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Effect of enhanced external counterpulsation on the rehabilitation of patients with acute myocardial infarction after drug-coated balloon-based percutaneous coronary intervention

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Abstract

Objective To observe, compare and explore the effect of enhanced extracorporeal counterpulsation (EECP) treatment on cardiac rehabilitation in patients with acute myocardial infarction (AMI) after undergoing percutaneous coronary intervention (PCI) using a drug-coated balloon (DCB).

Methods This study was a prospective randomised controlled trial of 60 patients with AMI after undergoing PCI using a DCB. Using a random number table method, the patients were randomly divided into control and rehabilitation groups, with 30 patients in each. The follow-up period was 6 months. Patients in the control group received conventional drug and exercise rehabilitation after undergoing DCB-based PCI; those in the rehabilitation group were also given an EECP-based rehabilitation regimen after 7 days of medication and exercise rehabilitation. The effects of EECP on the rehabilitation of patients with AMI after undergoing DCB-based PCI were evaluated by observing changes in cardiac function before and after treatment in the two groups of patients, including cardiac output (CO), stroke volume (SV), brain natriuretic peptide (BNP), left ventricular ejection fraction (LVEF) and 6-minute walking distance (6MWD).

Results After 6 months of treatment, the control versus the rehabilitation groups' cardiac function results were as follows: CO (5.00 ± 0.67 vs. 4.64 ± 0.58, $P = 0.023$), SV (70.53 ± 3.33 vs. 65.57 ± 6.10, $P < 0.001$), BNP (157.63 ± 15.37 vs. 219.40 ± 16.73, $P < 0.001$), LVEF (65.57 ± 4.33 vs. 60.10 ± 2.92, $P < 0.001$) and 6MWD (455.43 ± 39.75 vs. 400.73 ± 36.81, $P < 0.001$). The patients in the rehabilitation group showed improved cardiac function compared with the control group, with statistically significant differences. Furthermore, the improvement in the New York Heart Association cardiac function grading ($P < 0.001$) and Canadian Cardiovascular Association angina grading ($P < 0.001$) in the rehabilitation group were significantly improved compared with the gradings of the control group.

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Conclusion Using EECP treatment significantly improved the cardiac function of patients with AMI after undergoing DCB-based PCI and was beneficial for their cardiac rehabilitation.

Keywords Enhanced external counterpulsation, Acute myocardial infarction, Drug-coated balloon, Cardiac rehabilitation

Introduction

Cardiovascular diseases are responsible for increased morbidity and mortality in China's population; this may be a result of an ageing population and the prevalence of metabolic risk factors [1]. Cardiovascular diseases are responsible for 40% of deaths, particularly premature death, in China [1, 2], with acute myocardial infarction (AMI), the most dangerous type of cardiovascular disease, being the leading cause of death and disability [3].

Early revascularisation considerably improves the survival rate of patients with AMI [4]. With the development of coronary interventions and the establishment of chest pain centres, revascularisation predominated by percutaneous coronary interventions (PCIs) and coronary artery bypass grafting (CABG) is currently the clinically preferred therapeutic option [5]. Generally, a PCI involves balloon dilation and coronary stent implantation. The use of a drug-coated balloon (DCB) is an emerging technology that has been proven to be effective and safe [6, 7]; consequently, it has become a popular PCI.

In clinical practice, most patients undergoing surgical treatment experience frequent refractory angina attacks. However, there is little research on rehabilitation methods for patients after undergoing a PCI or assessing the effectiveness of the treatment. Intra-aortic balloon counterpulsation (IABP) is a widely used method of mechanical circulatory assistance, which supports cardiac circulation by filling and emptying the balloon placed in the aorta [8]. This method can increase coronary perfusion pressure, reduce myocardial damage, ensure heart, brain and kidney perfusion, reduce cardiac afterload and improve cardiac contractility [9]. Therefore, IABP is commonly used in patients with critical cardiovascular diseases; however, although it has clinical benefits, it is also accompanied by a high incidence of complications and is associated with poor prognosis [10].

