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Possible omadacycline induce acute pancreatitis: a case report and literature review

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Abstract

Background Omadacycline is a new generation of tetracycline antibiotics, and its clinical application is increasing. We report the first case of acute pancreatitis possibly induced by omadacycline.

Case presentation The patient was admitted to the emergency intensive care unit due to community-acquired pneumonia. The initial treatment consisted of meropenem combined with levofloxacin, and the regimen was subsequently switched to omadacycline combined with cefoperazone/sulbactam due to sputum culture showing carbapenem-resistant Acinetobacter baumannii. Seven days after the administration of omadacycline, abdominal tenderness occurred, and CT scan revealed an enlarged gallbladder with exudation from the pancreatic head. The patient was diagnosed with acute pancreatitis and improved after dis-continuing omadacycline.

Conclusions Omadacycline, like other tetracycline antibiotics, may cause pancreatitis. Combination medications can be an important factor in this adverse reaction.

Keywords Omadacycline, Acute pancreatitis, Combination medications

Background

Omadacycline is a semisynthetic third-generation tetracycline derivative of tetracycline that inhibits bacterial protein synthesis by binding to the 30 S ribosomal subunit [1]. The substitution of amino methyl functional groups at C7 and C9 can prevent bacterial resistance caused by efflux and ribosomal methylation [2]. To date, the US Food and Drug Administration has only approved indications for the treatment of community-acquired bacterial pneumonia and acute bacterial skin and skin structure infections for omadacycline, but there are also reports of multidrug-resistant negative bacterial infections in other organs in the clinic [3].

The most frequent adverse reactions of omadacycline were nausea and vomiting, with reported incidences rates of 14.9% and 8.7% in Phase III trials [4]. Pancreatitis was not reported in these trials, but the Package Insert

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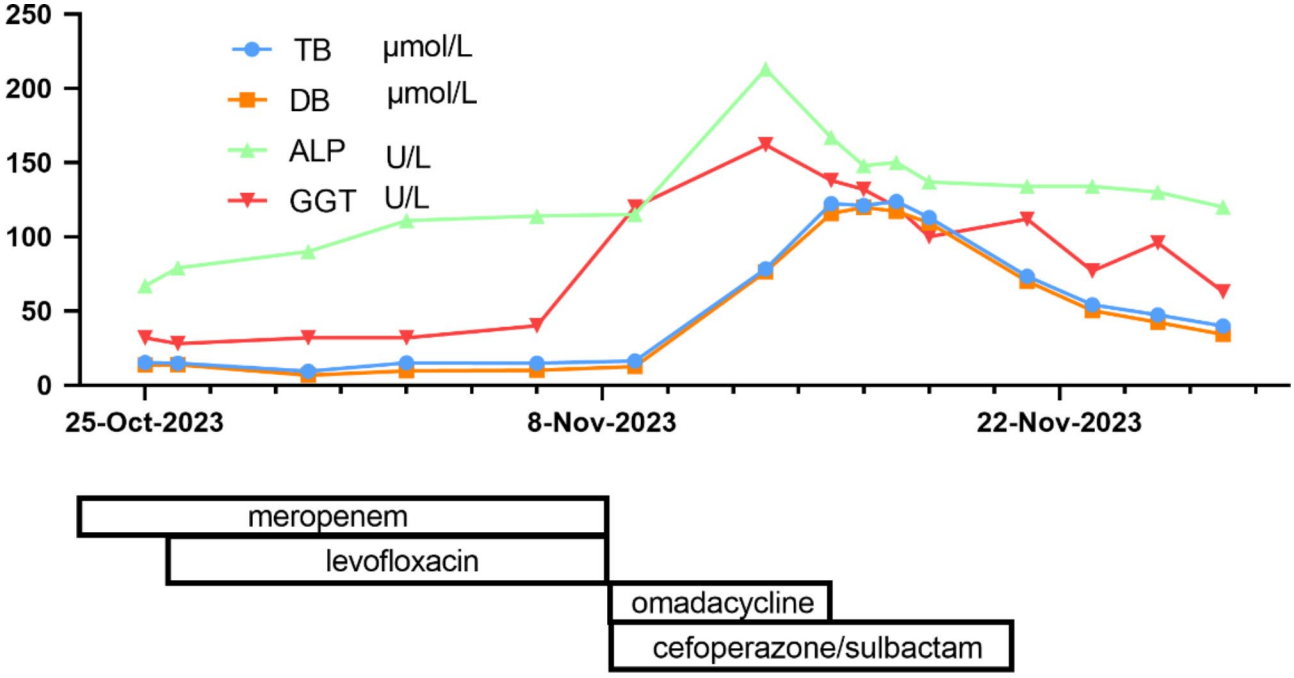

