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One-Year Cardiovascular Outcomes in Patients Treated with OCT-Guided Coronary Angioplasty with Stenting - A Single Centre Study

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Abstract

Purpose: Optical coherence tomography (OCT) provides superior-resolution images than coronary angiography and accurately evaluates the vessel size and plaque morphology guiding the treatment strategy before and after stent implantations. Very limited data is available in the public domain in India on OCT-guided PCI. The aim of this study is to assess the safety and effectiveness of OCT-guided PCI in a real-world setting in India.

Methods: Records of patients ≥ 18 years who underwent OCT-guided PCI between April 2016 and December 2018 at KLE's Hospital, Department of Cardiology and had one-year follow-up data were retrospectively analysed. All patients underwent pre- and post-PCI angiography and post-PCI OCT. The primary endpoint was post-PCI minimum stent area (MSA) and target lesion failure (TLF) at one year.

Results: A total of 204 patients with 299 coronary lesions were analysed. Pre-dilatation and post-dilatation were performed in 82% and 58% of cases, respectively. The mean MSA and stent expansion with OCT guidance was 4.57 ± 1.82 mm2 and 81.80 ± 14.01%, respectively. No edge dissection, thrombus, abrupt closure, or perforation were observed on post-PCI angiography. OCT was useful in detecting stent malapposition (3%), stent dissection (1%), and tissue/thrombus prolapse (10%). Post-stenting optimisation was done in 8% of cases. Post-PCI OCT was associated with better clinical outcomes with a very low incidence of target lesion failure (TLF) at one year (1.5%).

Conclusions: Optical coherence tomography-guided PCI was safe and resulted in optimal MSA. It was also beneficial in detecting suboptimal stent deployment and optimising PCI with better clinical outcomes at one year after the index PCI.

Keywords: Optical coherence tomography; Percutaneous coronary intervention; Coronary angiography

Abbreviations: AWMI: Anterior Wall Myocardial Infarction; BP: Blood Pressure; BPM: Beats Per Minute; CABG: Coronary Artery Bypass Grafting; LVEF: Left Ventricular Ejection Fraction; NSTEMI: Non-ST-Elevation Myocardial Infarction; IWMI: Inferior Wall Myocardial Infarction; PAMI: Primary Angioplasty During Myocardial Infarction; PCI: Percutaneous Coronary Intervention; STEMI: ST-Elevation Myocardial Infarction; ACC/AHA: American College of Cardiology/American Heart Association; LAD: Left Anterior Descending Artery; NC: Non-Complaint; TIMI: Thrombolysis In Myocardial Infarction; PCT: Percutaneous Coronary Intervention; OCT: Optical Coherence Tomography.

Introduction

Coronary angiography (CA) is routinely used to assess the extent and severity of coronary artery disease (CAD) and guide percutaneous coronary interventions (PCIs). However, CA provides only two-dimensional images of the lumen, and hence, it is unable to accurately evaluate the vessel dimensions and plaque characteristics [1]. Furthermore, CA may sometimes be inadequate for deciding a treatment strategy and defining optimal stenting outcomes. Intravascular imaging with optical coherence tomography (OCT) has emerged as an effective alternative to CA guidance for optimizing PCIs [2-4].

Optical coherence tomography is a feasible and safe imaging modality for the guidance of PCIs of coronary lesions, including complex lesions in calcific and tortuous vessels [4]. It has greater spatial resolution [5-8] and thus allows evaluation of more details regarding the microstructure of the vessel wall than intravascular ultrasound (IVUS)-guided imaging [4,6]. Specifically, OCT has been shown to identify thin cap fibroatheroma, a feature that may not be possibly detected with precision by IVUS [9-12]. Further, intimal hyperplasia, internal and external elastic laminae, echo lucent regions corresponding to large lipid pools, tissue protrusion, edge dissection, and incomplete stent apposition may be more frequently identified by OCT- versus IVUS-guided imaging [9,13,14].

