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STUDY PROTOCOL

Efficacy of Tender Point Infiltrations (TPI) in Patients with Acute and Subacute Zoster-Associated Pain: Study Protocol for a Randomized, Prospective, Multicenter, Blinded Endpoint, Open-Label Controlled Trial

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Introduction: Herpes zoster (HZ) can adversely influence patients' quality of life and sometimes it can develop postherpetic neuralgia (PHN). To date, it remains challenging manage well using currently available therapies. Tender point infiltration (TPI) might have the potential to be an analgesic therapy for acute and subacute HZ pain. However, current evidence remains insufficient. Therefore, the purpose of this protocol is to design a study to: 1) evaluate the analgesia efficacy and safety of TPI for acute and subacute HZ; 2) to explore the positive predictors of TPI for prevention of PHN.

Methods and Analysis: This study is designed as a randomized, prospective, multicenter, blinded endpoint, open-label controlled trial including a 12-month follow-up period. 176 qualified participants will be randomly split into the standard group or TPI group in a ratio of 1:1. Primary outcome will be the presence of PHN 12 months posttreatment. Secondary outcomes include the presence of PHN at month 3 and month 6 posttreatment. Visual Analogue Scales (VAS) for assessment of pain, consumption of oral analgesia drugs, patient satisfaction scores on the 5-point Likert scale, patients' quality of life scored on the WHOQOL-BREF at day 1, week 2, month 1, month 3, month 6 and month 12, proportion of patients receiving repeated TPIs and block points each time for TPI group. Multivariable logistic analyses will be performed to identify predictive factors for the prevention of PHN at month 12 after treatment. Safety evaluation will be determined by adverse events during the trial.

Keywords: tender point infiltration, herpes zoster, zoster-associated pain, randomized controlled study, study protocol

Introduction

Herpes zoster (HZ) is a skin infection disease caused by reactivation of varicella zoster virus latent in the sensory ganglion, in which a typical feature is that it causes herpes along the sensory nerve in the corresponding segment, accompanied by unilateral spontaneous zoster-associated pain (ZAP), usually described as burning or stinging in quality, sometimes also including itch, aching, and pain paroxysms.[1] Studies have suggested a model of pain resolution that is divided into three phases: acute ZAP within 1 month of the onset, subacute ZAP (with 1–3 months of the onset), or postherpetic neuralgia (PHN) (with more than 3 months of the onset).[2] In the acute phase, the dorsal root ganglion shows inflammation, hemorrhagic necrosis, and neural loss.[3] Mechanical allodynia was common, in which it has reported in 65–87% of cases and was associated with the presence of intense pain.[4] The subacute phase is likely a transition phase. The most fearful complication in the chronic

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phase is PHN, which may persist for months to years and is often refractory to pharmacological therapies.[5] Early recognition and analgesic treatment of herpes zoster can relieve acute symptoms and may also reduce the occurrence of PHN.[6]

The conventional therapies for HZ infection can be seen in two phases.[7] Those in acute phase are mainly antiviral (acyclovir and famciclovir),[8] analgesic drugs (opioids, acetaminophen or nonsteroidal anti-inflammatory agents, gabapentin, etc),[9–12] while these conventional drug therapies could yield potential side effects, and part of patients are not fully satisfied with the analgesic effect. It is considered that supplementary and alternative local therapies may have better results with less side effects and reduce medical costs to relieve pain associated with HZ infection. These options, including nerve blockade (epidural injection, paravertebral injection, sympathetic block, intercostal nerve block, intracutaneous injection),[13–15] pulsed radiofrequency,[16] acupuncture,[17] fire needling acupuncture,[18] electrical nerve stimulation,[19] lidocaine patch,[20] capsaicin cream,[21] and botulinum toxin injection[22] have been reported to give positive therapeutic effects on acute herpes zoster neuralgia (AHN), however, evidence for the efficacy of existing local therapies is limited and risks may occur due to high invasiveness of some procedures, there is insufficient evidence and expert agreement to make recommendations for these intervention strategies as first-line treatments in guidelines.

