

## 论著·临床研究

## 临床衰弱指数对急性心肌梗死患者在院心脏康复后远期预后的预测价值

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**[摘要]** **目的**·探讨临床衰弱指数 (Clinical Frailty Scale, CFS) 对急性心肌梗死 (acute myocardial infarction, AMI) 患者在院心脏康复 (cardiac rehabilitation, CR) 后远期预后的预测价值。**方法**·序贯纳入 2020 年 5 月至 2022 年 5 月在上海交通大学医学院附属第六人民医院心脏中心接受诊治的 501 例 AMI 患者。采集患者基本临床信息, 制定分级在院 CR 方案。根据患者出院前的 CFS 等级将患者分为 3 组, 即正常 (norm) 组、脆弱 (vulnerable) 组和衰弱 (frail) 组, 比较 3 组患者 1 年主要心血管事件率, 包括全因死亡率及心力衰竭 (心衰) 再住院率。采用 Logistic 回归分析研究影响主要心血管事件率的危险因素, 通过受试者操作特征 (receiver operator characteristic, ROC) 曲线分析各危险因素对主要心血管事件率的预测价值, 建立最佳风险预测模型。**结果**·AMI 患者在院 CR 后衰弱程度与高龄、B 型利钠肽前体峰值 (peak pro-B-type natriuretic peptide, peak proBNP) 呈正比, 与性别差异呈反比 ( $P<0.05$ )。随患者衰弱程度增加, 两种事件率均增高; 其中全因死亡率 (分别为 2.6%、5.6%、15.2%) 的组间差异有统计学意义 ( $P=0.002$ ), 心衰再住院率 (分别为 19.6%、22.2%、24.2%) 的组间差异无统计学意义。两两比较, frail 组全因死亡率显著高于 norm 组 ( $P=0.004$ ), 但 vulnerable 组与 norm 组的差异无统计学意义。CFS 分级能够敏感预测 AMI 患者 1 年后的全因死亡风险 ( $\beta=1.89$ ,  $OR=6.61$ ,  $P=0.001$ ), 且叠加 CFS 分级的风险模型预测效应最佳 ( $AUC=0.845$ ,  $P=0.000$ )。**结论**·接受在院 CR 的 AMI 患者出院前进行 CFS 分级, 有助于识别 1 年内全因死亡风险较高的人群。

**[关键词]** 急性心肌梗死; 在院心脏康复; 临床衰弱指数; 主要心血管事件率; 全因死亡**[DOI]** 10.3969/j.issn.1674-8115.2024.05.008 **[中图分类号]** R541.4 **[文献标志码]** A

## Predictive value of Clinical Frailty Scale in long term prognosis of patients with acute myocardial infarction after in-hospital cardiac rehabilitation

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**[Abstract]** **Objective**·To investigate the predictive value of the Clinical Frailty Scale (CFS) in the long term outcomes in acute myocardial infarction (AMI) patients who completed in-hospital cardiac rehabilitation (CR). **Methods**·A total of 501 AMI patients treated in the Cardiology Center of Shanghai Sixth People's Hospital, Shanghai Jiao Tong University of Medicine from May 2020 to May 2022 were prospectively enrolled, with their baseline clinical data collected. The patients completed graded in-hospital CR and were assessed by CFS based on their completion of CR before discharge. Patients were then categorized into three groups (norm group, vulnerable group and frail group) according to their CFS level. The difference in 1-year major cardiovascular event (all-cause death and re-hospitalization for heart failure) rates among the three groups was investigated. Logistic regression analysis was performed to explore the effective risk factors relevant to the outcomes, and receiver operator characteristic (ROC) curves were generated to analyze the prognostic value. Finally, an optimal prediction model was developed. **Results**·The CFS level in AMI patients who completed CR was positively correlated with age and peak pro-B-type natriuretic peptide (peak proBNP), and inversely correlated with gender difference ( $P<0.05$ ). Accompanied with the elevated CFS level, the incidence of both outcomes increased,

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and there were significant differences in all-cause death (2.6%, 5.6% and 15.2%,  $P=0.002$ ), and while no significant differences in re-hospitalization for heart failure among the three groups (19.6%, 22.2% and 24.2%). All-cause death of the frail group was significantly higher than that of the norm group ( $P=0.004$ ), while there was no significant difference between the vulnerable group and the norm group. CFS could sensitively predict the 1-year all-cause death in AMI patients ( $\beta=1.89$ ,  $OR=6.61$ ,  $P=0.001$ ), and the risk model combined with CFS had the best predictive effect ( $AUC=0.845$ ,  $P=0.000$ ). **Conclusion** Assessment by CFS in AMI patients who completed in-hospital CR contributes to identifying AMI patients with high risk of all-cause death in 1 year.