In addition, studies have demonstrated that enhanced external counterpulsation (EECP) is an effective, non-invasive and cost-effective strategy for the treatment of ischemic diseases in patients with coronary heart disease or heart failure [11]. This method uses a non-invasive cardiovascular circulatory assist device. Airbags are wrapped around the patient's buttocks, thighs and calves, and an electronic control system is employed to detect the R-wave of the electrocardiogram and calculate the heart's systolic and diastolic phases. During the heart's diastolic phase, the airbags are sequentially inflated to apply external pressure to the body, driving blood from the lower limbs and buttocks back to the aorta, thereby increasing the cardiac output (CO) and reducing the peripheral resistance [12, 13]. This treatment can decrease blood viscosity, alleviate myocardial damage, increase coronary artery blood flow [14], improve microcirculation, reduce platelet aggregation and lower thromboxane levels to improve vascular function and enhance blood circulation.

Although the incidence of acute myocardial infarction is high and drug-coated balloon intervention has become an important treatment for this disease, little attention has been paid to patients with AMI after undergoing a DCB-based PCI. Therefore, this study aimed to evaluate the effects and safety of EECP in restoring the cardiac function of patients with AMI after undergoing a DCB-based PCI to identify new treatment options for the cardiac rehabilitation of these patients.

Materials and methods

Study participants

This study was conducted in compliance with ethical standards, and informed consent was obtained from all the enrolled patients. The study participants were 60 patients with AMI who received DCB-based PCI between November 2023 and January 2024. A random number table method was used to randomly divide the patients into control and rehabilitation groups, with 30 cases in each. There were 17 men and 13 women in the control group, and 19 men and 11 women in the rehabilitation group, with an average age of 56.72 ± 8.54 and 57.21 ± 7.76 years, respectively.

The inclusion criteria were as follows: (1) patients with AMI diagnosed based on the universal definition of myocardial infarction criteria [15]; (2) a single vessel infarcted, and Syntax score ≤ 22; (3) patients treated using DCB; (4) patients without EECP contraindications; (5) patients aged 18–75 years; (6) patients who had signed informed consent and were able to cooperate in completing the study.

The exclusion criteria [16, 17] were as follows: (1) patients with lower limb deep venous thrombosis and active thrombophlebitis; (2) patients with moderate to severe valvular heart disease, especially those with aortic insufficiency and/or stenosis; (3) patients with moderate to severe pulmonary arterial hypertension (mean pulmonary arterial pressure > 50 mmHg); (4) patients with aortic, cerebral or dissecting aneurysms; (5) patients with uncontrolled hypertension (> 180/110 mmHg); (6)

patients with decompensated heart failure (cardiac function of grade IV); (7) patients with arrhythmia that might interfere with the electrocardiographic gating function of the EECP device; (8) patients with haemorrhagic diseases or obvious bleeding tendencies; (9) patients with infected lesions in their limbs that may affect EECP; (10) pregnant women; and 11. patients with ventricular aneurysm and mural thrombus detected through echocardiography.

Methods

During the observation period after undergoing DCB-based PCI, patients in the control group received antiplatelet agents (100 mg of aspirin and 75 mg of clopidogrel, once a day), β-blocker (25–100 mg of metoprolol, twice a day, with the dose adjusted based on the patient's heart rate) and statins (10–20 mg of rosuvastatin, every night). In addition, the patients received exercise rehabilitation (e.g. aerobic, resistance and flexibility training) for 30–60 min, 3–5 times/week.

Patients in the rehabilitation group received the same medication and exercise rehabilitation as the control group during the trial period after undergoing DCB-based PCI DCBs; in addition, they were provided with EECP treatment after 7 days of medication. The treatment adopted a P-ECP/TI EECP device with a pressure setting of 0.020–0.035 MPa. Based on patients' actual tolerance, the treatment pressure and inflation and exhaust times were adjusted to a diastolic/systolic blood pressure ratio of > 1.2 and a diastolic/systolic pressure area of 1.5–2.0. The treatment was applied daily for 1 h, 6 days a week, for a total of 36 h.