Tender point infiltration (TPI) might figure as an alternate, which is one of the easiest and most time-efficient procedures by injecting local anesthetic with or without steroid in the area that produces pain directly under the palpation. Our previous retrospective analysis had shown that TPI with local anesthetic and steroids obtained a high effective rate of more than 90% 2 weeks, 1 month, and 3 months after the treatment for acute and subacute ZAP,[23] however broad clinical studies with large sample size are missing and the quality of evidence is low. Thus, it is necessary to carry out randomized control trials with good methodological quality to clarify the efficacy of TPI on the clinical outcomes of patients with acute/subacute ZAP. The hypothesis is that patients with acute/subacute ZAP treated with TPIs with local anesthetic and steroids under the basis of standard treatment will show better clinical outcomes compared with subjects treated with standard treatment only.

Objectives

The primary objective of the trial is to investigate PHN incidence of standard treatment alone (standard group) and standard treatment plus TPI (TPI group) at month 12 after treatment. Secondary objective is to explore the proportion of patients with PHN at month 3 and month 6 after treatment, Visual Analogue Scales (VAS) for assessment of pain, alternation of oral analgesia drug consumption, satisfaction scores, quality of life (WHOQOL-BREF) at each follow-up time point, proportion of patients receiving repeated TPIs and block points each time (for TPI group), and adverse events related to the treatments. Another objective would be to analyze the correlation between patients' baseline characteristics and the incidence of PHN at 12 months after treatment in TPI group, thus help guide clinical decision making. We aim at finding an effective, safe, and non-destructive option, which can be performed with low technical requirement and high convenience.

Methods and Analysis

Trial Design and Setting

This prospective, multicenter, randomized, blinded endpoint, open-label controlled study is designed to compare PHN incidence of standard treatment alone (standard group) and standard treatment plus TPI (TPI group) for acute/subacute ZAP at month 12 after treatment. Beijing Tiantan Hospital of Capital Medical University associated with the other two hospitals, Sanbo Brain Hospital of Capital Medical University and Jilin province people's hospital, is responsible for recruiting 176 eligible patients in the clinical practice setting. Clinical trial information will be posted on the bulletin board of each hospital, in online advertisements, and on advertisement boards in public spaces. Acute and subacute HZ patients in each hospital will be randomly and evenly assigned to the TPI group and the standard group at a 1:1 ratio. The total follow-up study period per patient is 12 months. Ethical approval has been given by the institutional review board of Beijing Tiantan Hospital (KY2024-045-02). The study will start enrolling the first patient in December 2025 and will be completed when the last patient completes follow-up in June 2027. The study will be completed when the last patient completes follow-up. The flow diagram of the study is illustrated and summarized in Figure 1. The timeline and detailed schedule of patients is displayed in Table 1.

