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Research paper

An observational study assessing the use of Sirolimus-eluting balloons for side-branch treatment in the provisional stenting of coronary bifurcations

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ABSTRACT

Background: Drug eluting balloons (DEB) are a feasible method of rapid delivery of drug to a coronary vessel wall. Their efficacy has been established for the treatment of in-stent restenosis and small vessel disease but there is limited data for their use in bifurcation lesions.
Objective: The aim of this study was to assess the effectiveness of provisional upfront side-branch DEB use in bifurcation lesions compared to a simple balloon (POBA) or upfront 2 stent bifurcation strategy.
Methods: We conducted an observational study of 625 patients undergoing PCI to bifurcation lesions. All the patients had a DES deployed in the main vessel (MV). Decision on revascularization option for the side branch (SB) was made by the operator. The primary endpoint was target vessel failure. Secondary endpoints were target vessel myocardial infarction and all-cause mortality.
Results: 311 patients had upfront DEB to the SB whilst the remaining were treated with either DES (188) or POBA (126). Baseline characteristics were similar aside from history of previous MI, which were higher in patients treated with DES or POBA, p = 0.009 whereas patients with previous CABG were likely to undergo DEB treatment (p = 0.004). TVF was more likely to occur in the POBA group (7.5 %) compared to the DEB (3.3 %) and DES (3.3 %) groups (p = 0.0019). There was no significant difference in TV-MI (p = 0.62) or death (p = 0.98) between the groups.
Conclusion: This study suggests that provisional bifurcation stenting with upfront Sirolimus DEB use in the SB is an effective treatment for non-LMS bifurcation PCI.

1. Introduction

Coronary artery bifurcation lesions account for 15–20 % [1] of coronary stenoses and are amongst the most technically challenging lesions when it comes to treatment with percutaneous coronary intervention (PCI). Given the complexity of stenting, the incidence of restenosis and stent thrombosis is higher in bifurcation lesions compared to others [1,2]. It remains generally accepted based on randomized trials and meta-analyses that keeping it simple remains the preferred strategy for treating bifurcations, mostly due to a high incidence of myocardial infarction (MI) and in-stent thrombosis following complex strategies. However, the disadvantage of a simple or provisional strategy can result in residual ostial disease or potentially occlusion of the side branch (SB) due to plaque shift after stent implantation in the main vessel. Drug-eluting balloons (DEBs) now offer a potential therapeutic strategy for SB treatment during PCI of bifurcation lesions.

Drug eluting balloons (DEB) could be an effective method of delivering antiproliferative drug to the coronary vessel wall without leaving a permanent implant behind and therefore minimize the potential for SB occlusion whilst keeping the procedure simple. Several published studies have reported the use DEB in the main vessel (MV) and/or SB in combination with a bare metal stent (BMS) in the MV with only a few single-center studies investigating the combination of a drug-eluting stent (DES) in the MV followed by a DEB in the SB published to date.

Abbreviations: DES, drug eluting stent; DEB, drug eluting balloon; MV, main vessel; SB, side branch; LMS, left main stem; PCI, percutaneous coronary intervention; TVF, target vessel failure; TV-MI, target vessel myocardial infarction.

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There is very limited data looking at the use of upfront SB treatment with DEB followed by MV drug-eluting stent insertion especially with the use of Sirolimus DEB.

In this study, we assess the effectiveness of provisional up-front DEB use for bifurcation lesions compared to balloon angioplasty (POBA) or two stent bifurcation approach.

2. Methods

2.1. Study design and patient population

This was an observational study evaluating the effectiveness of provisional DEB use in bifurcation lesions for patients undergoing PCI at Barts Heart Centre, London, United Kingdom. Between September 2016 to August 2020, 625 patients underwent PCI to bifurcation lesions. Patients presenting with ST segment elevation myocardial infarction (STEMI), cardiogenic shock and those undergoing treatment of left main stem (LMS) bifurcation disease were excluded from the analysis.

2.2. Ethics

Data was collected as part of a national cardiac audit and all patient identifiable fields were removed prior to analysis. It was advised by the local ethics committee that formal approval was not required.

