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E-mail: cjim_en@cjim.cn

Original Article

# Observational Study of Chinese Medicine Syndrome Distribution in Patients with Acute Myocardial Infarction and Its Impact on Prognosis*

ZHU Hong-min[1], ZHOU Jing-min[1], JIN Xue-juan[1], FU Ming-qiang[1], ZHU Ling-ti[1], CUI Xiao-tong[1], FAN Yue[2], CAI Ding-fang[2], and GE Jun-bo[1]

**ABSTRACT** **Objective**: To investigate the distribution of Chinese medicine (CM) syndrome in patients with acute myocardial infarction (AMI) on admission and its impact on prognosis. **Methods**: A total of 525 AMI patients were prospectively recruited and classified into 4 groups based on their clinical characteristics: excess-heat, excess-cold, deficiency-heat and deficiency-cold syndromes. Major adverse cardiovascular events (MACEs) were followed up. **Results**: The excess syndrome was more common than deficiency syndrome (72.95% *vs*. 27.05%; *P*<0.05). Totally 495 (94.29%) of 525 AMI patients were followed up (median 277 days). There were 59 (11.92%) MACEs. After adjusted with confounding factors in Cox regression models, the hazard ratio (95% confidence interval) of excess-heat, excess-cold, deficiency-heat and deficiency-cold syndrome groups were 1, 1.25 (0.63, 2.49; *P*<0.05), 2.37 (1.14, 4.94; *P*<0.05), 3.76 (1.71, 8.28; *P*<0.05), respectively. **Conclusions**: Excess syndrome was more common in AMI patients and had better prognosis, while deficiency-cold syndrome had the poorest prognosis. CM syndrome was of value in predicting long-term outcomes in AMI patients.

**KEYWORDS** acute myocardial infarction, Chinese medicine syndrome, prognosis

Acute myocardial infarction (AMI) is a common and serious disease with rigorously high morbidity and mortality. Modern medicine found that AMI was caused by the progression and rupture of coronary atherosclerotic plaque and acute thrombosis in the coronary artery, and all the patients were treated with antiplatelet agents, anticoagulants and statins, or thrombolysis or percutaneous coronary intervention (PCI) in some cases. Chinese medicine (CM) had documented AMI for a long time and recommended syndrome differentiation for treatment guidance. Different types of syndrome originating from different inner etiopathogenesis might result in different prognosis and deserve different treatments. However, the epidemiological data of different CM syndrome are unknown and its prognostic value needs investigating. Therefore, the present study prospectively observes the distribution of different CM syndromes in AMI patients on admission and their long-term prognosis.

## METHODS

### Study Population

From June 1, 2011 to May 31, 2012, all AMI patients admitted to Zhongshan Hospital, Fudan University were recruited. Unstable angina, subacute myocardial infarction were excluded. AMI was diagnosed according to Universal Definition of Myocardial Infarction.[1] The demographic data, diagnosis, CM syndrome information, biochemical parameters, complications, medicine as well as discharge diagnosis were recorded.

### Classification of CM Syndrome Status

AMI syndrome differentiation of CM was based on the "Accident and emergency specification of the chest heart pain (coronary heart disease, myocardial infarction)",[2] which was formulated by the Acute Collaborative Group Northeast Group in Medical Administrative Department of State Administration of Traditional Chinese Medicine. Based on CM syndrome diagnostic criteria, a score system for the definition of the CM syndrome was developed. The symptom was


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1. Department of Cardiology, Zhongshan Hospital, Fudan University, Shanghai (200032), China; 2. Department of Integrated Traditional and Western Medicine, Zhongshan Hospital, Fudan University, Shanghai (200032), China
Correspondence to: Prof. GE Jun-bo, Tel: 86-21-64041990 Ext. 2745, Fax: 86-21-64437078, E-mail: jbge@zs-hospital.sh.cn
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scored 4 if patients spoke it spontaneously; 3 if the symptom was severe or persistent; 2 if the symptom was severe but paroxysmal; 1 if the symptom was mild or occasional; and 0 if the symptom was not existed. The signs (including tongue-appearance and pulse manifestation) were also scored by severity according to an experienced CM doctor. The symptoms and signs of each CM syndrome were as follows.