Fig. 1 Patient's anti-infection regimens and bile related indicators

suggested that adverse reactions, including pancreatitis related to tetracyclines, may occur [5].

Acute pancreatitis (AP) represents an acute inflammatory state of the pancreas that occurs due to the activation of digestive enzymes. This condition may give rise to necrotizing pancreatitis, and secondary infections from necrotizing pancreatitis is associated with a high rate of mortality. The traditional treatment is open necrosectomy, but now it has been found that minimally invasive step-up approach may lower the morbidity and pancreatic insufficiency [6].

To the best of our knowledge, this case we reported is the first case of acute pancreatitis possibly induced by omadacycline.

Case presentation

A 67-year-old male patient who presented with chest tightness, tachypnea, fever, fatigue, cough, and yellow sputum was transferred to our hospital and admitted to the emergency intensive care unit (EICU) with "respiratory failure".

On the day of admission, laboratory analysis revealed an arterial blood ph of 7.32, a PO_2 of 57.8 mmHg, a PCO_2 of 21.6 mmHg, a procalcitonin (PCT) > 100 ng/ml, a C-reactive protein (CRP) of 241.24 mg/l, and a white blood cell (WBC) of 13.77*109/L. Blood amylase and lipase had not been tested. A lung computed tomography (CT) scan revealed bilateral pneumonia with massive consolidation in the right lobe, an abdominal CT scan revealed no cholecystitis, no cholelithiasis or pancreatitis, and B-mode ultrasonography revealed no dilation of the left or right intrahepatic bile ducts, common bile duct or main pancreatic duct. The initial anti-infective regimen consisted of meropenem and levofloxacin.

After two weeks treatment, the patient still had fever, and lung CT showed that some lesions had progressed compared to previous findings. Sputum culture revealed carbapenem-resistant Acinetobacter baumannii, and the anti-infective regimen was adjusted to cefoperazone/sulbactam combined with omadacycline.

After one week of treatment with this anti-infection regimen, the nurse found that the patient experienced abdominal tenderness, and the abdominal contrast-enhanced CT image showed a decreased density of the uncinate process of the pancreas and encapsulated effusion at the pancreatic head. B-mode ultrasonography revealed a liquid dark area around the pancreatic head, which was approximately 1.5 cm wide. There was still no dilation in the intrahepatic bile ducts, common bile duct or main pancreatic duct. But an amylase of 218 U/L was lower than 3 times the upper limit of normal, and a lipase of 20.2 U/L within the normal limits. The patient was clinically diagnosed with AP according to the guideline [7]. His alkaline phosphatase (ALP) level increased to 213 U/L, glutamyl transferase (GGT) level increased to 160 U/L, total bilirubin (TB) level increased to 123.8 μmol/L, direct bilirubin (DB) level increased to 117.2 μmol/L. The patient was simultaneously diagnosed with cholestasis.

The patient was a factory worker with a history of drinking for 6 years, and quit for 1 year; smoking for more than 20 years, and quit for 1 year too; hypertension for 7 years, taking amlodipine and metoprolol; pancreatitis,

gallstones and autoimmune disease were not mentioned. He did not overeat or overdrink this time with a normal triglyceride level of 1.9mmol/L and calcium ion level of 1.08mmol/L, clinical pharmacist suggested that the patient's pancreatitis may be caused by omadacycline, and the drug should be stopped. Seventeen days after the discontinuation of omadacycline, abdominal CT revealed no signs of pancreatitis, and the patient's abdominal pain also disappeared.