Administering the EECP included the following steps: (1) firmly connecting the patient's electrocardiograph lead electrode; (2) pressing the electrocardiograph machine's key to adjust the electrocardiograph input and display the patient's electrocardiograph and the inflation-exhaust waveform on the screen (Fig. 1); (3) wrapping the airbags (Fig. 2) around the patient's calves, thighs and buttocks; (4) pressing the decompression key (P−), which allowed the machine to automatically select safe and appropriate filling and exhaust times; (5) pressing the open button of the counterpulsation pump, then pressing the P + key to slowly increase the pressure to the appropriate value. The patient's treatment response was observed during EECP, and their electrocardiogram and blood pressure were monitored to adjust the pressure and time of the treatment.

Outcome measures

The primary outcome measures were the CO, stroke volume (SV), brain natriuretic peptide (BNP), left ventricular ejection fraction (LVEF) and 6-minute walking distance (6MWD) [18].

The secondary outcome measures were the New York Heart Association (NYHA) cardiac function and the Canadian Cardiovascular Association (CCS) angina gradings. All indicators were evaluated at baseline (before treatment) and 1, 3 and 6 months after treatment.

Follow-up

All patients were followed up for 6 months by phone and during outpatient visits. The follow-up data included the occurrence of adverse cardiovascular events, including cardiac death, recurrent myocardial infarctions, revascularisation and hospitalisation for heart failure.

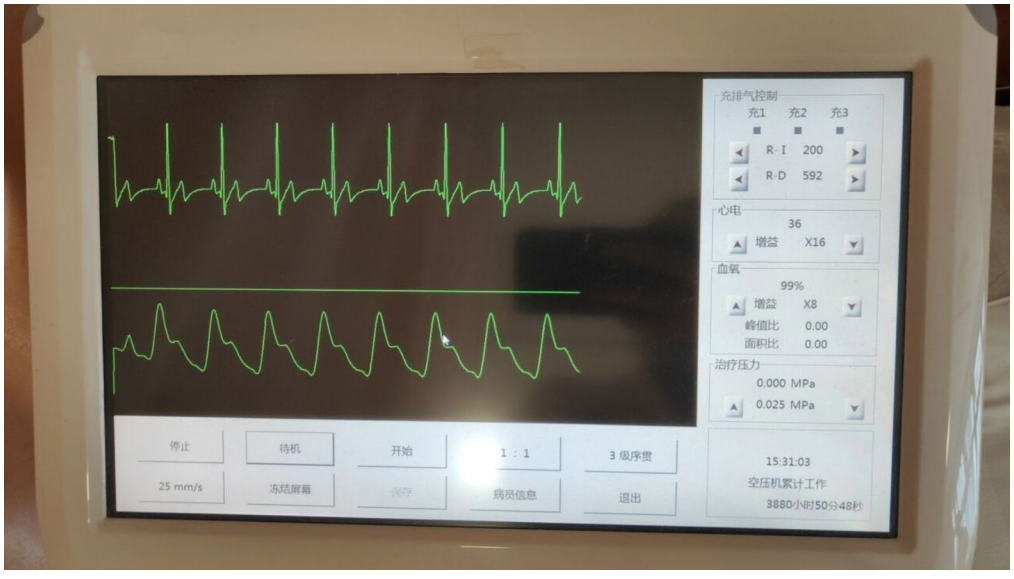

Fig. 1 The pictures of electrocardiograph and the inflation-exhaust waveform on the screen

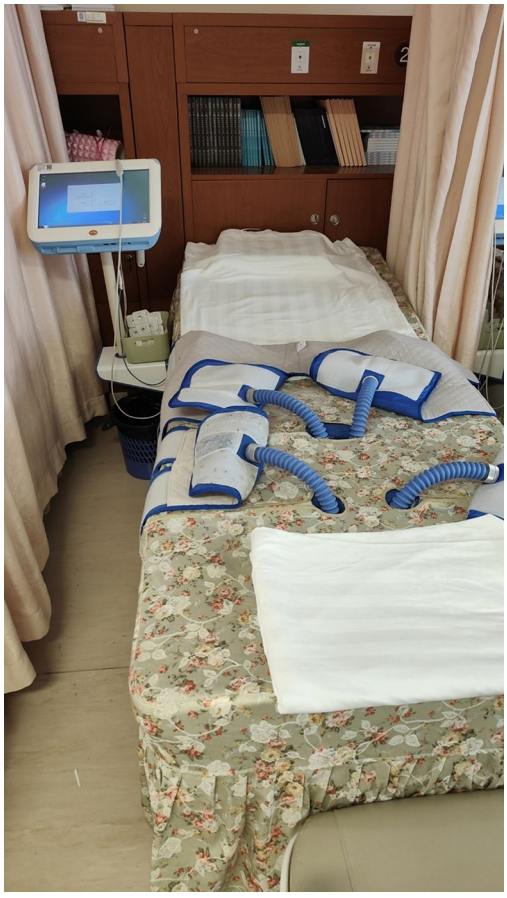

Fig. 2 The pictures of airbags

Table 1 Comparison of baseline characteristics between the two groups of patients