**[Key words]** acute myocardial infarction (AMI); in-hospital cardiac rehabilitation; Clinical Frailty Scale (CFS); major cardiovascular event; all-cause death

随着人口老龄化的加剧和代谢紊乱综合征发病率的升高, 心血管疾病 (cardiovascular disease, CVD) 的发病率和死亡率持续增高, 2020 年分别占我国农村、城市人口死因的 48.00% 和 45.86%, 居首位<sup>[1]</sup>。高龄人群往往基础状态更衰弱且合并多种疾病, 因此 CVD 的发病率和死亡率更高<sup>[2-5]</sup>。衰弱是一种以生物储备减少为特征的综合征, 表现为应激事件后人体稳态调节能力下降<sup>[6-7]</sup>。这也意味着在面对急性心血管事件, 如急性心肌梗死 (acute myocardial infarction, AMI) 发生后, 衰弱人群的预后更差。多项随机对照试验证实衰弱人群发生 AMI 后, 近期和远期心血管事件发生率更高<sup>[8-12]</sup>。

随着急诊再血管化和优化药物治疗方案的普及, AMI 患者整体预后得到普遍改善, 其中衰弱患者受益更多, 生活质量和心血管事件发生率都得到明显改善<sup>[13-14]</sup>。目前, 关于衰弱状态的评价缺乏公认、权威的统一标准<sup>[2,15]</sup>。2023 年欧洲心脏病学会的急性冠脉综合征 (acute coronary syndrome, ACS) 指南推荐临床衰弱等级 (Clinical Frailty Scale, CFS) 量表用于评价患者衰弱程度, 并依据疾病风险和患者衰弱程度, 制定个性化的治疗方案 (I 类推荐, B 类证据)<sup>[2]</sup>。CFS 量表是 2005 年由 ROCKWOOD 等<sup>[16]</sup> 在加拿大健康与老龄化研究的第二次随访中提出的, 经过多次修正, 将评估对象的衰弱程度评为 1~9 级, 其中 1~3 级代表健康、有活力, 4~5 级代表脆弱性增加, 6~9 级代表衰弱。2017 年在 5 家瑞典医院的 SWEDEHEART 注册研究中引入 CFS 量表, 2020 年其成为所有医院的强制性量表<sup>[14]</sup>。EKERSTAD 等对 3 381 例 AMI 患者的注册研究发现, CFS 等级与短期的心血管事件率相关<sup>[14]</sup>; 对 307 例非 ST 段抬高 AMI 患者的随机对照试验发现, CFS 等级与 1 年、5 年的心血管事件率相关<sup>[17]</sup>。

心脏康复 (cardiac rehabilitation, CR) 是根据 CVD 患者的年龄、衰弱程度、危险分层及合并症情

况, 由专业的 CR 团队制定并实施个性化康复方案, 内容包括心血管相关危险因素的评估与管理、运动处方制定、膳食咨询、戒烟咨询、患者教育、社会心理因素管理和重返职业<sup>[18-19]</sup>。2023 年欧洲心脏病学会的 ACS 指南再次将 CR 作为 AMI 患者二级预防中最有效且经济效益最佳的医疗方式 (I 类推荐, A 类证据)<sup>[2]</sup>。研究显示, CR 能改善患者衰弱程度<sup>[19-23]</sup>, 并降低心血管事件率<sup>[21,24-26]</sup>。相关指南推荐所有适合的 AMI 患者均应进行早期下床活动 (II a 类推荐)<sup>[18-19]</sup>。本中心的前期研究<sup>[27]</sup> 已证实, AMI 患者早期在院 CR 是安全、可行的, 且能有效缩短住院时间。准确识别预后不佳的高风险患者, 指导个体化治疗和降低远期心血管事件率仍是临床工作的重点。本次前瞻队列研究对成功再血管化的 AMI 患者, 进行在院 CR; 出院前采用 CFS 量表评估并分级, 随访 1 年后的主要心血管事件, 包括全因死亡及心力衰竭 (心衰) 再住院率, 探讨 CFS 分级对识别优化药物及介入治疗后仍具有不良预后风险的 AMI 人群的价值。