(1) Deficiency syndrome: physical tiredness, mental fatigue, shortness of breath, chest tightness, pale white complexion, spontaneous perspiration, low voice, disinclination to talk, dull eyes, tender tongue, thinly coated tongue, and weak pulse. (2) Excess syndrome: full physical strength, mental excitement, vigorous breath, florid complexion, lustrous eyes, pain rejected pressing, rough tongue, thickly coated tongue, and strong pulse. (3) Cold syndrome: aversion to cold, cold limbs, thermophilic, tastelessness in the mouth, prefer warm beverages, loose stools, clear abundant urine, pale tongue, white tongue fur, and tight pulse. (4) Heat syndrome: aversion to heat, hot limbs, psychrophilic, bitter taste, prefer cool drinks, dry stool, scanty dark urine, purple-red tongue, yellowish tongue fur, and rapid pulse.

The recruited AMI patients were first classified into 2 classes: excess syndrome and deficiency syndrome, and then into 4 groups: excess-heat, excess-cold, deficiency-heat and deficiency-cold syndromes. CM syndrome of each patient was finally determined according to higher scores.

### Follow-up

Telephone or outpatient follow-up were performed after discharging periodically. Follow-up period was defined as the time between hospital admission and onset of major adverse cardiovascular events (MACEs). MACEs were defined as cardiac death, non-fatal myocardial re-infarction, non-fatal stroke and readmission due to heart disease.

### Covariables

Potential confounding factors include age, gender, smoking status, body mass index (BMI), hypertension, diabetes, dyslipidemia, AMI types [ST segment elevation myocardial infarction (STEMI) or non-ST segment elevation myocardial infarction (NSTEMI)] and target vessel revascularization (yes or no). In the present study, hypertension was defined as a systolic blood pressure (SBP) of at least 140 mm Hg or a diastolic blood pressure (DBP) at least 90 mm Hg, or current use of antihypertensive agents. Diabetes mellitus was defined as fasting blood glucose (FBG) more than 7.0 mmol/L (126 mg/dL), or current use of medication for diabetes. Dyslipidemia was defined as subjects having being diagnosed as dyslipidemia in the past (either treated or untreated), taking lipid-lowering drugs at present and blood sample test on admission meeting at least one of the following four conditions:[3] total cholesterol (TC) >5.18 mmol/L, triglycerides (TG) >1.70 mmol/L, low-density lipoprotein cholesterol (LDL-C) >3.37 mmol/L, high-density lipoprotein cholesterol (HDL-C) <1.04 mmol/L.

### Statistical Analysis

Summary statistics (means, standard deviation, and proportions) were used to characterize the study population. Survival curve was drawn using Kaplan-Meier method. Log-rank test and Cox proportional hazard models were used to compare MACEs-free survival rate of AMI patients with different CM syndromes and the long-term prognosis, respectively. All analyses were performed with Stata 10.0 and *P* values less than 0.05 were considered significant.

## RESULTS

### Characteristics of Study Population

A total of 554 admitted patients diagnosed as AMI were screened. Among them, 25 patients who refused to sign an informed-consent and 4 patients lacking CM syndrome information were excluded. Therefore, a total of 525 AMI patients were finally entered the present study, with 389 male patients (63.2 ± 11.0 years) and 136 female patients (72.2 ± 10.6 years). STEMI was present in 316 (60.19%) patients and NSTEMI in 209 (39.81%) patients, 339 patients (64.57%) were combined with hypertension, 152 (28.95%) with diabetes, 383 (72.95%) with dyslipdemia, 415 patients (79.00%) underwent emergency PCI, 13 patients (2.53%) underwent coronary artery bypass grafting (CABG), 97 patients (18.48%) merely received standardized medication and no patient received thrombolysis.

### Prevalence of CM Syndrome and Components CM Syndrome

There were 383 excess syndrome patients (72.95%) and 142 deficiency syndrome patients (27.05%). Constituent ratio of excess-heat, excess-

cold, deficiency-heat and deficiency-cold syndromes were 36.76%, 36.19%, 17.33%, 9.71%, respectively. Proportion of STEMI patients was higher in the excess syndrome group than that of the deficiency syndrome group (65.27% *vs*. 55.63%, *P*<0.05), while proportion of NSTEMI patients in the deficiency syndrome group was higher than that of the excess syndrome group (44.37% *vs*. 34.73%, Table 1, *P*<0.05), however, proportion of STEMI patients in the 4 CM syndromes was not significantly different (*P*=0.243, Table 2).