Characteristics	Control group ($n=30$)	Rehabilitation group ($n=30$)	*P* value
Age (years, ±SD)	56.72 ± 8.54	57.21 ± 7.76	0.821
Gender (male/female)	17/13	19/11	0.598
BMI (kg/m^2, ±SD)	24.3 ± 3.1	24.7 ± 2.9	0.607
Smoking history (n, %)	16(53.3%)	18(60.0%)	0.602
Drinking history (n, %)	14(46.7%)	13(43.3%)	0.795
Hypertension (n, %)	18(60.0%)	20(66.7%)	0.592
Diabetes (n, %)	9(30.0%)	11(36.7%)	0.584
Hyperlipidemia (n, %)	15(50.0%)	17(56.7%)	0.605
Infarcted vessel (n, %)			0.934
- Left anterior descending artery	16(53.3%)	15(50.0%)	
- Left circumflex branch	8(26.7%)	9(30.0%)	
- Right coronary artery	6(20.0%)	6(20.0%)	
NYHA grading (n, %)			0.857
- Grade II	18(60.0%)	17(56.7%)	
- Grade III	12(40.0%)	13(43.3%)	
CCS grading (n, %)			0.795
- Grade I	5(16.7%)	6(20.0%)	
- Grade II	16(53.3%)	14(46.7%)	
- Grade III	9(30.0%)	10(33.3%)	

Statistical analysis

Based on the pilot study results, the LVEF improvement in the rehabilitation group was expected to be 5% higher than that in the control group, with a standard deviation of 6%. Therefore, the required sample size for each group was calculated to be 28 patients, assuming $\alpha = 0.05$ (two-tailed) and $\beta = 0.1$. Ultimately, 30 patients were determined for each group to allow for the possible dropout rate.

Statistical analyses were conducted using SPSS software (v.25.0, IBM Corp., Armonk, NY, USA). Measurement data were expressed as the mean ± standard deviation (SD). Analysis of variance and the Kruskal–Wallis test were used for the inter- and intra-group comparisons at different time points, respectively. In addition, counting data were expressed in percentages and compared using either the χ^2 test or Fisher's exact test. A value of $P < 0.05$ indicated a statistically significant difference.

Results

Comparison of baseline data

As presented in Table 1, there was no statistically significant difference between the two group's baseline characteristics, including the patients' gender, age, body mass index, smoking and drinking history, comorbidities (hypertension, diabetes and hyperlipidaemia), infarcted vessels, preoperative NYHA cardiac function grading and CCS angina grading (all $P > 0.05$), indicating comparability between the groups.

Comparison of cardiac function

Table 2 shows that improvements in the indicators, including the CO, SV and LVEF, were statistically higher in the rehabilitation group than in the control group (all $P < 0.05$).

Comparison of brain natriuretic peptide levels

There was a statistically significant difference in the BNP levels between the rehabilitation and control groups. The BNP levels were significantly decreased in the rehabilitation group compared with the control group ($P < 0.05$, Table 3).

Comparison of 6-minute walking distance

The 6MWD in the rehabilitation group was longer than that in the control group, with a statistically significant difference ($P < 0.05$, Table 4).

Comparison of cardiac function and angina gradings

Table 5 shows that the improvement in the NYHA cardiac function and CCS angina gradings in the rehabilitation group after 6 months of EECP was significantly higher than that in the control group (both $P < 0.05$).