## 1 对象与方法

### 1.1 患者一般资料

序贯入组 2020 年 5 月 1 日至 2022 年 5 月 31 日在上海交通大学医学院附属第六人民医院内科就诊并成功接受急诊经皮冠状动脉介入治疗 (primary percutaneous coronary intervention, PPCI) 的 AMI 患者。

### 1.2 纳入与排除标准

AMI 患者纳入标准<sup>[28]</sup>: ① 出现典型的缺血性胸痛症状, 伴或不伴有心电图动态改变, 如相应导联 ST 段抬高或下移, T 波倒置或新发的左束支传导阻滞。② 心肌坏死标志物浓度动态改变。排除标准:

① 血流动力学不稳定。② 合并陈旧性心肌梗死、活动性心肌炎、心肌病、严重的心瓣膜病等。③ 合并严重感染、恶性肿瘤等影响短期预后的疾病。共纳入552例AMI患者,1年后通过门诊及电话对患者是否发生主要心血管事件(全因死亡及心衰再住院)进行随访。心衰再住院定义为以心衰加重为主要原因的入院,需要静脉使用利尿剂、血管活性药物治疗。

### 1.3 患者信息采集

采集患者基本信息,包括年龄、性别、体质量指数(body mass index, BMI)、基础疾病(高血压、糖尿病)、吸烟史、饮酒史、住院期间心肌酶I峰值(peak cardiac troponin I, peak cTnI)和B型利钠肽前体峰值(peak pro-B-type natriuretic peptide, peak proBNP)浓度,其中proBNP及cTnI的采集时间点为患者入院即刻、PPCI后24 h内每6 h 1次及24 h后每

日1次。

### 1.4 CR方案及患者分组

根据相关指南<sup>[2,18-19,29]</sup>,在院CR启动标准:① PPCI治疗后8 h无新发或再发胸痛。② 过去8 h无新发心律失常或心电图改变。③ 心肌损伤标志物浓度无进一步升高。④ 无明显心衰失代偿表现。经CR小组评估,决定患者是否进行CR及康复方案。在院CR方案分为4级,从床上活动逐步过渡至下床独立步行(表1)。根据患者出院前最后一次康复情况,按照CFS量表分级标准,将患者分为3组,其中1~3级为正常(norm)组,4级为脆弱(vulnerable)组,5~9级为衰弱(frail)组。整个CR过程中,均对患者进行心电活动、血压、指脉氧饱和度监护。在院CR提前终止标准:低血压、心率上升>40次/min,心电图ST段改变、恶性心律失常、指脉氧饱和度<90%、胸闷胸痛、头晕、跌倒等。

表1 AMI患者在院CR方案及对应CFS分组

Tab 1 In-hospital CR program for AMI patients and its corresponding CFS group

CR grade	CR place	CR training	CR progression test	CFS group
1	Bed	Active/passive ROM exercise; breathing exercise; sitting position	Able to perform ROM exercise in sitting position	Frail
2	Bedside	Active transfer to chair; chair sitting ROM exercise; ambulation along bedside	Able to stand for 2 min	Vulnerable
3	Ward	Ambulation with telemetry monitor, 10 min, twice a day	Able to walk for 200 m	Norm
4	Ward	Ambulation without telemetry monitor, 10 min, 2-3 times a day	Able to walk for 500 m	Norm

Note: ROM—range of motion.