Patient's anti-infection regimens and bile related indicators are shown in Fig. 1, and the abdominal CT scan images are shown in Fig. 2.

Discussion

There are many causes of acute pancreatitis, including biliary diseases and alcohol exposure. Other causes include idiopathic pancreatitis, endoscopic retrograde cholangiopancreatography, trauma, medication, infection, hypercalcemia, hypertriglyceridemia, tumors, and autoimmune diseases. Although the overall incidence rate of drug-induced pancreatitis (DIP) is approximately 5% [8], it has gradually attracted clinical attention. Tetracyclines are a class of drugs with a relatively high incidence [9].

As far as we know, the first case of tetracycline induced pancreatitis was reported by Schultz et al. in 1963 [10]; the first case of minocycline induced pancreatitis was

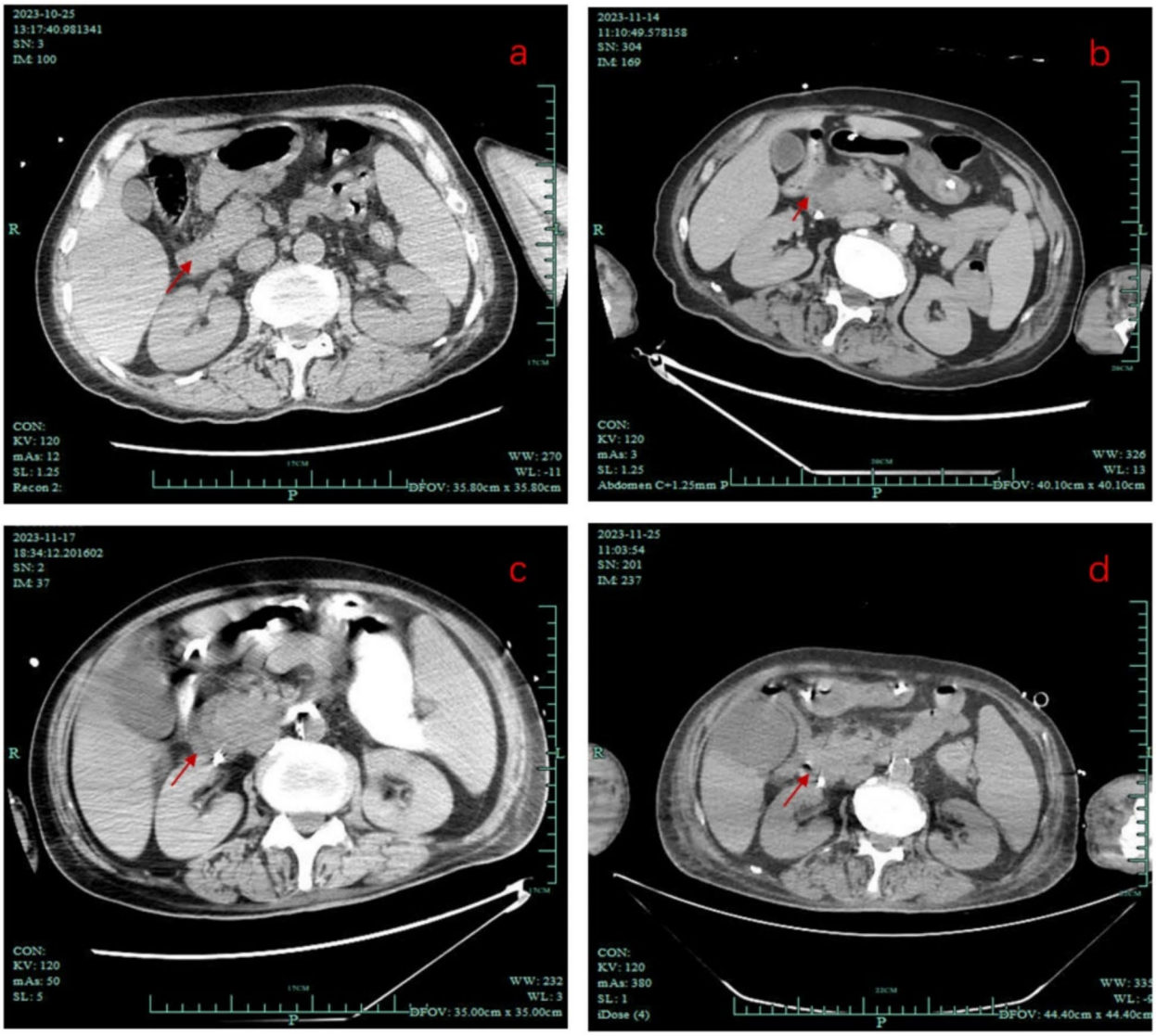

Fig. 2 Patient's abdominal CT scan images before and after use of omadacycline. (**a**) no pancreatitis on the day of admission; (**b**) encapsulated fluid accumulation in the pancreatic head on 6 days after omadacycline; (**c**) slight exudation in the pancreatic head on 9 days after omadacycline; (**d**) disappearance of edema in the pancreatic head on 17 days after omadacycline

reported by Boudreux et al. in 1993 [11]; In 2008, the first case of tigecycline induced pancreatitis was reported [12]; Two years later, the first case of doxycycline induced pancreatitis was reported [13]; In 2023, the first case of eravacycline induced pancreatitis was reported [14]. This case report seems to be the first literature on omadacycline-induced pancreatitis.