Several clinical studies have revealed the potential benefits of OCT guidance, both pre- and post-PCI. In the ILUMIEN I observational study, OCT was successfully applied: (1) pre-PCI to guide physician decision-making regarding procedural strategy, resulting in modification of the planned

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strategy in more than half of cases, and (2) post-PCI for optimisation of the PCI procedural technique (stent under-expansion and malappposition that were not detected by CA were detected by OCT, resulting in additional post-dilatations and stent implantations). The rate of major adverse cardiac events (MACEs), including stent thrombosis, was also low with OCT-guided PCIs [15]. In the Centro per la Lotta contro l'Infarto–Optimisation of Percutaneous Coronary Intervention (CLI-OPCI II) study, OCT assessment helped in the detection of suboptimal stent deployment in about 31% of lesions; multivariable analysis revealed that OCT-detected suboptimal stent deployment was an independent risk factor for MACEs [16]. In another study, post-stent OCT helped in the detection of stent edge dissection, incomplete stent apposition, irregular protrusion, and minimal stent area; the last two parameters were found to be independent predictors of one-year device-oriented clinical endpoints [17]. Furthermore, OCT imaging has been found to successfully identify underlying morphological abnormalities, including strut malapposition, neoatherosclerotic lesions, major stent under expansion, coronary evagination, isolated uncovered struts, edge-related disease progression, and neointimal hyperplasia in-stent thrombosis cases [18].

Owing to the potential benefits of OCT-guided PCI, this technique was compared with the conventional CA-guided PCI in the Does Optical Coherence Tomography Optimize Results of Stenting (DOCTORS) study. This was a randomised multicentre study conducted among 240 patients with non-ST segment elevation myocardial infarction. The study findings revealed that OCT-guided PCI resulted in better optimisation of stent expansion compared to CA-guided PCI, without any increase in periprocedural myocardial infarction [19]. In another study, the use of OCT helped in the detection of a high rate of stent edge dissections post-PCI; most of the OCT-detected edge dissections (84%) were not detected by CA. Furthermore, detailed OCT assessment of the detected dissections facilitated the additional management of these dissections [20]. In the ILUMIEN III-OPTIMIZE PCI study, OCT guidance was associated with a higher final median minimum stent area (MSA) when compared to angiography guidance, although the difference was not statistically significant [21]. Better optimization of PCI with OCT may help translate into better clinical outcomes after the index PCI intervention. Several meta-analyses in large patient populations have revealed that OCT-guided PCI may be associated with a significantly lower rate of MACEs and cardiovascular death when compared with CA-guided PCI [2,3].

Optical coherence tomography has been made available in India over the past few years, but its use is largely limited to research purposes. There is a dearth of published literature on the feasibility, safety, and effectiveness of the use of OCT-guided PCI in routine clinical practice settings in India.

The present study aims to assess the safety and effectiveness of OCT-guided PCI in real-world settings at a tertiary care centre in India. This study is based on the hypothesis that OCT may result in a high luminal gain and stent expansion and less degree of untreated dissections post-PCI and better clinical outcomes at one year after the index PCI intervention.

Research Methodology

Study design and population

This is a retrospective observational study. Clinical and procedural records were collected for all consecutive CAD cases who underwent PCI under OCT guidance in our hospital setting between April 2016 and December 2018. All patients aged >18 years who underwent PCI under OCT guidance and had one-year clinical follow-up data were considered for inclusion into the study.

Procedures

The medical records of all eligible study patients were reviewed, and baseline characteristics such as age, sex, medical history, concomitant medications, details of clinical presentation, vital signs, details of electrocardiogram and echocardiogram, and laboratory assessments were collected. Pre-procedural CA was performed in all cases according to validated standards. Pre-procedural parameters that were recorded included: (1) number of target vessels and lesions; (2) target vessel details; (3) ostial involvement; (4) presence of thrombus, chronic total occlusion, or bifurcation lesions; (5) degree of calcification (none, mild, moderate, and severe); (6) complexity of lesions according to the American College of Cardiology (ACC)/American Heart Association (AHA) (A, B, C) [22]; (7) thrombolysis in myocardial infarction (TIMI) flow; and (8) diameter stenosis. The PCI procedure was performed with standard techniques and catheters using a femoral approach in 200 cases and Radial approach in 4 cases. The dose of unfractionated heparin used during the procedure was 5000–8500 units. 8F guide catheters were used in all procedures except for one that used a 7F catheter. Stenting strategy, lesion preparation (debulking, pre-dilatation), and the number of stents used were left to each operator's discretion. The number of stents used, details of length and diameter of the stents, and stent overlap were recorded. Post-PCI, both CA and OCT were performed. St Jude's OPTISTM Mobile system was used in all cases for post stenting assessment by OCT. All images were digitally stored and deidentified. Optical coherence tomography images spanning the entire length of the stent plus 5 mm proximal and 5 mm distal reference segments were analyzed.

