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SCM



世界中医药学会联合会

World Federation of Chinese Medicine Societies

SCM **-20**

国际冠心病血瘀证病证结合诊断指南

Diagnostic guidelines for Blood Stasis Syndrome for Coronary Heart Disease

世界中联国际组织标准

International Standard of WFCMS

20**-**-**发布实施

Issued & implemented on ** **, 20**

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前 言

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本文件的起草程序遵守了世界中医药学会联合会发布的 SCM1.1-2021 《标准化工作导则第 1 部分：标准制修订与发布》。

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引 言

世界卫生组织发布《2022年全球卫生估计报告》指出，2019年全球73.6%的死亡归因于非传染性疾病，冠心病是主要的死亡原因，所致死亡人数占全球总死亡人数的16%。自2000年以来，死亡人数增加最多的也是冠心病，2019年达到了890万人。在美国，每7例死亡病人中就有1例死于冠心病，心脏病的直接和间接治疗费用超过2000亿美元，且该医疗负担还在不断上升。《中国心血管健康与疾病报告2020》指出，我国冠心病患病人数可达1139万，年冠心病死亡人数接近200万。降脂、抗血小板等治疗是干预冠心病的主要手段，在改善冠心病患者预后方面起到了一定作用，但冠心病患者的残余风险仍然较高。

根据传统中医药学关于血瘀证的理论认识，病证结合，将冠心病的主要病理环节如血栓形成、血小板活化、血管狭窄、痉挛等和血瘀证联系起来认识冠心病发生的中医病因病机，认为冠心病无论虚实，“心血脉瘀滞、不通则痛”总是其病因病机的一个重要方面。课题组首先倡导用活血化瘀方药治疗冠心病心绞痛、心肌梗死，临床疗效较传统的宣痹通阳法有了明显提高，并从血液生物流变学、血小板功能、细胞生物活性因子、基因蛋白表达的分子水平揭示了活血化瘀方药治疗冠心病的作用机制，使活血化瘀成为现代中医临床治疗冠心病的主流和首选疗法。同时，首先倡导采用随机、双盲、双模拟、多中心的临床研究方法客观评价活血化瘀方药治疗冠心病的安全性和有效性，显著提高了中医药临床研究的科学水平。

冠心病血瘀证是血瘀证研究中最活跃的领域，既往研究结果表明，冠心病血瘀证在宏观表征、理化指标、中医证候特点及证候演变规律上均具有其特殊性。因此，以冠心病为切入点，开展病证结合的血瘀证诊断及疗效评价标准研究具有重要意义。根据现代流行病学及病因学研究方法，通过文献研究筛选冠心病血瘀证诊断指标；通过多中心、大样本的真实世界研究，观察冠心病血瘀证的临床特点及证候演变规律；通过前瞻性、多中心、大样本的病因学研究，判定诊断指标的位置和权重，建立冠心病血瘀证诊断指标体系；通过专家咨询研究和大样本的诊断性试验，对冠心病血瘀证诊断指标体系进行优化；通过前瞻性、随机双盲对照的临床研究，采用“以药测证”、“以效测证”方法对诊断标准进行临床反证；最终建立敏感、可靠、临床实用的冠心病血瘀证病证结合诊断标准。

长期以来，由于冠心病血瘀证国际诊断标准的缺失，不仅严重限制血瘀证及活血化瘀研究的发展，影响心脑血管疾病等以血瘀证为主要证型的重大疾病中药临床疗效的客观评价，也限制了活血化瘀研究的国际交流与合作。

随着中医药全球化发展，制订适应现代临床科研需求的国际血瘀证诊断指南，指导以血瘀证为主要证候的全球范围内常见疾病和重大疾病诊疗具有积极意义。本《国际冠心病血瘀证病证结合诊断指南》即以《冠心病血瘀证诊断标准》为基础，邀请来自中国香港、中国台湾、中国澳门、韩国、美国、英国、德国、加拿大、澳大利亚、新加坡、马来西亚的16名专家作为指南工作组成员，对《冠心病血瘀证诊断标准》进行修改完善后，进一步广泛征求海内外专家意见研制而成，具有诊断条目简洁、涵盖面广、判断标准简单、符合临床实际、可操作性强等特点。