2.3. Interventional procedures

The interventional strategy was at the discretion of the operator, including access site, use of hydrophilic or non-hydrophilic sheaths, catheter types, pre/post dilatation, and management of side branch. All patients had a DES deployed in the MV. Decision on revascularization option for the SB was made by the operator at the time of treatment. This included the use of either provisional DES, DEB or POBA. In the majority of cases, pre-dilatation of the SB was initially undertaken followed by the delivery of Sirolimus DEB (MagicTouch). A DES was then deployed to the MV. Final kissing balloon dilatation was done with non-compliant balloons and only if there was >75 % stenosis in the SB. In most of the cases, the degree of stenosis was assessed angiographically. All patients undergoing angioplasty received a loading dose of Aspirin 300 mg and either Ticagrelor 180 mg or Clopidogrel 600 mg prior to the procedure. This was followed by regular dual antiplatelet therapy for a minimum of 12 months. During PCI, unfractionated Heparin was given at a loading dose of 70–100 U/kg and ACT maintained >250 s. Glycoprotein IIb/IIIa inhibitors were used as per local guidelines.

2.4. Data collection

Patient data has been entered into our database at the time of the procedure, as per the standards of the British Cardiovascular Intervention Society (BCIS). This data was then retrospectively analyzed. We included patient demographics such as age, gender, and renal disease. Cardiovascular risk factors included diabetes mellitus (DM), hypercholesterolemia, hypertension, smoking, family history of coronary artery disease, previous myocardial infarction (MI) and coronary artery bypass grafting (CABG). They were then further characterized based on clinical presentation into acute coronary syndrome or stable coronary artery disease.

2.5. Endpoints and definitions

Bifurcation lesions were defined as per Medina classification [3]. Target vessel was defined as the MV or SB. The primary endpoint was target vessel failure (TVF). TVF included target vessel MI and target vessel revascularization (TVR) either by PCI or CABG. Secondary end points were TV-MI and all-cause mortality.

Table 1
Baseline characteristics and cardiovascular risk factors.

Characteristics	DEB (311)	POBA (126)	Stent (188)	p value
Age	61.33 ± 9.4	65.24 ± 11.8	62.36 ± 11.3	0.001
Gender: male	252 (81.0 %)	78 (62.0 %)	146 (78.0 %)	0.001
Renal disease	48 (15.4 %)	18 (14.3 %)	18 (10.0 %)	0.072
Risk factors				
Diabetes	99 (32.0 %)	35 (28.0 %)	51 (27.1 %)	0.568
Hypertension	154 (50.0 %)	72 (57.0 %)	101 (54.0 %)	0.189
Hypercholesterolemia	211 (68.0 %)	73 (58.0 %)	111 (59.1 %)	0.188
Smoking	174 (56.0 %)	59 (47.0 %)	89 (47.4 %)	0.190
Family history of CAD	66 (21.2 %)	23 (18.2 %)	34 (18.1 %)	0.438
Previous MI	14 (4.5 %)	35 (27.8 %)	40 (21.3 %)	0.009
CABG	34 (10.9 %)	3 (2.3 %)	8 (4.3 %)	0.004
Clinical presentation				0.287
ACS	165 (53.0 %)	78 (61.9 %)	115 (61.2 %)	
Stable/staged case	80 (27.7 %)	42 (33.3 %)	65 (34.5 %)	

ACS - acute coronary syndrome, CABG - coronary artery bypass grafting, CAD - coronary artery disease, DEB - drug eluting balloon, MI - myocardial infarction, POBA - percutaneous old balloon angioplasty.

2.6. Statistical analysis

Categorical data are summarized using absolute values (percentage). Normally distributed, continuous data are presented as mean ± standard deviation or, where skewed, as median and IQR [25th to 75th centile]. Normally distributed continuous variables were compared using the Student's *t*-tests, and the Mann–Whitney *U* test was used to compare non-normally distributed continuous variables. Categorical data were compared using the Pearson $\chi 2$ test. Long-term survival was described by the Kaplan–Meier method, and comparisons in LV thrombus resolution and survival between groups were made using the log-rank statistic. A two-sided p-value <0.05 was considered statistically significant. Cox regression analysis was used to estimate hazard ratios. All statistical analyses were performed using SPSS version 27.0 (SPSS Inc.) or GraphPad Prism version 9.0.