## Baseline Clinical Characteristics Stratified by CM Syndrome Status

The difference between excess syndrome group and deficiency syndrome group is shown in Table 1. In the deficiency syndrome group, diabetes were more common, N-terminal pro-brain natriuretic peptide (NT-proBNP), serum uric acid (UA), BMI and FBG levels were higher, while estimated glomerular filtration rate (eGFR) and left ventricular ejection fraction (LVEF) values were lower (all *P*<0.05).

Table 2 provided more clinical information for the 4 CM syndromes. Both BMI and LVEF were statistically different among groups (*P*<0.05).

## Prospective Relationship of CM Syndrome with Incident MACEs

A total of 495 (94.29%) patients were successfully followed up. The last follow-up time was February 8, 2013 and the median follow-up time was 277 days. There were 59 MACEs (11.92%) being defined as study group, while other 436 patients were control group.

The incidence of MACEs was lower in the excess syndrome group than that in the deficiency syndrome group (9.39% *vs*. 18.8%, *P*=0.004). Further analysis revealed that incidences of MACEs were 9.34%, 9.44%, 16.67%, 22.45% in the excess-heat, excess-cold, deficiency-heat, and deficiency-cold syndromes, respectively (*P*=0.027, Table 3).

The MACEs-free survival rate of the deficiency syndrome group was lower than that of the excess syndrome patients (*P*=0.001, Figure 1). The survival rate of the deficiency-cold syndrome group was lower than that of the excess-cold (*P*=0.037) and excess-heat (*P*=0.009) groups, while the rate of deficiency-heat syndrome group was lower than the excess-heat group (*P*=0.002, Figure 2).

**Table 1. Baseline Clinical Characteristics of Study Population Stratified by CM Syndrome Status ($\bar{x} \pm s$)**

| Item | Deficiency syndrome (142 cases) | Excess syndrome (383 cases) | *P*-value |
|---|---|---|---|
| Age (Year) | 65.7 ± 11.3 | 65.5 ± 11.7 | 0.833 |
| Male [Case (%)] | 102 (71.8) | 287 (74.9) | 0.471 |
| Smoking [Case (%)] | 65 (45.8) | 198 (51.7) | 0.228 |
| Hypertension [Case (%)] | 95 (66.9) | 244 (63.7) | 0.497 |
| Diabetes [Case (%)] | 51 (35.9) | 101 (26.4) | 0.032 |
| Dyslipdemia [Case (%)] | 109 (76.8) | 274 (71.5) | 0.700 |
| BMI (kg/m$^2$) | 25.5 ± 3.8 | 24.3 ± 3.2 | <0.001 |
| FBG (mmol/L) | 8.5 ± 4.1 | 7.3 ± 3.0 | <0.001 |
| TC (mmol/L) | 4.44 ± 1.02 | 4.39 ± 1.16 | 0.675 |
| TG (mmol/L) | 1.56 ± 0.77 | 1.68 ± 1.20 | 0.252 |
| LDL-C (mmol/L) | 2.67 ± 0.91 | 2.56 ± 0.86 | 0.232 |
| HDL-C (mmol/L) | 1.05 ± 0.29 | 1.09 ± 0.37 | 0.350 |
| cTnT (ng/mL) | 1.33 (0.58–3.87) | 1.40 (0.50–3.00) | 0.516 |
| NT-proBNP (pg/mL) | 1239 (652–3104) | 1145 (526–2259) | 0.037 |
| hs-CRP (mg/L) | 8.5 (5.4–27.8) | 7 (5.4–23.0) | 0.531 |
| UA (μmol/L) | 348 ± 127 | 321 ± 91 | 0.008 |
| eGFR [mL/(min•1.73 m$^2$)] | 78.5 ± 31.5 | 87.6 ± 29.7 | 0.002 |
| LVEF [Case (%)] | 50.7 ± 12.2 | 54.7 ± 10.0 | <0.001 |
| STEMI [Case (%)] | 79 (55.63) | 250 (65.3) | 0.043 |
| Coronary revascularization* [Case (%)] | 115 (81.0) | 313 (81.7) | 0.847 |