Details of diameter stenosis, MSA, edge dissections, thrombus, perforation, TIMI flow, stent under expansion, stent malapposition, lesion coverage, tissue prolapse, and additional interventions were noted. Post-dilatation was at the discretion of the operator and was performed mostly using non-compliant balloons. Dual antiplatelet therapy and other medications per the ACC/AHA guidelines were administered. In all, 180 (88.2%) patients had clinic visit follow-up at 1 year and remaining patients 24 (11.8%) had telephonic follow up.

Endpoints and Definitions

The primary endpoints were post-PCI MSA as assessed by OCT and target lesion failure (TLF) at one-year post-PCI. Target lesion failure was defined as a composite of cardiac death, target vessel myocardial infarction (TV-MI), and clinically driven target lesion revascularization (TLR). Secondary endpoints included the individual endpoints of TLF (cardiac death, TV-MI, and TLR) at one year after the index PCI, percentage of edge dissections detected and treated during OCT guidance, and degree of stent expansion post-PCI under OCT guidance.

Stent malapposition was defined as a clear separation of stent struts from the vessel wall without any tissue behind the struts with the distance from the adjacent intima >0.2 mm and not associated with any side branch. Stent expansion was defined as minimal stent area divided by proximal and distal reference lumen areas, respectively. Tissue prolapse was defined as a protrusion of material with an irregular surface into the lumen between stent struts.

Statistical Analysis

No formal sample size calculations were performed for this study, as it is an observational, single-arm study. Categorical variables have been presented as numbers and percentages and continuous data as mean and standard deviation.

Results

Baseline characteristics

Between April 2016 and December 2018, a total of 204 patients with 299 CAD lesions underwent PCI with post-stenting OCT assessment. The mean age of the study population was 57.68+10.46 with 16% of females. The key

risk factors included diabetes (45.6%), arterial hypertension (50.5%), and smoking (39%). The most common indications for PCI were ST-elevation myocardial infarction (STEMI) (45%), followed by unstable angina (40%), non-ST-elevation myocardial infarction (NSTEMI) (10%) and stable angina (4%). Other baseline clinical characteristics are summarized in Table 1.

Table 1. Baseline patient characteristics.

Variables, n (%)	Patients (N=204)
Age (mean ± SD) (years)	57.68 ± (10.46)
Gender	
Male	172 (84.31)
Female	32 (15.69)
Comorbidities	
Hypertension	103 (50.49)
Diabetes mellitus	93 (45.59)
Dyslipidaemia	12 (5.88)
Peripheral arterial disease	2 (0.98)
Renal diseases/dysfunction	4 (1.96)
Previous medical history	
Previous PCI	6 (2.94)
Previous CABG	4 (1.96)
Social history	
Smoker	85 (40.10)
Clinical presentation	
Systolic BP (mean ± SD) (mmHg)	127.17 ± (19.77)
Diastolic BP (mean ± SD) (mmHg)	79.46 ± (10.64)
Pulse rate (mean ± SD) (bpm)	81.82 ± (14.09)
LVEF %*(mean ± SD)	52.03 ± (7.95)
PCI indication	
Unstable angina	81 (39.71)
STEMI	93 (45.59)
NSTEMI	21 (10.29)
Stable angina	9 (4.41)

Lesion characteristics and procedural details

Table 2 summarizes the baseline vessel/lesion characteristics and procedural details. Target lesion location was in the left anterior descending coronary artery in 70%, right coronary artery in 17%, and left circumflex in 7% of the cases. Percutaneous coronary intervention was performed on a single lesion in most cases (61%). While direct stenting was done in 16% of the lesions, pre-dilatation and post-dilatation with a non-complaint balloon were performed in 84% and 58% of the lesions, respectively. Multiple overlapping stents were implanted in 13% of cases.

Table 2. Baseline vessel/lesion characteristics and procedural details.

