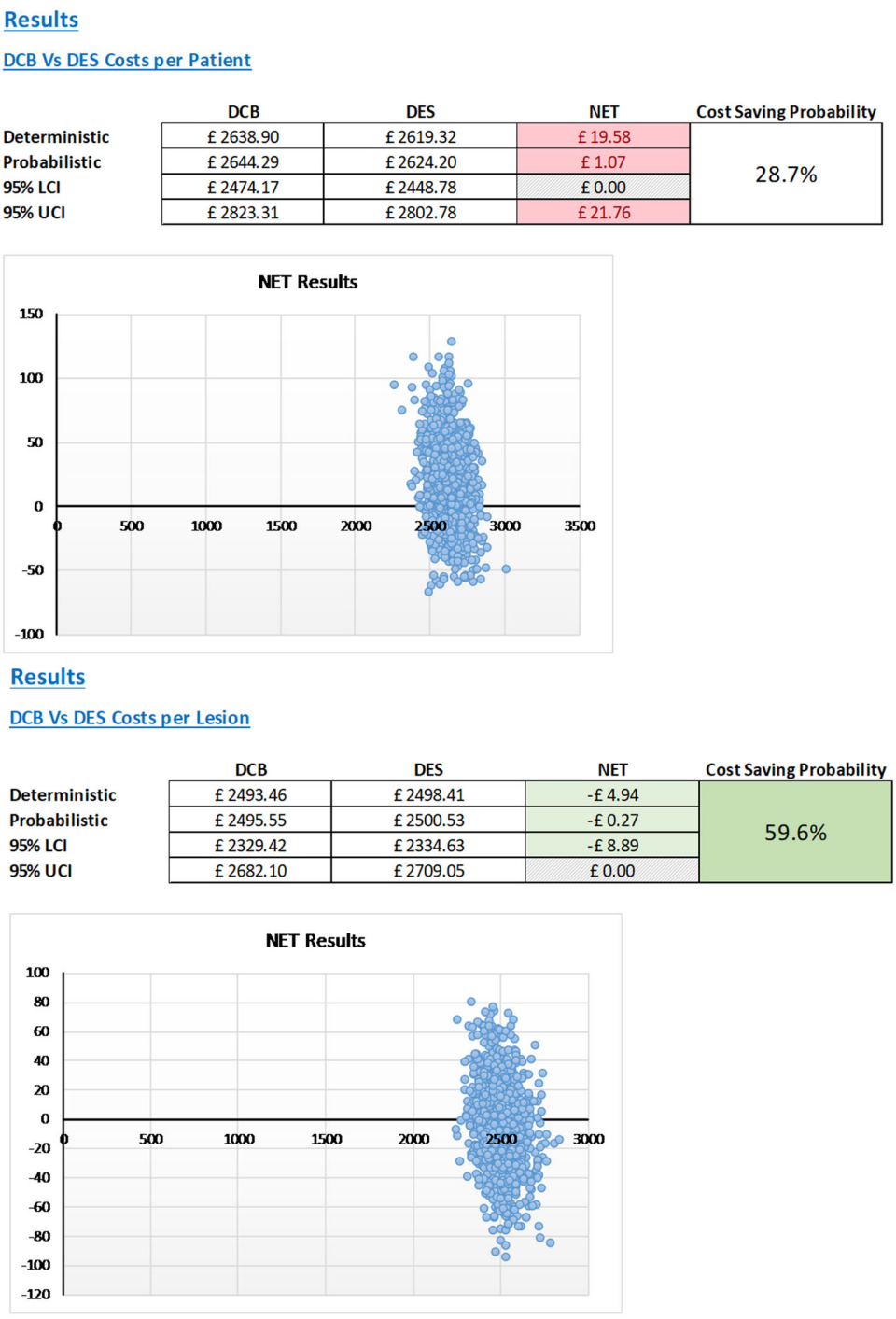

FIGURE 2 Per patient and per lesion costs if 1 year duration of antiplatelet medications. Cost-effectiveness analysis showing per patient and per lesion costs for DCB versus DES for 1 year duration of antiplatelet medications. DCB, drug coated balloon; DES, drug eluting stent. [Color figure can be viewed at wileyonlinelibrary.com]

5.1 | Impact on daily practice

1. There are very limited data about the cost effectiveness of DCB-only angioplasty versus DES for do novo coronary artery disease.
2. In this analysis of 1952 all-comer, consecutive patients treated for de novo coronary artery disease, DCB was more expensive by £9.02 per patient but cheaper by £15.51 per lesion.
3. This study demonstrates for the first time that cost of DCB-only angioplasty is not different to DES-angioplasty. Therefore, cost should not be implicated in the decision between DCB and DES.

ACKNOWLEDGMENTS

This is an investigator-initiated study partially supported by the National Institute for Health Research Capability Fund from Norfolk

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and Norwich University Hospital and B Braun Ltd. Dr Natasha Corballis was an NIHR Academic Clinical Fellow and is currently funded by the NIHR DRF program.

CONFLICTS OF INTEREST STATEMENT

Vassilios Vassiliou received honoraria for speaking at conferences by Daichii-Sankyo and Novartis and a research grant from B Braun for investigator-initiated research. Simon Eccleshall received research grants for investigator-initiated research and lecture honoraria from B Braun. He also acts as a consultant for B Braun, Medtronic, and MedAlliance. The remaining authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Merinopoulos I, Gunawardena T, Corballis N, et al. Cost effectiveness analysis of drug coated balloon only angioplasty for de novo coronary artery disease. *Catheter Cardiovasc Interv*. 2023;102:987-996. doi:10.1002/ccd.30878

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