Omadacycline is mainly used in the respiratory and infectious disease departments of our hospital, but there had been no evidence of omadacycline induced pancreatitis. This patient was admitted to EICU and the medication situation was complex, which may be related to the occurrence of the adverse reaction.

Saini et al. classified drugs into 4 major groups based on the quality of literature reported on DIP, with the 3rd level being further divided into 3 sub-groups [15]. Class 1: High Quality of Evidence for causation of acute pancreatitis: Randomized Controlled Clinical Trials; Class 2: Moderate quality of evidence for causation of acute pancreatitis: Case-control studies and/or pharmacoepidemiology studies; Class 3: Low-quality evidence for causation of acute pancreatitis: High-quality case reports; Class 3a: Case reports showing "rechallenge and consistent latency"; Class 3b: Case report showing rechallenge only; Class 3c Case report showing consistent latency only; Class 4: Very low-quality evidence: high-quality case reports but no rechallenge nor consistent latency.

We searched for reports on tetracycline antibiotics induced pancreatitis in PubMed from 2000 to the present day, and classified the combination medications based on the above method, as shown in Table 1.

Upon review, it was found that the tetracyclines reported in the literature includes minocycline, doxycycline, tigecycline, and eravacycline. The highest level of combination medication is class 2, with 4 reported cases, including Selective serotonin receptor inhibitors and metronidazole. There are 2 reported cases of class 3, which were fenofibrate and oestrogen. Many cases

Table 1 Combination medications with classification in tetracyclines induced pancreatitis