### 1.5 统计学方法

采用SPSS 26.0软件进行统计学分析,定量资料采用Kolmogorov-Smirnov法进行正态性检验,符合正态分布的定量资料以 $\bar{x}\pm s$ 表示,组间比较采用单因素方差分析;不符合正态分布的定量资料以 $M(Q_1, Q_3)$ 表示,组间比较采用Mann-Whitney  $U$ 检验。定性资料以 $n(\%)$ 表示,并采用 $\chi^2$ 检验或Fisher确切概率法进行组间比较。将影响患者预后的危险因素纳入单因素Logistic回归分析,计算OR值和95%CI。绘制受试者操作特征(receiver operator characteristic curve, ROC)曲线,并计算曲线下面积(area under the curve, AUC)评价相关指标对终点事件的诊断效能。 $P<0.05$ 表示差异有统计学意义。

## 2 结果

### 2.1 基线数据比较

共纳入552例AMI患者,失访51例(9.2%),最终纳入接受在院CR的AMI患者501例,其中norm组342例(68.3%),vulnerable组126例(25.1%),frail组33例(6.6%)。3组患者的年龄、性别、peak proBNP比较,差异具有统计学意义( $P<0.05$ )。根据CFS分级,越衰弱的人群,年龄、peak proBNP越高,性别差异越小。随患者衰弱程度增加, BMI及peak cTnI呈下降趋势,糖尿病患病率升高,吸烟及饮酒者的占比减小,但差异均无统计学意义。3组患者中,吸烟者均多于不吸烟者,男性均多于女性。详见表2。



表2 不同CFS组别AMI患者基线资料

Tab 2 Baseline data of AMI patients grouped by CFS

Variable	Norm (n=342)	Vulnerable (n=126)	Frail (n=33)	Overall (n=501)	P value
Age/year	59.9±12.2	66.4±12.4	70.5±13.7	62.2±12.8	0.000
Male/n (%)	296 (86.5)	93 (73.8)	23 (69.7)	412 (82.2)	0.001
BMI/(kg·m <sup>-2</sup> )	24.9±3.5	24.8±3.4	24.1±3.6	24.9±3.5	0.386
Peak proBNP/(ng·L <sup>-1</sup> )	1 024 (448, 2 107)	1 840 (807, 3 650)	2 767 (1 020, 5 993)	1 140 (523, 2 820)	0.000
Peak cTnI/(μg·L <sup>-1</sup> )	30.0 (9.0, 93.0)	30.0 (6.8, 92.6)	25.5 (8.7, 97.7)	29.8 (8.3, 93.3)	0.862
Diabetes/n (%)	116 (33.9)	51 (40.5)	14 (42.4)	181 (36.1)	0.313
Hypertension/n (%)	201 (58.8)	88 (69.8)	23 (69.7)	312 (62.3)	0.060
Smoking/n (%)	233 (68.1)	73 (57.9)	18 (54.5)	324 (64.7)	0.056
Drinking/n (%)	112 (32.7)	30 (23.8)	7 (21.2)	149 (29.7)	0.093

2.2 组间主要心血管事件率比较

随着患者衰弱程度增大,AMI后1年的总体心血管事件率升高,但差异无统计学意义。3组患者1年的全因死亡率分别为2.6%、5.6%、15.2%,差异有统计学意义( $P=0.002$ );其中frail组全因死亡率最高,

frail组与norm组的差异有统计学意义( $P=0.004$ ),vulnerable组与norm组的差异无统计学意义( $P=0.150$ )。3组患者随衰弱程度增大,心衰再住院率升高,但差异无统计学意义。详见表3。

表3 主要心血管事件率组间比较

Tab 3 Intergroup comparison of major cardiovascular event rates among the three groups

Variable	Norm/n (%)	Vulnerable/n (%)	Frail/n (%)	P value
Overall events	76 (22.2)	35 (27.8)	13 (39.4)	0.061
All-cause death	9 (2.6)	7 (5.6)	5 (15.2) <sup>①</sup>	0.002
Re-hospitalization for heart failure	67 (19.6)	28 (22.2)	8 (24.2)	0.710

Note: <sup>①</sup> $P=0.004$ , compared with the norm group.

2.3 Logistic回归分析全因死亡的危险因素

将全因死亡设为因变量,年龄、性别、BMI、心肌损伤标志物峰值浓度、基础疾病、吸烟史、饮酒史及CFS分级为自变量,进行单因素Logistic回归分析。结果显示peak proBNP及frail组是发生全因死亡的危险因素( $\beta=0.00$ ,  $OR=1.01$ ,  $P=0.000$ ;  $\beta=1.89$ ,  $OR=6.61$ ,  $P=0.001$ ),frail组较norm组风险升高5.61倍( $P=0.001$ ),vulnerable组较norm组风险升高1.18倍( $P=0.131$ ),见表4。