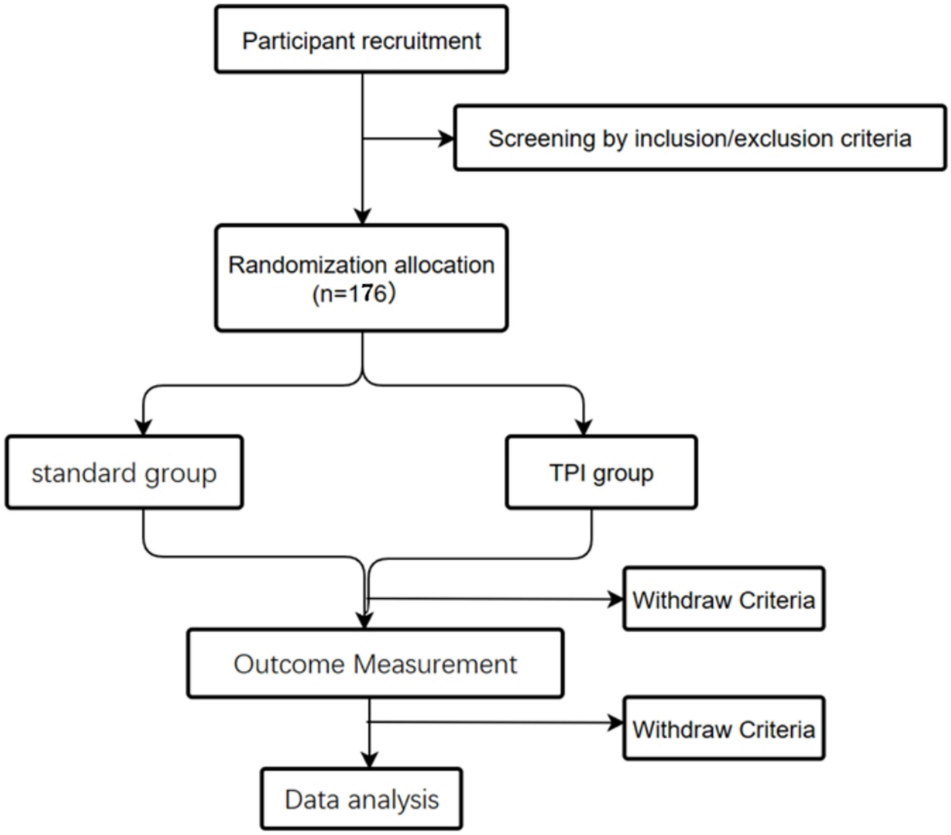

Figure 1 Flow diagram of the study.

Eligibility Criteria

Inclusion Criteria

1. Patients with onset of HZ rash less than 90 days.
2. HZ affected the spinal nerves (cervical/thoracic/lumbar nerve).
3. Aged 18 to 80 years (inclusive).
4. Pain intensity > 7 cm on a visual analogue scale (VAS 0–10 cm).
5. Agreed to sign the informed consent form.

Table 1 Participants' Schedule

	−1 day	0 day	30 min	1 day	2 weeks	1 month	3 months	6 months	12 months
Enrollment									
Eligibility screening	×								
Informed consent	×								
Allocation		×							
Intervention									
Standard treatment plus TPI		×							
Standard treatment alone		×							

(*Continued*)

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Table 1 (Continued).

	−1 day	0 day	30 min	1 day	2 weeks	1 month	3 months	6 months	12 months
Assessment									
Baseline data	×								
Vital signs			× (TPI group)						
VAS score		×	× (TPI group)	×	×	×	×	×	×
Consumption of oral drugs		×		×	×	×	×	×	×
Patient satisfaction scores				×	×	×	×	×	×
WHOQOL-BREF		×		×	×	×	×	×	×
Adverse reactions			× (TPI group)	×	×	×	×	×	×

Notes: "×" denotes the steps to be performed by patients at the corresponding time points.

Exclusion Criteria

1. Infection at the puncture site.
2. Poor general situation unable to be treated.
3. A history of abuse of narcotics.
4. Non-compliance or inability to complete the self-evaluation questionnaires.
5. Pregnancy or lactation.
6. Patients using immunosuppressants and those with severe systemic diseases such as hematological malignancies, cancers, or autoimmune disorders.

Withdrawal Criteria

1. Lost to follow-up during the study.
2. Subjects receiving other treatment options during the trial.
3. Subjects experiencing severe comorbidities or special physiological changes during the trial, thus classified as not suitable to continue the trial.
4. Patients voluntarily withdraw from the study.

Recruitment and Informed Consent

Experienced attending doctors will enroll patients with HZ no more than 90 days at the department of pain management in each hospital. All the participants will be informed in detail of the following information: the purpose of the study, interventions, benefits, possible risks, and corresponding responses. All patients will be given at least 24 hours to consider whether to participate in the study. They will sign the informed consent form voluntarily and have the right to withdraw from the study at any time with any reason. The informed consent of this study has been approved by the Ethics Committee of Beijing Tiantan Hospital. All the candidates enrolled in this study will receive strict evaluations based on the above inclusion and exclusion criteria.

Randomization and Blinding

The study design is randomized, prospective, multicenter, blinded endpoint, open-label controlled trial. After the patients are recruited and sign the consent form, stratified block randomization based on patients' baseline characteristics is used to assign participants from 3 hospitals into two group, standard group and TPI group, balancing their course of disease. During the process of randomization, each subject will be assigned a randomization code and will be given the treatment option with the code. This study has an open-label design, thus participants and doctors could not all be blinded to the study conditions. However, telephone follow-ups at different time points after the treatments will be conducted by

responsible physicians blinded to the allocation status of the patients. The data input will be completed by data-entry personnel who are not on the research team, and the data analysis will be completed by statisticians blinded to the allocation information.