Author	Country	Number of cases	Year of report	Tetracyclines	Combination Medications with classification
Boyle [16]	USA	1	2001	Minocycline	Fluoxetine (2), fluticasone, levothyroxine, theophylline
Achecar [13]	Spain	1	2010	Doxycycline	Amikacin, rifampicin
Ocal [17]	Turkey	1	2010	Doxycycline	Ornidazole
Wachira [18]	USA	1	2013	Doxycycline	Citalopram (2)
Rawla [19]	USA	1	2017	Doxycycline	Gabapentin, oxycodone
Paulraj [20]	USA	1	2020	Doxycycline	Fenofibrate (3)
Shah [21]	USA	1	2021	Doxycycline	Sertraline(2)
Reiche [22]	USA	1	2022	Doxycycline	Ceftriaxone
Glison [12]	France	1	2008	tigecycline	Imipenem, amikacin
Lipshitz [23]	USA	1	2009	Tigecycline	Levothyroxine
Marshall [24]	USA	1	2009	Tigecycline	Pantoprazole (4), and hydromorphone
Hung [25]	USA	1	2009	Tigecycline	Meropenem, vancomycin, clindamycin
Prot-Labarthe [26]	France	1	2010	Tigecycline	Colistin, amikacin and rifampin
Mascarello [27]	Italy	1	2012	Tigecycline	Amikacin, propofol (4)
Marot [28]	Belgium	1	2012	Tigecycline	Piperacillin- Tazobactam, Vancomycin
McGovern [29] *	USA	1st	2014	Tigecycline	Oestrogen (3b); acetaminophen
McGovern [29] *	USA	2nd	2014	Tigecycline	Metronidazole (2)
McGovern [29] *	USA	3rd	2014	Tigecycline	furosemide (4), omeprazole (4)
Hemphill [30]	USA	1	2015	Tigecycline	Tobramycin, meropenem, and vancomycin
Hemphill [30]	USA	2nd	2015	Tigecycline	Amikacin, clarithromycin
Davido [31]	France	1	2016	Tigecycline	Imipenem, amikacin
Akhter [32]	USA	1	2018	Tigecycline	Clofazimine
Lin [33]	China	1	2018	Tigecycline	Tacrolimus, mycophenolate mofetil (4), and prednisone (4)
Yazirli [34]	Turkey	1	2021	Tigecycline	Tacrolimus, amiodarone (4), acetaminophen, prednisolone (4), and ranitidine (4)
Chang [35]	China	1	2022	Tigecycline	Imipenem-cilastatin, polymyxin E sulfate, ganciclovir, voriconazole, amphotericin B, prednisone (4), tacrolimus
Ren [36]	China	1	2023	Tigecycline	Amikacin, levofloxacin, meropenem
Stefanos [14]	USA	1	2023	Eravacycline	Ceftriaxone
This case	China	1	2024	Omadacycline	Propofol (4), furosemide (4), cefoperazone/sulbactam, levofloxacin, meropenem

*Only cases possibly or probably related were included

combination medications were at class 4, including the case we reported, propofol and furosemide. Other common combination medications include ceftriaxone, acetaminophen, ornidazole (derivatives of metronidazole), etc. There have been cases of pancreatitis caused by ceftriaxone [37, 38], ornidazole [39]. Acetaminophen overdose is considered as class 2 [40], while normal dose of acetaminophen is not included in the classification. Immunosuppressive drugs such as prednisone and tacrolimus which combined used in organ transplant patients are also listed in Table 1, but it is not yet clear whether the pancreatitis is related to medication or the disease itself. With the increase of reports and comprehensive literature search, this classification of DIP will continue to be updated.

Based on these reports, we have examined the patient's other medications besides the anti-infection regimen. The patient was sedated with propofol throughout the entire process; furosemide for diuresis from November 3rd to November 7th, but later switched to continuous renal replacement therapy treatment due to deteriorating renal function. Propofol, and furosemide belong to Class 4, while cefoperazone/sulbactam and levofloxacin do not yet belong to any above classification. Although the above drugs do not have a clear time correlation with the patient's pancreatitis, but they may have a combined effect on the pancreatitis induced by omadacycline.

In the past, the Naranjo scale [41] was commonly used to determine the correlation between adverse drug reactions. A probability assessment scale for DIP on the basis of the Naranjo scale, which was developed by Weissman et al. [42] in 2020, was more specific for pancreatis. According to the revised assessment scale, the association between omadacycline and AP in this case was assessed as "possible" on a 5-point scale, as shown in Table 2. But this probability assessment scale ignores the situation of concomitant medication and may increases the possibility of specific drugs causing AP, which need further revision.

The mechanism of tetracyclines-induced pancreatitis is not yet clear, but several possible mechanisms have been proposed: (1) Accumulation of toxic metabolites [43]; (2) Tetracyclines associated hypertriglyceridemia [44]; (3) High biliary tract drug concentration [45]; (4) Inhibiting the transport of digestive enzymes in the pancreas, leading to an increase in digestive enzymes [46, 47].

There was no evidence of biliary stones in this case, and pancreatitis was accompanied by cholestasis, which is the most common type of liver injury caused by tigecycline [48]. We speculate that cholestasis may be related to pancreatitis, the transport of bile and pancreatic enzymes, microlithiasis formed by the combination of drugs and calcium, may play a certain role.