Variables, n (%)	Patients (N = 204)
Target vessel	
Left anterior descending artery	142 (69.60)
Right coronary artery	34 (16.67)
Left circumflex artery	15 (7.35)
Left main-LAD	4 (1.96)
First obtuse marginal branch	3 (1.47)
Second obtuse marginal branch	1 (0.49)
Third obtuse marginal branch	1 (0.49)
RAMUS	4 (1.96)
Lesion complexity	
ACC/AHA type A	149 (55.19)
ACC/AHA type B	86 (31.85)
ACC/AHA type C	35 (12.96)
Lesion characteristics	
Ostial lesion	40 (14.81)
Thrombus	7 (2.59)
Calcified lesion	
Mild	2 (0.74)
Moderate-to–Severe	4 (1.48)
Bifurcation lesions	6 (2.22)
TIMI flow	
0	3 (1.11)
1	7 (2.59)
2	11 (4.07)
3	183(89.7)
Procedural details	
Direct stenting	33 (16.18)
Pre-dilatation	171 (83.82)
Rotational atherectomy	5 (2.45)
Thrombus aspiration	4 (1.96)

Scoring balloon	3 (1.47)
Multiple stents	77 (37.75)
Stent overlap	26 (12.75)
Post-dilatation using NC Balloon	118 (57.84)

Primary outcomes

Post-PCI OCT revealed a final mean MSA of 4.57 ± 1.82 mm2 with proximal MSA 5.43 ± 1.93 mm2 and distal MSA 4.87 ± 1.90 mm2 (Table 3). Target lesion failure at one-year follow up was seen in 3 cases (1.47%).

Secondary outcomes

One patient suffered cardiac death and two patients underwent target lesion revascularization at 1-year follow-up. The mean percent stent expansion noted on post-PCI OCT was 81.80 ± 14.01% proximally and 87.20+13.21% distally. Edge dissection, thrombus, abrupt closure, and perforations were not observed with post-PCI angiography. However, post-PCI OCT identified stent under expansion in 6%, stent malapposition in 3% (Figure 1), stent edge dissection in 1%, and tissue/thrombus prolapse in 5% cases. Complete lesion coverage was achieved in all except one case (99.5%) (Figure 2).

Table 3. Post-PCI OCT primary assessments.

Primary assessments	
Minimum stent area (mm^2)	4.57 ± (1.82)
Proximal minimum stent area (mm^2)	5.43 ± (1.93)
Distal minimum stent area (mm^2)	4.87 ± (1.90)
Area stenosis (%)	16.91 ± (9.02)
Proximal reference lumen area (mm^2)	6.88 ± (2.80)
Distal reference lumen area (mm^2)	5.69 ± (2.37)
Note: All values are presented as mean ± SD	

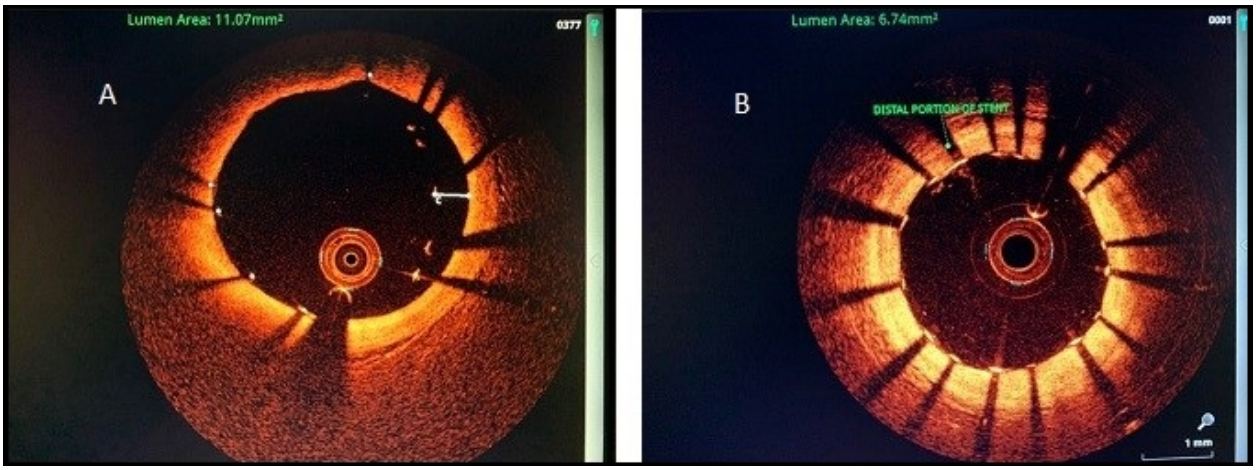

Figure 1. OCT showing malaopposed stent (A) and welapposed stent (B).