3. Results

Over the study period, 625 patients underwent treatment for bifurcation lesions of which 311 patients had a Sirolimus DEB to the SB whilst the remaining received SB treatment with either a DES (188) or POBA (126). Use of DEB for SB treatment increased over the study period ($p = 0.001$).

3.1. Baseline data

Baseline characteristics and risk factors (Table 1) were similar between the groups apart from age, previous history of MI and CABG. Elderly patients were more likely to be treated with POBA only to the SB ($p = 0.001$). Previous MI cases were likely to undergo intervention with a DES (21.3 %) or POBA (27.8 %) compared to a DEB (4.5 %), $p = 0.009$ whereas majority of patients with prior CABG underwent DEB treatment (10.9 %) compared to DES (4.3 %) or POBA (2.3 %), $p = 0.004$.

3.2. Procedural data

Predominantly, the lesions were located in the left anterior descending artery (LAD) and its diagonal branches (61.8 %). The bifurcation lesions were classified as per visual assessment by the operator into Medina classification, majority being Medina class 1,1,1 (60 %). However, overall, there was no difference in distribution

Table 2
Classification of coronary bifurcation lesions based on Medina and Anatomy.

	DEB (311)	POBA (126)	Stent (188)	p value
Medina classification				0.001
1,1,1	199 (64.0 %)	66 (52.4 %)	110 (58.5 %)	
0,1,1	35 (11.2 %)	16 (12.7 %)	24 (12.8 %)	
1,1,0	22 (7.1 %)	14 (11.1 %)	22 (11.7 %)	
1,0,1	8 (2.6 %)	17 (13.5 %)	8 (4.2 %)	
0,0,1	25 (8.0 %)	0	2 (1.1 %)	
0,1,0	8 (2.6 %)	0	2 (1.1 %)	
1,0,0	14 (4.5 %)	13 (10.3 %)	20 (10.6 %)	
Main branch				0.003
LAD	172 (55.3 %)	76 (60.4 %)	138 (73.4 %)	
Cx	43 (13.8 %)	14 (11.1 %)	28 (14.9 %)	
RCA	54 (17.4 %)	19 (15.1 %)	12 (6.4 %)	
OM	40 (12.9 %)	9 (7.1 %)	8 (4.2 %)	
Other	2 (0.6 %)	8 (6.3 %)	2 (1.1 %)	
Side branch				<0.001
Diagonal	172 (55.3 %)	76 (60.4 %)	138 (73.4 %)	
OM	42 (13.5 %)	14 (11.1 %)	28 (14.9 %)	
PDA	20 (6.4 %)	6 (4.6 %)	4 (2.2 %)	
PLV	37 (11.9 %)	9 (7.2 %)	8 (4.2 %)	
Avcx	38 (12.3 %)	9 (7.2 %)	8 (4.2 %)	
Other	2 (0.6 %)	12 (9.5 %)	2 (1.1 %)	

AvCx - antrioventricular circumflex artery, Cx - circumflex artery, DEB - drug eluting balloon, LAD - left anterior descending artery, OM - obtuse marginal artery, PDA - posterior descending artery, PLV - posterior left ventricular artery, POBA - percutaneous old balloon angioplasty, RCA - right coronary artery.

Table 3
Angiographic size of the coronary vessels.

	DEB (311)	POBA (126)	Stent (188)	p Value
Diameter (mm)	2.43 ± 0.35	2.18 ± 0.32	2.62 ± 0.19	<0.001
Length (mm)	23.08 ± 6.3	15.10 ± 2.52	20.88 ± 6.5	<0.001

DEB - drug eluting balloon, POBA - percutaneous old balloon angioplasty.

amongst the groups (Table 2). Baseline angiographic analysis (Table 3) confirmed that the length and diameter of the SB were different between the groups, $p < 0.001$. The lesions were smaller in diameter (2.18 ± 0.32 mm) and length (15.10 ± 2.52 mm) in the POBA group compared to those in the DEB (diameter-2.43 ± 0.35 mm, length-23.08 ± 6.3 mm) and DES (diameter-2.62 ± 0.19 mm, length- 20.88 ± 6.5 mm) groups.