2.4 不同风险模型预测全因死亡的ROC曲线

分别将peak proBNP、CFS分级纳入Logistic单危险因素模型,绘制全因死亡的ROC曲线,计算AUC。Peak proBNP的AUC为0.824(95%CI 0.718~0.929,  $P=0.000$ );在peak proBNP叠加CFS分级后,预测效应更佳,AUC升高至0.845(95%CI 0.761~0.930,

表4 全因死亡率的单因素Logistic回归分析

Tab 4 Univariate Logistic regression of all-cause death

Variable	$\beta$	SE	OR (95% CI)	P value
Age	0.02	0.02	1.03 (0.99–1.06)	0.180
BMI	-0.11	0.07	0.90 (0.78–1.03)	0.122
Peak cTnI	0.00	0.00	1.00 (1.00–1.00)	0.728
Peak proBNP	0.00	0.00	1.01 (1.01–1.01)	0.000
Female	-0.65	0.50	0.52 (0.20–1.39)	0.193
Diabetes	-0.50	0.45	0.61 (0.25–1.46)	0.267
Hypertension	0.43	0.49	1.54 (0.59–4.04)	0.380
Smoking	-0.53	0.45	0.59 (0.24–1.41)	0.234
Drinking	-0.06	0.49	0.94 (0.36–2.48)	0.905
Vulnerable (compared to norm)	0.78	0.52	2.18 (0.79–5.97)	0.131
Frail (compared to norm)	1.89	0.59	6.61 (2.07–21.06)	0.001

$P=0.000$ )。详见图1。



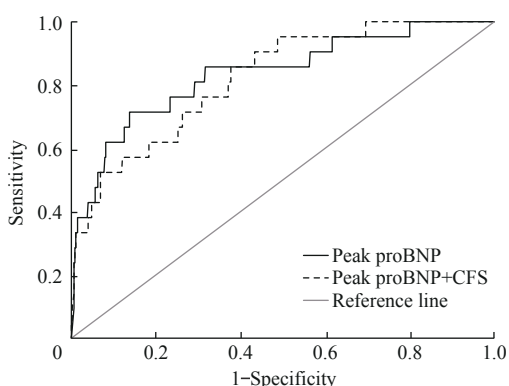


图1 不同风险模型预测全因死亡率的ROC曲线

Fig 1 ROC curves for prediction of all-cause death by different risk models

### 3 讨论

本中心在国内率先开展AMI患者的在院CR。前期研究已发现,对接受PPCI治疗8 h后的AMI患者进行评估,并实施个性化的在院CR方案,协助患者早期锻炼,能有效提高患者活动能力,缩短住院时间,而且是安全的<sup>[27]</sup>。该结果与YNDIGEGN等<sup>[30]</sup>和SETO等<sup>[31]</sup>的研究结论一致。在国内规范开展早期在院CR的研究中,本次队列研究纳入的AMI患者规模较大,且引用了国际推荐的CFS量表进行衰弱状态评价。本研究序贯入组501例成功实施PPCI的AMI患者,制定4个级别的在院CR方案,并于出院前进行CFS分级以期识别高危患者,指导制定临床策略。人群数据特征契合临床,患者年龄较大,男性占比、高血压患病率及吸烟率均过半,BMI>24 kg/m<sup>2</sup>,证实年龄、性别、代谢相关疾病(高血压、超重及肥胖)、吸烟是AMI的危险因素;此外,frail组人群特征表现出高龄、性别差异小、糖尿病及高血压的患病率高,证实高龄及合并症是衰弱的危险因素。以上结论与EKERSTAD等<sup>[14]</sup>对AMI患者进行CFS分级的研究结论相符。本研究还发现,越衰弱的人群,peak proBNP越高,并且按peak proBNP三分位后,peak proBNP与全因死亡率呈正相关。LI等<sup>[32]</sup>多次监测PCI后患者不同时段proBNP,发现proBNP越高,全因死亡率、心衰再住院率、再发心肌梗死事件率越高。本研究结果与之相符。此外,在本研究中,peak cTnI与患者衰弱程度无明显相关性;且将cTnI三分位后,3组的全因死亡率无显著差异。而对男性CVD患者的随访研究<sup>[33]</sup>发现,cTnI与3年内发展至