Table 2 Comparison of cardiac function indicators between the two groups of patients before and after treatment (± SD)

Indicators	Groups	Before treatment	One month after treatment	Three months after treatment	Six months after treatment	*P* value
CO (L/min)	Control group	4.19 ± 0.44	4.38 ± 0.51	4.52 ± 0.55	4.64 ± 0.58	< 0.001*
	Rehabilitation group	4.18 ± 0.40	4.57 ± 0.53	4.82 ± 0.61	5.00 ± 0.67	< 0.001*
P value		0.925	0.162	0.045	0.023	
SV (ml)	Control group	59.42 ± 5.44	62.13 ± 5.78	64.25 ± 5.92	65.57 ± 6.10	< 0.001*
	Rehabilitation group	59.27 ± 4.47	64.81 ± 5.12	68.37 ± 4.86	70.53 ± 3.33	< 0.001*
P value		0.906	0.061	0.004	< 0.001	
LVEF (%)	Control group	55.27 ± 2.63	57.42 ± 2.81	59.18 ± 2.87	60.10 ± 2.92	< 0.001*
	Rehabilitation group	55.03 ± 2.71	59.75 ± 3.42	63.21 ± 4.01	65.57 ± 4.33	< 0.001*
P value		0.731	0.005	< 0.001	< 0.001	

*Intra-group comparison at different time points

Table 3 Comparison of BNP levels between the two groups of patients before and after treatment (± SD, ng/L)

Groups	Before treatment	One month after treatment	Three months after treatment	Six months after treatment	*P* value
Control group	378.53 ± 21.38	312.67 ± 19.45	261.32 ± 17.86	219.40 ± 16.73	< 0.001*
Rehabilitation group	384.23 ± 20.63	285.41 ± 18.72	209.75 ± 16.94	157.63 ± 15.37	< 0.001*
P value	0.297	< 0.001	< 0.001	< 0.001	

*Intra-group comparison at different time points

Table 4 Comparison of 6MWD between the two groups of patients before and after treatment (± SD, m)

Groups	Before treatment	One month after treatment	Three months after treatment	Six months after treatment	*P* value
Control group	375.53 ± 40.68	385.27 ± 38.94	393.61 ± 37.82	400.73 ± 36.81	< 0.001*
Rehabilitation group	374.43 ± 41.10	402.67 ± 40.23	431.85 ± 40.57	455.43 ± 39.75	< 0.001*
P value	0.916	0.091	< 0.001	< 0.001	

*Intra-group comparison at different time points

Table 5 Comparison of NYHA cardiac function grading and CCS angina grading before and after treatment between the two groups of patients

Grading	Groups	Before treatment	Six months after treatment	*P* value
NYHA grading	Control group			0.038
	Grade II	18(60.0%)	22(73.3%)	
	Grade III	12(40.0%)	8(26.7%)	
	Rehabilitation group			< 0.001
	Grade I	0(0%)	8(26.7%)	
	Grade II	17(56.7%)	20(66.7%)	
	Grade III	13(43.3%)	2(6.7%)	
CCS grading	Control group			0.047
	Grade I	5(16.7%)	9(30.0%)	
	Grade II	16(53.3%)	17(56.7%)	
	Grade III	9(30.0%)	4(13.3%)	
	Rehabilitation group			< 0.001
	Grade 0	0(0%)	7(23.3%)	
	Grade I	6(20.0%)	18(60.0%)	
	Grade II	14(46.7%)	5(16.7%)	
	Grade III	10(33.3%)	0(0%)	

Occurrence of adverse events

Patients in both groups did not experience any serious adverse events during the follow-up period. Two patients (6.67%) in the rehabilitation group experienced minor skin abrasions, which were cured after local nursing and did not affect the subsequent EECP treatment.

Discussion

This study's results demonstrate that EECP significantly improves the cardiac function of patients with AMI after undergoing DCB-based PCI, including increasing the CO, SV and LVEF, reducing BNP levels, extending the 6MWD, and improving the NYHA cardiac function and CCS angina gradings. These findings are consistent with those of previous studies [19, 20], further confirming the effectiveness of EECP in the rehabilitation of patients with cardiovascular diseases. Although the EECP treatment significantly improved the cardiac function of patients with AMI, the BNP and 6MWD did not reach normal levels in some patients; this may be because most of the patients included in this study were older adults with other cardiac diseases. In addition, the short follow-up period of the study may have influenced the study's findings.