Trial Interventions

Routine physical examinations and vital sign monitoring will be performed for all participants. For patients in TPI group, hemogram, fasting blood sugar, liver function tests and kidney function tests will be prescribed. According to European consensus-based (S2k) guidelines treatment of herpes zoster, patients with onset of skin lesions within 72 hours will start antiviral treatment (Valacyclovir 1000 mg, three times daily for 7 days), for patients with cutaneous symptoms for more than 72h, initiation of systemic antiviral therapy will be determined by the presence of dissemination signs.[24] Besides, they will receive daily 300 mg pregabalin in divided doses (150 mg/12 hours). Once the patient reports mild pain (VAS ≤ 3), the trial for reducing the pregabalin dose will be done. If the VAS value increased to more than 3, the patient was returned to the last controllable pregabalin dose.[25,26] Furthermore, nonsteroidal anti-inflammatory drug celecoxib (200 mg on request, up to two times daily)[27] and tramadol (100 mg on request, up to 400mg daily)[28] will be available for as-needed analgesia, so that a sufficient pain therapy is guaranteed. The use of oral analgesics other than celecoxib and tramadol is prohibited, and no epidural, paravertebral or other nerve blocks can be administered during the entire follow-up period.

For TPI group, patients will be allocated to receive the same drug therapy as the standard group. In addition to the initial drug therapy, these patients will also receive TPIs. The skin will be marked at the area of worst pain on palpation. If the participant has less than 20 tender points, all the tender points will be infiltrated. A maximum of 20 tender points will be infiltrated at one session. The infiltration solution was prepared with 4mL of 2% lidocaine and diprospan (0.5mL, diprospan® betamethasone propionate 2.5 mg and betamethasone sodium phosphate 1 mg), diluted to a total volume of 20mL with normal saline. Depending on the tender point location, the patient may be sitting or laid down, the skin of the participant was marked with a permanent marker at the assessed tender points and the area was cleaned with Aner idoine skin disinfectant. The clinicians then pinch the tender point between their fingers and stabilize the tissue. Once stabilized, the clinician will insert the needle perpendicular to the skin surface over the chosen tender points using a 25G needle (BD PricisionGlide™, 30 Tuas Avenue 2, Singapore). The clinician should ensure the needle is not in a vascular structure and then inject 1 mL of prepared solution into each tender point. The solution will be administered into each tender point as a single shot in 10 seconds, and stretching will be done after all the injections in order to help distribute the solution across the muscle. After 30 minutes, by observation of vital signs and accessing pain intensity, all patients will be permitted to leave the hospital. Up to 3 injections can be given in responders with suboptimal pain relief at 2-week intervals each.[23] All TPI procedures will be conducted by experienced physicians in pain management. No additional nerve blockade or other invasive therapy will be performed during the 12-month follow-up.

Study Outcomes

Demographic and baseline information include age, gender, body mass index (BMI), disease duration, side, affected dermatomal level (cervical/thoracic/lumbar), underlying disease, previous medications, VAS scores, and scores on the World Health Organization Quality of Life Questionnaire (WHOQOL-BREF) will be collected and recorded.

Primary Outcome

The primary outcome will be the presence of PHN 12 months after treatment, which will be defined as persistent pain with a score of higher than 0 on the VAS (0 = "no pain at all" to 10 = "worst pain imaginable").[24,29]

Secondary Outcome

1. The presence of PHN at month 3 and month 6 after treatment (any pain with a VAS score of higher than 0).
2. VAS score: VAS scores will be evaluated before the treatment (baseline), 30min after the intervention (for TPI group), then day 1, week 2, month 1, month 3, month 6 and month 12 following the treatment.

3. Consumption of oral drugs: Dose of celecoxib, pregabalin and tramadol will be recorded on day 1, then week 2, month 1, month 3, month 6 and month 12 following the treatment.
4. Patient satisfaction scores on the 5-point Likert scale[30] (1: Very dissatisfied, 2: Dissatisfied, 3: Not sure, 4: Satisfied, 5: Very satisfied) will be evaluated on day 1, then week 2, month 1, month 3, month 6 and month 12 following the treatment.
5. Quality of life: Scores on the WHOQOL-BREF[31] will be evaluated on day 1, then week 2, month 1, month 3, month 6 and month 12 following the treatment.
6. Proportion of patients receiving repeated TPIs and block points each time (for TPI group) during the study period.
7. Predictive factors for the prevention of PHN at month 12 post treatment: the correlation between patients' baseline characteristics and the incidence of PHN will be analyzed 12 months after treatment in TPI group.