Note: *Including PCI and CABG

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**Table 2. Baseline Clinical Characteristics of Different CM Syndromes ($\bar{x} \pm s$)**

| Item | Excess-heat (193 cases) | Excess-cold (190 cases) | Deficiency-heat (91 cases) | Deficiency-cold (51 cases) | *P*-value |
|---|---|---|---|---|---|
| Age (Year) | 65.4 ± 12.0 | 65.6 ± 11.3 | 64.4 ± 11.0 | 68.1 ± 11.5 | 0.422 |
| Male [Case (%)] | 140 (72.5) | 147 (77.4) | 70 (76.9) | 32 (62.6) | 0.164 |
| Smoking [Case (%)] | 102 (52.9) | 96 (50.5) | 43 (47.3) | 22 (43.1) | 0.597 |
| Hypertension [Case (%)] | 119 (61.7) | 125 (65.8) | 57 (62.6) | 38 (74.5) | 0.497 |
| Diabetes [Case (%)] | 54 (28.0) | 47 (24.7) | 34 (37.4) | 17 (33.3) | 0.149 |
| Dyslipdemia [Case (%)] | 139 (72.0) | 135 (71.1) | 72 (79.1) | 37 (72.6) | 0.534 |
| BMI (kg/m$^2$) | 24.4 ± 3.4 | 24.1 ± 2.9 | 25.5 ± 3.6 | 25.5 ± 4.2 | 0.004 |
| FBG (mmol/L) | 7.2 ± 2.7 | 7.3 ± 3.3 | 8.4 ± 4.1 | 8.8 ± 4.1 | 0.082 |
| TC (mmol/L) | 4.45 ± 1.32 | 4.33 ± 0.99 | 4.41 ± 0.96 | 4.50 ± 1.12 | 0.628 |
| TG (mmol/L) | 1.74 ± 1.50 | 1.63 ± 0.80 | 1.61 ± 0.79 | 1.46 ± 0.72 | 0.327 |
| LDL-C (mmol/L) | 2.57 ± 0.87 | 2.55 ± 0.85 | 2.71 ± 0.90 | 2.60 ± 0.94 | 0.603 |
| HDL-C (mmol/L) | 1.10 ± 0.41 | 1.08 ± 0.32 | 1.01 ± 0.25 | 1.13 ± 0.33 | 0.222 |
| cTnT (ng/mL) | 1.43 (0.52–3.03) | 1.40 (0.50–2.93) | 1.39 (0.52–3.67) | 1.20 (0.62–4.69) | 0.922 |
| NT-proBNP (pg/mL) | 1202 (526–2394) | 1060 (537–1923) | 1237 (652–2992) | 1446 (628–4537) | 0.152 |
| hs-CRP (mg/L) | 6.7 (5.4–22.5) | 7.8 (5.4–23.0) | 7.4 (5.0–23.8) | 9.3 (5.4–30.7) | 0.644 |
| UA (μmol/L) | 323 ± 97 | 319 ± 85 | 349 ± 130 | 347 ± 124 | 0.271 |
| eGFR [mL/(min•1.73 m$^2$)] | 87.3 ± 25.7 | 87.9 ± 33.4 | 80.9 ± 30.7 | 74.2 ± 32.7 | 0.108 |
| LVEF [Case (%)] | 53.9 ± 11.0 | 55.5 ± 9.0 | 50.4 ± 12.7 | 51.4 ± 11.5 | 0.029 |
| STEMI [Case (%)] | 125 (64.8) | 125 (65.8) | 51 (56.0) | 28 (54.9) | 0.243 |
| Coronary revascularization* [Case (%)] | 154 (79.8) | 159 (83.7) | 74 (81.3) | 41 (80.4) | 0.847 |