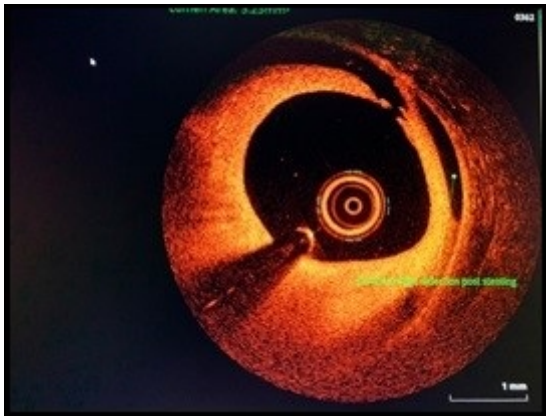

Figure 2. OCT showing minor edge dissection.

Additional stenting or ballooning was required in 8% cases. A representative case of OCT-guided stenting is shown in Figure 3. No patient developed contrast-induced nephropathy post-PCI guided by OCT. Similarly, no patient developed acute stent thrombosis.

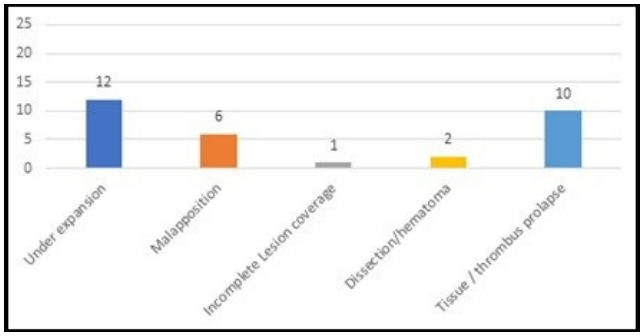

Figure 3. Post PCI optimisation by OCT.

Discussion

This retrospective, observational, single-centre study evaluated the procedural and clinical outcomes following OCT guidance for routine PCI. Our study confirms that OCT could be applied successfully post-PCI in routine clinical practice settings in India. Post-PCI OCT was beneficial in identifying stent under expansion, stent malapposition, stent dissection, and thrombus prolapse, all of which were not apparent on CA. Optical coherence tomography helped in the optimisation of the stent by additional stenting and ballooning in 8% of cases. Further, it was also associated with a very low

incidence of TLF at one year (1.5%). None of the patients developed renal failure or any other procedure-related complications post-PCI guided by OCT.

The 2018 European Society of Cardiology and the European Association for Cardio-Thoracic Surgery (ESC/EACTS) guidelines on myocardial revascularization recommend OCT for selected patients to optimize stent implantation with the same class of recommendation and level of evidence as IVUS. Furthermore, guidelines have recommended that IVUS and/or OCT should be considered to detect stent-related mechanical problems leading to restenosis (Recommendation Class II a, Level of evidence C) [23].

The expert consensus group of the European Association of Percutaneous Cardiovascular Interventions defined a mean MSA of >4.5 mm2 in the non-left main lesions and relative stent expansion of 80% for an optimal result of PCI-guided by OCT [1]. Similarly, the CLI-OPCI II study suggested an MSA of ≥ 4.5 mm2 for optimal results [16]. The post-hoc analysis from the ILUMIEN II study yielded a stent expansion of 72.8% [14], and some of the key randomized trials including Doctors, Ilumien III: Optimize PCI observed stent expansion in the range of 78.9%-87.6% [19,21]. Our study has achieved one of the primary objectives. Most of the lesions treated in our study were of non-left main (98%), and the mean MSA and stent expansion were 4.57 ± 1.82 mm2 and 81.80 ± 14.01%, respectively.