In the DEB group 100 % of patients had a DEB treatment to the SB prior to MV stent deployment with 11.1 % undergoing further kissing balloon inflation at the end of the case. In the POBA group 100 % of patients had POBA to SB prior to MV stent deployment with 43 % undergoing kissing balloon inflation at end of the case. Xience DES (58.2 %) was the most commonly used DES, followed by Synergy (34.3 %) and Promus (7.5 %). No difference in stent type used was seen between the groups ($p = 0.465$). Final Balloon diameters were similar in the main vessel in all 3 groups (POBA 3.0 ± 0.45, DEB 3.2 ± 0.55, DES 3.15 ± 0.35, $p = 0.760$) although smaller balloons were used in the POBA only for final side-branch dilatation (2.25 ± 0.45) compared to DEB and DES groups (2.53 ± 0.35 and 2.60 ± 0.41). 94.7 % of the 2 stent bifurcation lesions were completed with final kissing balloons. In all the cases, kissing balloon inflation was undertaken either by semi or non-compliant balloons. Imaging with Intravascular ultrasound (IVUS) and Optical coherence tomography (OCT) was used in 38 % of the total number of cases. The lowest rates were seen in the POBA only group (16.5 %) when compared to the other groups, $p < 0.001$. However, there was no significant difference in the use of imaging between the DES (53.7 %) and the DEB (43 %) groups, $p = 0.131$.

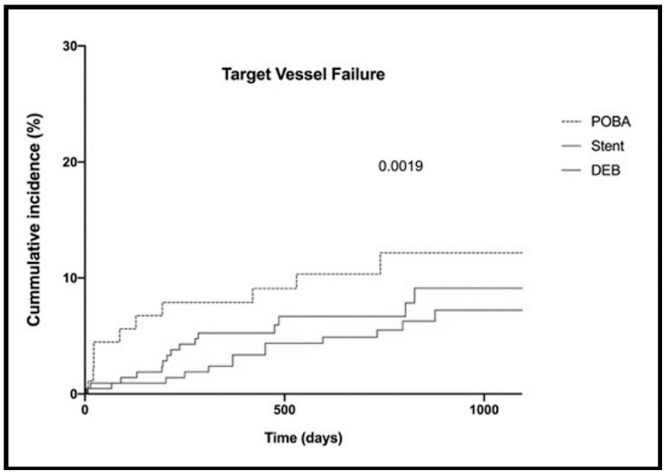

Fig. 2. Kaplan-Meier curve demonstrating the cumulative incidence of target vessel failure over the treatment period.

3.3. Outcomes

Over a median follow-up period of 810 days (IQR 410–1010 days), target vessel failure (TVF) was more likely to occur in the POBA group