Note: *Including PCI and CABG

**Table 3. MACEs Incidence and Cox Regression Test for AMI Patients with Different CM Syndromes**

| Syndrome | Case | MACE (59 Cases) | | | | HR (95% CI) | | |
|---|---|---|---|---|---|---|---|---|
| | | Cardiac death | Re-MI | Stroke | Re-admission | Incidence (%) | Unadjusted | Adjusted* |
| Excess-heat | 182 | 7 | 2 | 1 | 7 | 9.34 | 1 | 1 |
| Excess-cold | 180 | 5 | 3 | 3 | 6 | 9.44 | 1.02 (0.52, 2.01) | 1.25 (0.63, 2.49) |
| Deficiency-heat | 84 | 7 | 2 | 1 | 4 | 16.67 | 1.99 (0.98, 4.04) | 2.37 (1.14, 4.94) |
| Deficiency-cold | 49 | 4 | 3 | 1 | 3 | 22.45 | 3.09 (1.44, 6.61) | 3.76 (1.71, 8.28) |

Notes: *adjusted for age, gender, smoking status, hypertension, diabetes, dyslipidemia, BMI, AMI types and coronary revascularization

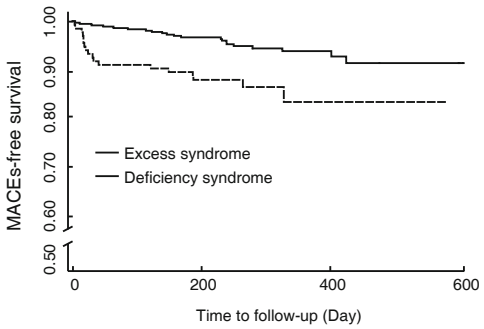


**Figure 1. Comparison of the MACEs-Free Survival Curves of Deficiency and Excess Syndromes in AMI Patients**

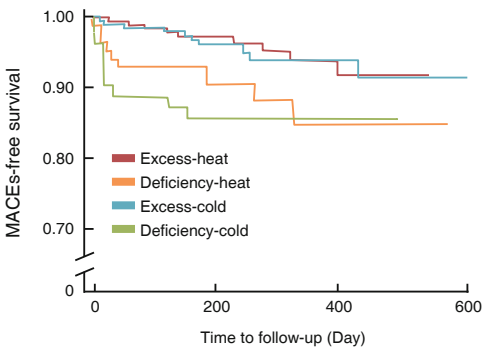


**Figure 2. Comparison of the MACEs-Free Survival Curves of Different CM Syndromes in AMI Patients**

Notes: Excess-heat *vs*. deficiency-heat, *P*=0.037; excess-heat *vs*. excess-cold, *P*=0.787; excess-cold *vs*. deficiency-cold, *P*=0.009; deficiency-heat *vs*. deficiency-cold, *P*=0.366; excess-heat *vs*. deficiency-cold, *P*=0.002; excess-cold *vs*. deficienc-heat, *P*=0.081

The excess-heat, excess-cold, deficiency-heat and deficiency-cold syndromes were regarded as dummy variables and were together introduced

into the Cox regression model. The hazard ratio (HR) of excess-heat, excess-cold, deficiency-heat and deficiency-cold syndrome groups was 1, 1.02 (0.52–2.01), 1.99 (0.98–4.04), 3.09 (1.44–6.61), respectively. After adjusted with confounding factors mentioned above, the HR value of each group was 1, 1.25 (0.63–2.49), 2.37 (1.14–4.94), 3.76 (1.71–8.28), respectively (Table 3).

## DISCUSSION

The differentiation and description of the characteristics of AMI has long been documented in CM. AMI was once termed as "Zhen Xin Tong", "Jue Xin Tong" or "Xin Bi" since ancient times. Several types of CM syndrome and their diagnosis criteria was formulated in 1995 by the State Administration of Traditional Chinese Medicine,[2] which included qi stagnation and blood stasis, phlegm stagnation, yin-blood deficiency and yang-qi deficiency. Some scholars put forward other kinds of syndromes according to their own clinical experience. However, all the above AMI syndrome differentiations were Zang-Fu differentiation, and had overlapped among each syndrome, which were also dependent on personal experience, thus leading to the lack of an objective CM criterion and also making it uneasy to practice.[4-7]

In the present study, we proposed a new classification based on the differentiation of the eight principles. For each AMI patient, we first discriminated excess syndrome or deficiency syndrome, then we discriminated heat syndrome or cold syndrome to make it more detailed. During the course of differentiation, we scored each clinical symptom or sign in order to quantify each CM syndrome. Therefore, two basic classes of AMI patients were excess syndrome and deficiency syndrome, 4 basic syndromes were excess-heat, excess-cold, deficiency-heat and deficiency-cold syndromes. This kind of differentiation was less subjective and more practical.