Bedside B-mode ultrasonography has the advantages of fast speed, high sensitivity and no radiation. This is an ideal imaging screening method for monitoring DIP, especially for ICU patients [36]. It is recommended that for patients treated with omadacycline, bedside B-mode ultrasonography should be used to monitor for cholestasis and pancreatitis, and CT scans should be performed for suspected patients.

The initial instructions for tigecycline did not list pancreatitis in adverse reactions. Due to the continuous reporting of tigecycline-induced pancreatitis after its launch, the manufacturer updated the package insert, listed pancreatitis as one of the adverse reactions in 2006. Our report may provide a basis for updating the package insert of omadacycline.

Table 2 Revised drug-induced pancreatitis probability assessment scale

	Question	Yes	No	Don't know	Score
1	Are there published reports of the drug causing acute pancreatitis?		0		
2	Was there short latency (≤ 7 d) between initiation of the drug and the diagnosis of acute pancreatitis?	2			
3	Was there a temporal relationship (≤ 1 mo) between initiation of the drug and onset of acute pancreatitis symptoms?	1			
4	Did the acute pancreatitis resolve following discontinuation of the drug?			0	
5	If a drug re-challenge was performed, did acute pancreatitis recur?			0	
6	Were all commonly recognized causes of acute pancreatitis ruled out? (e.g. gallstones/ choledocholithiasis, alcohol, hypertriglyceridemia, hypercalcemia, ERCP, trauma).	1			
7	Was a serum IgG4 level checked? (to rule out autoimmune pancreatitis).		0		
8	Does the patient have or was the patient recently diagnosed with an infection (bacterial, fungal, or viral) which could cause pancreatitis?		1		
9	Was an EUS and/or MRCP performed? (e.g., to rule out occult microlithiasis, pancreatic malignancy, and pancreatic divisum).			0	
10	Was genetic testing (SPINK-1, CFTR, and PRSS-1) performed to rule out hereditary pancreatitis? (in patients age < 30 year).		0		
	Summative score (> 9: highly probable, 6–8: probable,3–5: possible, and ≤ 2: doubtful.)				5

ERCP: Endoscopic retrograde cholangiopancreatography; EUS: Endoscopic ultrasound; MRCP: Magnetic resonance cholangiopancreatography

At present, reports of DIP are basically cases or case series, just like this article. Their evidence-based level is not high. We hold the view that the results of multiple reports on AP cases during therapy should be taken as a foundation for conducting prospective randomized controlled trials so as to improve the quality of evidence. The medication for EICU patients is complex, and there may will be reports of outpatient patients using omadacycline tablets induced AP in the future, which will increase the likelihood of DIP. Moreover, most of the harm mechanisms are still only suspected or remain unknown. Further studies are required to confirm the suspected etiopathogenetic mechanisms.

Conclusion

Omadacycline, like other tetracycline antibiotics, may cause pancreatitis. Clinician, pharmacists, and other medical staff need to be vigilant and monitor such adverse reaction, especially when combined with other medications that can cause pancreatitis.

Abbreviations

AP	Acute pancreatitis
EICU	Emergency intensive care unit
PCT	Procalcitonin
CRP	C-reactive protein
WBC	White blood cell
CT	A lung computed tomography
ALP	Alkaline phosphatase
GGT	Glutamyl transferase
TB	Total bilirubin
DB	Direct bilirubin
DIP	Drug-induced pancreatitis

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Author contributions

Qiang Xu: Methodology, Investigation, Writing- Original draft preparation. Yanlei Sang: Writing- Reviewing and Editing, Software. Huanran Zhang : Resources, Verification. Qingwei Zhao : Conceptualization, Supervision.

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Data availability

Data and materials are provided within the manuscript.

Declarations

Ethics approval and consent to participate

This study has been approved by the clinical research ethics committee of the First Affiliated Hospital of Zhejiang University School of Medicine with Reference Number 20240391 and the consent to participate was waived because this is a retrospective case report.

Consent for publication

All named authors have read the manuscript and have agreed to submit the paper to BMC Infectious Disease in its present form. Written informed consent was obtained from the next of kin for the publication of identity revealing information/images because the patient has passed away.

Competing interests

The authors declare no competing interests.

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