Follow-Up

The patients will be discharged from the hospitals after the procedure for TPI group. Regular outpatient and telephone follow-ups will be conducted in two groups. Follow-ups will be performed on day 1, then week 2, month 1, month 3, month 6 and month 12 following the treatment. For patients in TPI group, pain intensity will be evaluated and adverse effects will be recorded 30 min after treatment. Patients will be encouraged to actively report pain recurrence, adverse reactions and alternation of drug consumption by telephone or clinic visiting. A pain physician from each center will be responsible for the follow-up of the patients, review of patients' responses to treatment, and data collection.

Data Collection

Case report forms and standard operating procedures will be based on this study protocol. All the researchers will be systematically trained and will execute a test run before the recruitment process begins. The data required from the case report form will be recorded by the researchers in charge of enrolment and follow-up. The data and safety monitoring committee (DSMC) will monitor the safety and validity data every 6 months to make recommendations on whether to continue the study. Back-to-back and double-entry systems using Epidata 4.6 (EpiData Association, Denmark) will ensure the accuracy of data entry.

Safety

All adverse events will be recorded in detail and given appropriate treatment and follow-up until fully resolved or in a stable condition. Serious adverse events will be reported to the ethics committee, competent authorities, and trial sponsors within 24 hours. There will be regular meetings between the data collectors, monitor, principal investigator and other coresearchers involved in the project to assess the risks and benefits of the study. The DSMC has the right to terminate the study at any time.

Sample Size

The main purpose of this study will be to investigate the incidence of PHN. Based on the reported prevalence, the incidence of PHN in China is approximately 30% in patients with HZ.[32] Based on a previous study, the effectiveness of TPI treatment was 90%,[33] and the rate was likely to be 70% with standard treatment.[34] In order to obtain a clinically meaningful effect with 90% power, 79 patients are required per group (The α is 0.05, and the power is 90%), considering approximately 10% of the dropout rate, 88 patients will be recruited in each group (Figure 2). Therefore, the total sample size of this study will be 176 patients.

Numeric Results for Testing Two Proportions using the Z-Test with Unpooled Variance
H0: P1 - P2 = 0. H1: P1 - P2 = D1 ≠ 0.

Target Power	Actual Power*	N1	N2	N	P1	P2	Diff D1	Alpha
0.90	0.90070	79	79	158	0.9000	0.7000	0.2000	0.0500

Figure 2 Sample size calculation.

Statistical Analysis

The data analysis will be performed after the data for the entire sample has been collected, using the SPSS Statistic® v.25.0 software package. The significance level is established at 0.05 and the limits of the confidence interval at 95%.

A descriptive analysis of the baseline characteristics of the sample will be performed. All the quantitative variables will be analyzed using the Kolmogorov–Smirnov test with Lilliefors corrections, to ascertain whether they follow a normal distribution. Data will be presented as mean (SD) for normally distributed continuous variables, the non-normally distributed continuous variables will be presented as medians (interquartile range), and as frequency (percentage) for categorical variables. Two-sample t-tests or the Mann–Whitney/Wilcoxon signed-rank test will be used for data measurement, according to their distributions. The $\chi 2$ test or the Fisher exact test will be used for categorical data. A repeated measures analysis of variance on ranks will be performed for the repeated data, and Bonferroni correction will be used to correct multiple comparisons. Safety assessment will be evaluated using descriptive analysis. To control for potential residual imbalances in baseline HZ severity and other clinical features, covariate-adjusted analyses will be performed using multivariate logistic regression (for binary outcomes) and repeated-measures ANCOVA (for continuous outcomes), with baseline VAS scores, disease duration, dermatomal level, and other relevant covariates included.

The principles of intention-to-treat (ITT) analysis will be performed. In the event of follow-up losses, the outcome variables that have not been recorded will be completed with the last data recorded for each of these variables (Last-Observation-Carried-Forward-Analysis). Per protocol (PP) analysis will be performed as a complementary method to maintain adherence to protocol: participants who violate, discontinue, or withdraw from the assigned treatment will be excluded.