Although there are increasing researches about CM syndrome differentiation for AMI, few prospective studies were reported about the correlation between CM syndrome and long-term prognosis, so the impact of syndrome differentiation on the prognosis of AMI patients has not been clarified. Lin, et al[8] investigated MACEs in 142 AMI patients during their hospitalization, by using logistic regression analysis, they found that patients with qi-stagnation and blood-stasis were liable to arrhythmia, whereas patients with yang-qi deficiency were confronted with a higher risk of cardiac death during hospitalization. Li, et al[9] studied 194 AMI patients to find out the relationship between pathogenesis for yin-deficiency of AMI and immediate prognosis as well as its neuro-endocrine mechanism. They discovered that patients with AMI of yin-deficiency type was severer in myocardial damage, with longer hospitalization period and higher mortality, it is probably due to the hyper-activated sympathetic-adrenaline system and strengthened activity of aldosterone in them. However, the present study demonstrated that long-term prognosis of deficiency syndrome (especially deficiency-cold syndrome) was poorer than excess syndrome, the probable mechanism was that long-term activation of sympathetic-adrenaline system promoted myocardial remodeling, this process was beneficial for cardiac output in the early days, while latterly it enlarged the heart, weakened the myocardium, decreased the LVEF and so on, all of which would finally lead to chronic heart failure and increase mortality.

In the present study, we found the baseline clinical characteristics of excess syndrome and deficiency syndrome are different. The proportion of STEMI patients was higher in the excess syndrome group, while proportion of NSTEMI patients was higher in deficiency syndrome group. In the deficiency group, diabetes were more common, the level of NT-proBNP, serum UA and fast FBG levels were higher, and eGFR and LVEF values were lower. These differences contributed to the different prognosis of the two differentiation groups, with the worse prognosis in the deficiency syndrome group. We further studied the deficiency-cold syndrome group that had the highest MACEs and the lowest MACEs-free survival rate among 4 CM syndromes. When Cox proportional hazard model was introduced in the study, no matter before and after adjusting the confounding factors, the HR value of deficiency-cold syndrome were 3.09 and 3.76, hence we concluded that deficiency-cold syndrome was the worst CM syndrome of the long-term prognosis of AMI patients. This finding strongly implied that the differentiation of CM syndrome is of great value in predicting the prognosis of AMI patients.

Zhang, et al[10] compared the difference of

differentiation of CM syndromes before and after PCI operation in 116 AMI patients and found that excess syndrome including blood-stasis, cold-coagulation and phlegm-stagnation were obviously improved about 1 week after PCI procedure, whereas deficiency syndrome such as qi-deficiency and yin-deficiency were aggravated. This finding implicated the CM syndrome differentiation in AMI patients could change and might carry different clinical significance. In the present study, 79.00% of AMI patients received PCI operation and 2.53% received CABG operation, therefore, patients received coronary revascularization procedures needed adjuvant CM therapy with warming and recuperating the Heart (Xin)-yang prescriptions which underscored the importance of further CM treatment researches.

The present study had several limitations: (1) AMI patients were classified into 4 CM syndromes according to our own standards, but the sample size of each syndrome was relatively small; (2) we discovered that deficiency-cold syndrome had the worst prognosis, yet follow-up course was relatively short. Therefore, all the limitations underscore the importance of further studies with more patient numbers as well as longer follow-up time.

In conclusion, a new CM syndrome differentiation criterion was proposed. We found that the excess syndrome was more common than deficiency syndrome in AMI patients, while deficiency syndrome patients presented a poorer prognosis, especially, with deficiency-cold syndrome the poorest group. CM syndrome was of value in predicting long-term outcomes in AMI patients.

## Conflict of Interest

The authors declare no conflict of interests.

## Author Contributions

Ge JB and Zhou JM conceived and designed the experiments. Fan Y, Zhu HM, FU Ming-qiang and Zhu LT performed the experiments. Jin XJ and Cui XT analyzed the data. Cai DF and Fan Y provided technical support. Zhu HM wrote the paper. Zhou JM revised the paper. Zhu HM and Zhou JM contributed equally to this work.

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