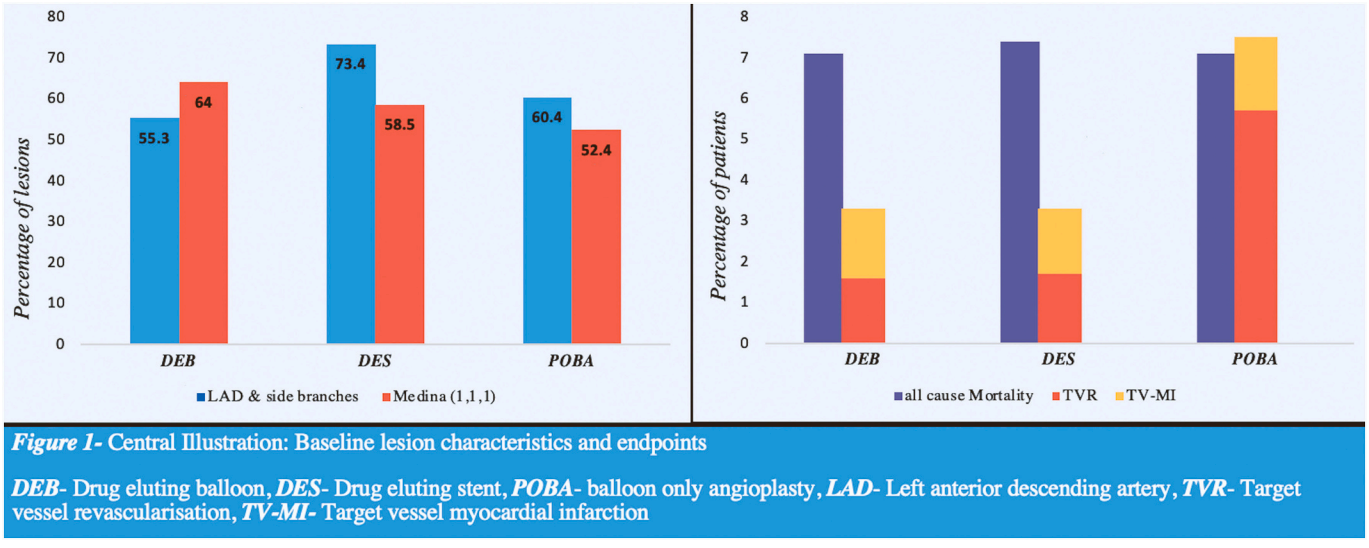

Fig. 1. Central illustration: Baseline lesion characteristics and endpoints.

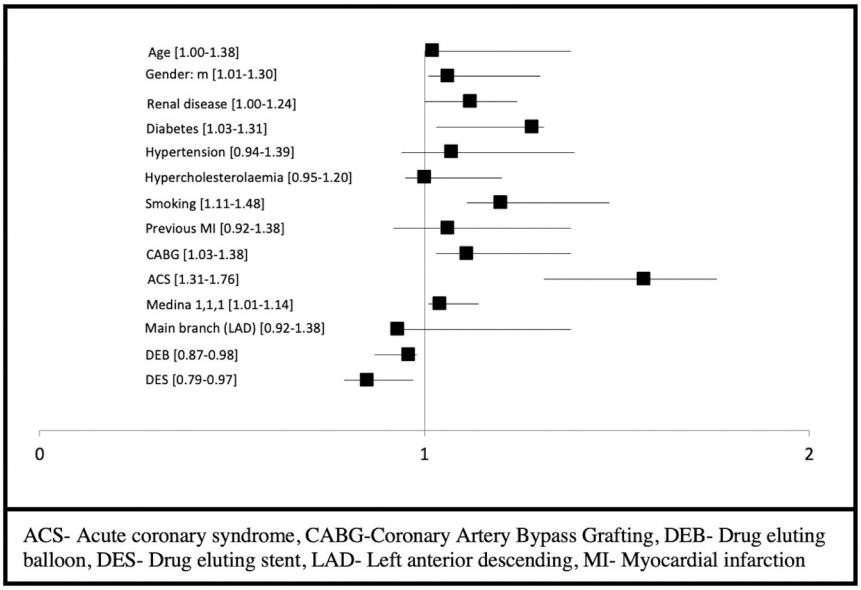

Fig. 3. Risk of major cardiovascular events (MACE).

(7.5 %) compared to the DEB and the DES groups, p = 0.0019 (Fig. 2). Interestingly, TVF occurred at a similar rate in the DES and DEB groups at 3.3 %. There was no significant difference in the secondary endpoints between the groups, which was death (p = 0.98) and target vessel MI (p = 0.62) (Fig. 1).

3.4. Regression

Multivariate Cox regression analysis was performed correcting for baseline and angiographic variables (Fig. 3). Compared to POBA only, both DEB (0.96 (0.87–0.98)) and 2 stent treatments (0.85 (0.79–0.97)) were associated with lower rates of TVF during follow-up. A greater reduction was seen with DES, but this was not significantly different from DEB treatment.

4. Discussion

To date, this is the first and largest observational study assessing the use of upfront Sirolimus DEB (MagicTouch) treatment in the SB of a bifurcation lesion compared to either plain old balloon angioplasty (POBA) treatment or a two-stent approach. Even though LMS bifurcation lesions were excluded in this study, the majority of the lesions treated were LAD and its associated diagonal branches (Fig. 1), therefore involving large territories and moderate to large sized SBs. Most importantly, there was no difference in target vessel failure amongst the DEB and DES groups. The risks and complications of a two-stent approach are well known such as stent thrombosis however, this is unlikely to occur with a DEB given the absence of a metallic scaffold. Additionally, it has benefits of potential vascular remodeling after angioplasty, less likely to cause carina shift and shorten the duration of dual antiplatelet treatment [4]. This study highlights the safety and effectiveness of the use of upfront Sirolimus DEB treatment for moderate/large sized SBs in the treatment of bifurcation lesions with the bonus of avoiding the complexities of a two-stent procedure.