衰弱状态及死亡率显著相关,这可能是患者群及治疗策略的差异导致的。本中心对AMI患者进行临床治疗策略规范及优化,包括及时血管再通、优化药物治疗及早期在院CR,改善了患者的衰弱情况。多项研究<sup>[20-23]</sup>亦发现,CR能改善患者衰弱程度。

鉴于AMI急性应激的影响,有研究推荐进行CFS评价时依据患者发病前2周的情况。但考虑到患者及家属很难作出准确的回顾性分析,本研究在患者进行早期在院CR后、出院前这一相对稳定的时刻,利用CFS量表对AMI患者行危险分层。结果发现,越衰弱的患者远期事件率越高,frail组与norm组存在显著差异,且frail组是全因死亡的有效预测因素,该组患者风险提升5.61倍,而peak proBNP对风险的预测因素仅提升0.01倍。这一结果与EKERSTAD等<sup>[14]</sup>发现AMI患者中frail组较norm组全因死亡风险显著升高相一致,该研究发现vulnerable组较norm组全因死亡率显著提升;而本研究并未发现2组总体事件率有显著差异,可能因为本研究中在院CR有效改善了vulnerable组的预后。这一现象契合了ROCKWOOD等<sup>[16]</sup>在2020年的修订CFS分级中单独列出4~5级并评价为vulnerable组的设定,意在预警这类人群存在衰弱程度进一步恶化的风险。当然,这有待进一步的对照研究证实。临床医师需重点关注这类患者,vulnerable组是不良预后的警示组,应对这类人群进行治疗策略优化。

在peak proBNP这一传统公认的预后相关因素的基础上叠加CFS分级建立危险因素模型,提升了对AMI患者全因死亡的预测效应,进一步验证了早期在院CR及CFS分级的临床价值。在院CR虽已被欧美指南推荐作为ACS二级预防的首要方式,但其规范与普及仍有待加强<sup>[2,18-19]</sup>。CFS分级易于临床操作,已被欧洲心脏病学会及美国心脏学会推荐为首选识别和评估ACS衰弱人群的方式,有待临床进一步推广。

综上所述,本研究对AMI患者进行分级在院CR训练,利用CFS量表对患者进行出院前衰弱状态评价,研究CFS分级与AMI患者1年预后的关系。期望本研究能够提醒各心脏中心更积极地实施在院CR,并利用CFS量表有效地识别具有较高不良预后风险的AMI患者,从而更精准地制定临床干预策略。

本研究尚存不足。本研究仅为单中心研究,研究

期限1年,而针对CVD这一慢性疾病的预后观察时间仍需延长。此外,患者入院前或随访时未对其进行CFS评价及研究CFS的动态变化,后续可进一步探讨个体不同时段衰弱情况的变化是否与预后有着更密切的关联。随着本中心CR的普及,可开展与未实施CR人群的对照研究,以期更全面地论证CR对AMI患者预后的改善程度。

#### 利益冲突声明/Conflict of Interests

所有作者声明不存在利益冲突。

All authors disclose no relevant conflict of interests.

#### 伦理批准和知情同意/Ethics Approval and Patient Consent

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The study were reviewed and approved by Ethics Committee of Shanghai Sixth People's Hospital, Shanghai Jiao Tong University School of Medicine with Approval Letter No. 2020-278-(1)(dated 08/

02/2021).Consent letters have been signed by the research participants or their relatives.

#### 作者贡献/Authors' Contributions

刘雨婷、潘静薇、俞莞琦、李歆旻参与了研究设计,俞莞琦、洪雯参与了康复方案制定与实施,刘雨婷、旦增曲央、肖活源参与了数据收集,刘雨婷、李歆旻、康桑参与了数据处理,刘雨婷负责文章撰写,潘静薇负责统计学指导和论文撰写指导。所有作者均阅读并同意了最终稿件的提交。

The study was designed by LIU Yuting, PAN Jingwei, YU Wanqi and LI Xinni. The CR program was designed and implemented by YU Wanqi and HONG Wen. Data were collected by LIU Yuting, DANZENG Quyang and XIAO Huoyuan. Data analysis was done by LIU Yuting, LI Xinni and KANG Sang. The manuscript was drafted by LIU Yuting. Statistical guidance and manuscript guidance were conducted by PAN Jingwei. All the authors have read the last version of paper and consented for submission.

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