Ethics and Dissemination

This RCT was designed in accordance with the principles of the Declaration of Helsinki. This protocol was approved by the institutional review board of Beijing Tiantan Hospital (KY2024-045-02) and registered on clinicaltrials.gov (NCT06344403). Signed consent will be obtained from all participants after they have been informed of the study procedures, possible risks and their right to withdraw from the trial. The study results will be submitted for publication in peer-reviewed journals. The anonymized patient-level dataset will be shared on clinicaltrials.gov.

Patient and Public Involvement

Neither patients nor the public will be involved in the formulation of research questions, designs, or outcome measurements. Recruitment will be conducted through research posters and physicians' presentations. Patients will be screened and enrolled by trained physicians. The results of this study will be distributed to all patients in the form of newsletters. All patients will be informed regarding relevant intervention in detail. The presence of PHN 12 months after treatment will be identified as key outcomes, with PHN incidence at other follow up time points, patient satisfaction, pain severity and analgesic consumption included as a secondary measure. Public representatives provided input on recruitment strategies, resulting in clearer, patient friendly study materials. Findings will be disseminated through written summaries for participants, patient advocacy discussions, and clinical meetings to inform future pain management strategies in ZAP.

Discussion

To the best of our knowledge, this study is the first to test whether TPI combined with standard treatment has better preventive effect against PHN compared with standard treatment alone. This study will add significant new knowledge to the management of acute and subacute ZAP with TPI.

Epidemiological studies have shown that the presence of PHN is proportional to the degree of acute pain and inflammation in HZ, repetitive painful stimuli that reach the central nervous system might lead to central sensitization, which is the most important mechanism of long-lasting chronic pain.[35] As a non-pharmaceutical therapy, the anti-inflammation and analgesia effect of TPI with anesthetic and corticosteroid in the territory that produce pain directly under palpation may play a role in attenuating central sensitization and minimizing nerve damage, which are common causes of the development of PHN.[36] Meanwhile, it also has the advantages of simple operation, lower medical expense and mild tissue damage.

The main strengths of our study design include sufficient duration of follow up of 12 months and multicentric setting, which will improve the quality of the trial. Our study also aims to identify potential correlations between patient baseline characteristics and PHN incidence rate in TPI group, thus finding positive factors for the prevention of PHN through TPI. This study has several limitations. Firstly, the trial design of this study is open-label, given to the characteristic of TPI procedure as well as the complete difference between the two therapies in two groups (ie, pharmacotherapy vs pharmacotherapy combined with injection therapy), it is difficult to blind TPI operators and patients in our study. Nevertheless, the design has an important strength of reproducibility. Besides, the purpose of blinding aims at avoiding the effect of subjective factors on the study results. In order to minimize the subjective influence, the outcome assessment and statistical analysis will be implemented by a third party who is blinded to the grouping. Secondly, we only use a single concentration of diprospan, if the results are satisfactory, a dose-effect response trial on the concentration of diprospan and the effectiveness of pain relief needs to be investigated. During the 12 month study period, the principal investigators will monitor all adverse events and complications in real time. The safety precautions in our study will be further improved based on the study process and adverse event reports.

If the results of this trial turn out to be positive, the study will contribute to clinical practice by providing evidence that will help guide decisions about the appropriate treatment of patients with acute and subacute ZAP, and may also provide a preventive option to the difficult situation of PHN. TPI can be used as a first line of HZ treatment and can also be a perfect add-on therapy in patients with acute and subacute ZAP. The results will be published once the study is completed.

Ethics and Consent Statements

This RCT follows the Declaration of Helsinki. It was approved by the ethics board of Beijing Tiantan Hospital (KY2024-045-02) and registered on clinicaltrials.gov (NCT06344403). All participants will provide written consent after being informed of the procedures, risks, and their right to withdraw. Results will be published in peer-reviewed journals, and anonymized data will be shared on clinicaltrials.gov.

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Rong Han and Xiangjun Zhou contributed equally to this work and should be considered as co-first author. Zhigang Zhao and Fang Luo contributed equally to this work and should be considered as co-correspondence authors.

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Disclosure

The authors declare that they have no competing interests in this work.

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