The mechanisms of EECP include the following: first, it improves the myocardial blood supply, as it promotes coronary collateral circulation development by increasing

diastolic aortic pressure and coronary perfusion pressure [21]; second, it mitigates cardiac load by decreasing peripheral vascular resistance [22]; third, it improves vascular endothelial function by increasing shear stress to promote the release of nitric oxide [23]; and finally, it inhibits inflammatory reactions, as it reduces the levels of inflammatory factors, such as C-reactive protein and tumour necrosis factor-α [24]. The principles of EECP and IABP are similar; the difference is that EECP can simultaneously squeeze the veins of the lower limbs, increase the venous return blood flow and increase the SV and CO through the Frank–Starling mechanism, whereas IABP has no such effect. In addition, compared with invasive IABP, the non-invasive characteristics of EECP make it more acceptable to patients and easier for clinicians to operate and promote [25].

Moreover, EECP poses several advantages compared with other cardiac rehabilitation methods, including that it is non-invasive and does not require surgical procedures, resulting in good patient compliance. The treatment has been demonstrated to have good safety; no serious adverse events were observed in patients in this study, except for minor skin abrasions in a few patients. In addition, EECP can be applied widely in patients who are not candidates for sports rehabilitation, such as older adults and patients with lower limb dysfunction. Additionally, EECP has been shown to improve patients' cardiac function and quality of life.

However, EECP also has several shortcomings. For example, it has a relatively long treatment period, with each course taking between 4 and 7 weeks, which may affect patients' daily life and work. Second, the equipment is initially costly, which may restrict its popularisation in grassroots hospitals. The treatment is also not applicable to some populations, such as patients with severe peripheral vascular diseases.

This study innovatively explored the rehabilitation effect of EECP on patients with AMI after DCB-based PCI for the first time, providing an additional therapeutic option for patients' cardiac rehabilitation. However, this study has several limitations. The first is the small sample size; the study's results remain to be validated by a multi-centre study with a larger sample size. Second, the enrolled patients were followed up over a short period; hence, this study failed to evaluate the long-term effect of EECP. Third, there was a lack of in-depth exploration of the effects of EECP, such as its impact on endothelial function and inflammatory factors.

The results of this study indicate that patients with AMI who receive DCB-based PCI can benefit from EECP for cardiac rehabilitation, improving their prognosis and quality of life. However, in clinical practice, special attention should be given to the following aspects: personalised patient evaluations that monitor indications and contraindications strictly; the timely adjustment of treatment parameters by monitoring patient reactions during treatment closely; and the development of a comprehensive rehabilitation plan by combining several other methods, such as sports and psychological rehabilitation.

Long-term follow-up studies to evaluate the long-term efficacy of EECP treatment should be conducted in the future. In addition, the effect of EECP combined with other rehabilitation methods, clarification of EECP's mechanisms and effects, including its impact on the coronary flow reserve, endothelial function and inflammatory factors, and identifying the predictive factors for optimal EECP treatment should be examined. The effects of EECP on the postoperative rehabilitation of patients undergoing PCI using coronary stent implantation or bypass grafting and the selection of populations applying EECP should also be evaluated. In addition, future studies are needed to further clarify the indications and contraindications of EECP, reduce the treatment cycle and cost, and broaden this technology's application.

Conclusion

In conclusion, EECP is a non-invasive, safe and effective cardiac rehabilitation method with promising applications in the rehabilitation of patients with AMI after undergoing DCB-based PCI. Future clinical studies are needed to validate EECP's effects and safety, optimise treatment plans and provide alternative treatment options for the rehabilitation of patients with AMI.

Author contributions

Conception and design of the research: Hao XJ, Lu YM. Acquisition of data: Hao XJ, Zhang Y, Huang DM. Analysis and interpretation of the data: Zhang Y, Huang DM, Gu WX. Statistical analysis: Hao XJ, Zhang Y, Gu WX. Obtaining financing: None. Writing of the manuscript: Hao XJ, Zhang Y. Critical revision of the manuscript for intellectual content: Lu YM.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with the Declaration of Helsinki and approved by the ethics committee of Chongming Hospital Affiliated to Shanghai University of Health & Medicine Sciences, and informed consent was obtained from all participants.

Competing interests

The authors declare no competing interests.

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