Currently, the European Society of Cardiology and the European Bifurcation Club recommends MV stenting with provisional SB stenting as the default approach for coronary bifurcation lesions [5,6]. Moreover, in cases with SB ostial disease, pre-dilatation of the SB before MV stenting is essential. The single stent strategy is supported by the results of meta-analysis of randomized trials which demonstrated that a one-stent approach resulted in reduction of all-cause mortality [7].

Alternatively, implantation of two stents is an attractive course of action as studies have shown that the application of double stents, such as Culotte, DK crush and T-stenting can achieve good results. But this does not hold true for all bifurcation lesions. Apart from LMS bifurcations, the SB are often smaller in diameter and stenting at the ostium can result in carina shift, greater incidence of recoil and lower acute luminal gain. Moreover, inadequate coverage of the ostium of the SB or excessive protrusion of stent struts into the MB can occur. Thus, resulting in an increased risk of stent thrombosis and ISR when two or more stents are deployed at bifurcation sites [1,8]. Therefore, management of SB can be a challenge to the operator.

Drug eluting balloons are an effective way to deliver drug to the coronary vessel wall with the added advantage of not leaving a metallic mesh behind. It has already shown to be an effective alternative to DES for ISR [9] and diffuse small vessel coronary disease [10]. However, its use in bifurcation lesions is not well established. A few single arm trials suggested the safety of DEB for SB coronary bifurcation lesions [11–13]. But these early trials used 1st generation Paclitaxel DEB for both the MV and side branches followed by Bare metal stenting in the MV. Comparatively, the BIOLUX-I study [14] was a multicenter study and enrolled 35 patients with bifurcation lesions. They showed that the combination use of Everolimus-eluting stent in the MV and Paclitaxel-eluting balloon for the SB is a safe and effective treatment for bifurcation lesions. Similarly, DEBSIDE study consisted of 50 patients and used a DES for MV and a new Paclitaxel eluting (DANUBIO) balloon for the SB [15]. They showed that the use of the DANUBIO balloon was safe and effective. The rate of major adverse cardiac events and target lesion revascularization was 10 % and 2 % respectively at 6 months. Recently, the BEYOND study [16] showed that DEB use for SB in bifurcation lesions resulted in better angiographic results as well as reduction in target vessel re-stenosis compared to balloon only angioplasty. Even though the above studies had a small cohort of patients, cumulatively they do suggest the potential for DEB use in bifurcation lesions, especially with the presence of newer generation drug eluting balloons i.e., containing Sirolimus. These studies along with our results, suggest that the use of DEB for treatment of SB in bifurcation lesions is promising. Hence, we propose the use of DEB for SB in bifurcation lesions and a two-stent strategy should only be used in cases of a compromised result or in cases of TVF with upfront DEB use.

4.1. Limitations

The study has its limitations, firstly, there is likely to be selection bias given the retrospective and observational nature of the study. Although we showed similarities in target vessel revascularization, cases were retrospectively enrolled in which DEB or DES were possible. Secondly, there is operator bias driven by oculostenotic reflex in detection and repeat intervention of the target vessel. Moreover, there were differences in the timings of repeat angiography which were mainly based on patient's symptoms and clinical presentation. Lastly, we did not account for left main bifurcation lesions and hence are unsure of the use of DEB in these cases especially in a non-dominant left system.

5. Conclusion

This study suggests that Sirolimus drug eluting balloon is as effective as drug eluting stents in the management of non-LMS side branch bifurcation lesions. Further study is needed to confirm this promising data.

CRediT authorship contribution statement

Johanna Jones: Data curation, Methodology, Formal analysis, Writing – original draft. **Kyriacos Mouyis:** Data curation, Writing – review & editing. **Angelos Tyrlis:** Data curation, Writing – review & editing. **Krishnaraj S. Rathod:** Supervision, Formal analysis, Writing – review & editing. **Oliver Guttmann:** Writing – review & editing. **Andrew Wragg:** Writing – review & editing. **Constantinos O'Mahony:** Writing – review & editing. **Anthony Mathur:** Writing – review & editing. **Andreas Baumbach:** Writing – review & editing. **Daniel A. Jones:** Supervision, Formal analysis, Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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