Data from the CLI-OPCI registry suggest that the use of OCT could improve clinical outcomes in patients undergoing PCI. In this registry, OCT-guided PCI in comparison with angiography-guided PCI was associated with a significant reduction in the incidence of cardiac death (1.2% vs. 4.5%; p=0.010), cardiac death or MI (6.6% vs. 13.0%; p=0.006), and TLF (9.6% vs. 14.8%; p=0.044) [24]. Further, a recent meta-analysis by Kuku et al. reported that OCT-guided PCI was associated with a significant reduction in the composite of cardiac death, MI, and repeat revascularization than angiography-guided PCI [3]. In the OPINION [25,26] and ILUMIEN III: OPTIMIZE PCI [21] trials, OCT-guided PCI was non-inferior to IVUS-guided PCI for target vessel failure (TVF) and procedural MACE, respectively. The Pan-London PCI cohort study observed that PCI guided by OCT improves both short- and long-term outcomes and is associated with a lower incidence of in-hospital MACE, resulting from the reduced incidence of MI and mortality in the long term.26 The rate of TLF post-PCI with OCT guidance at 12 months was very low (1.5%) in our study. Death occurred in one female patient who had evolved AWMI, and two patients experienced TLR. There were no cases of TVR, AMI, or stent thrombosis.

Cases of edge dissection, malapposition, and under-expansion were commonly observed post-PCI OCT in ILUMIEN I15 trial, which lead to further optimisation in 25% of patients. ILUMIEN III: OPTIMIZE PCI [21] observed that better resolution of OCT detected stent malapposition, leading to fewer untreated major stent malappositions versus IVUS guidance or angiography. Similarly, DOCTORS [19] and OCTACS [27] trial observed a higher incidence of post-stent optimisation procedures (such as post dilatation and additional stent implantations) in the OCT-guided PCI versus angiography-guided PCI. In line with these studies, post-PCI assessment by angiography in our study yielded suboptimal results, while post-PCI OCT due to its superior resolution was successful in identifying stent under expansion, malapposition, tissue/thrombus prolapse, and dissections. Additional stenting was performed in three cases: two cases of stent dissection and one case with incomplete coverage. Further, additional ballooning was performed in 14 cases who experienced stent under expansion and stent malapposition.

Upcoming studies investigating OCT-guided PCI are the Comparison between Optical Coherence tomography guidance and Angiography guidance in percutaneous coronary intervention (COCOA) trail. This is a large-scale, multicentre, single-country (Japan), prospective randomised controlled, open-label, parallel-group, superiority study comparing OCT-guided PCI with angiography-guided PCI with a hypothesis that OCT-guided PCI would achieve greater stent area than angiography guidance (NCT03176810) [28]. The Optical CoherenCe Tomography-GUided Coronary Intervention in Patients With Complex leslons (OCCUPI) trial is a prospective, multicentre, randomised trial to establish the superiority of OCT-guided PCI versus angiography-guided PCI on clinical outcomes in patients with complex lesions (NCT03625908) [29]. The Optical Coherence Tomography Versus Intravascular Ultrasound-Guided Percutaneous Coronary Intervention (OCTIVUS) trial is a prospective, open-label, multicentre, dual-arm randomised trial to demonstrate the non-inferiority of OCT-guided PCI to IVUS-guided PCI regarding target vessel failure at one-year (NCT03394079) [30]. Finally, the ILUMIEN IV trial (Observational Study of Optical Coherence Tomography [OCT] in Patients Undergoing Fractional Flow Reserve [FFR] and Percutaneous Coronary Intervention), a prospective, multinational, multicentre, superiority, single-blind clinical trial, is designed to demonstrate that OCT-guided PCI can achieve larger post-PCI lumen dimensions and improve the clinical cardiovascular outcomes than PCI guided by angiography (NCT03507777) [31].

Conclusion

In conclusion, OCT-guided PCI was found to be safe and effective in our routine clinical setting and was valuable in detecting major stent malapposition, tissue prolapse, and edge dissections that were not apparent on angiography. Further, OCT guidance was associated with better clinical outcomes at one year. Randomised studies comparing OCT-guided PCI versus angiography or IVUS-guided PCI are warranted to further establish its efficacy and safety in Indian settings.

Limitations

The major limitations of this study are its observational, non-comparative design; limited sample size; and lack of pre-stenting OCT.

Ethics Approval

Approved by Institutional EC.

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Conflicts of Interest

Authors have no conflict of interest to declare.

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