本文件主要适用于医学临床、科研工作者使用。

国际冠心病血瘀证病证结合诊断指南

1 范围

本文件规定了冠心病血瘀证诊断的主要指标、次要指标以及辅助指标等内容。
本文件适用于冠心病血瘀证的临床与科研工作。

2 规范性引用文件

“下列文件中的内容通过文中的规范性引用而构成本文件必不可少的条款。其中，注日期的引用文件，仅该日期对应的版本适用于本文件；不注日期的引用文件，其最新版本（包括所有的修改单）适用于本文件。

1986 中国中西医结合研究会活血化瘀专业委员会 《血瘀证诊断标准》

2011 中国中西医结合学会活血化瘀专业委员会 《血瘀证中西医结合诊疗共识》

2016 中国中西医结合学会活血化瘀专业委员会 《冠心病血瘀证诊断标准》

3 术语和定义

下列术语和定义适用于本文件。

3.1

冠心病

由于冠状动脉粥样硬化使管腔狭窄或闭塞导致心肌缺血、缺氧或坏死而引发的心脏病，统称为冠状动脉粥样硬化性心脏病，简称冠心病，归属于缺血性心脏病，是动脉粥样硬化导致器官病变最常见类型。

3.2

血瘀证

血液运行不畅，或血流瘀滞，或血溢脉外而停蓄于体内所引起的证候，临床以疼痛、肿块、出血、面色或唇舌紫黯或发绀、脉涩或结代为主要表现。

4 诊断标准

4.1 主要指标

4.1.1 胸痛位置固定（10分）。

4.1.2 舌质色紫或暗（10分）。

4.1.3 舌有瘀斑、瘀点（10分）。

4.1.4 冠状动脉造影显示至少一支冠状动脉狭窄 $\geq 75\%$ （9分）。

4.1.5 超声或造影证实冠状动脉血栓或心腔内附壁血栓（8分）。

4.2 次要指标

- 4.2.1 胸痛夜间加重（6分）。
- 4.2.2 口唇或齿龈紫暗（7分）。
- 4.2.3 舌下静脉曲张或色紫暗（7分）。
- 4.2.4 冠状动脉造影现实至少一支冠状动脉狭窄 $\geq 50\%$ ，但 $< 75\%$ （6分）。
- 4.2.5 部分凝血活酶时间(APTT) 或凝血酶原时间(PT)缩短（5分）。

4.3 辅助指标

- 4.3.1 面色黧黑（2分）。
- 4.3.2 脉涩（4分）。
- 4.3.3 冠状动脉 CTA 或冠状动脉造影现实血管明显钙化或弥漫病变（3分）。
- 4.3.4 纤维蛋白原升高（3分）。

5 判定标准

符合冠心病诊断标准，科研工作需满足：

- a) 冠状动脉造影显示至少一支冠状动脉狭窄 $\geq 50\%$ ；
- b) 冠心病血瘀证计分 ≥ 19 分可诊断为血瘀证，计分高低可评价冠心病血瘀证程度；
- c) 冠心病血瘀证诊断必须包含主要指标、次要指标中至少 1 项宏观指标，单纯生化指标不能诊断。

附录 A
(资料性)
指南研究过程

A.1 研究方法

A.1.1 文献研究

采用系统评价的标准化步骤整理古今文献，通过检索中文古籍数据库发现中医古籍中与冠心病血瘀证相关的临床表现主要包括胸满、胸痛、胸闷、心痛、怔忡、舌青、脉涩等 22 项。检索中国期刊全文数据库(CNKI)、中国生物医学文献数据库(CBM)、中文科技期刊全文数据库(VIP)、中国重要会议论文全文数据库、美国国立医学图书馆(PubMed)，以“冠心病”“血瘀证”为检索词，根据各数据库的特点采用主题词、关键词与自由词相结合的方式进行搜索。英文数据库检索采用相应的译文。共检出与冠心病血瘀证相关的研究 1825 项，经反复筛选后有“冠心病血瘀证与高敏 C-反应蛋白(hs-CRP)相关性研究”等 74 项诊断性试验最终纳入分析，Meta 分析显示共有 hs-CRP、Hcy、D-二聚体等 122 项指标与冠心病血瘀证明显相关。

A.1.2 真实世界研究

采集京津地区 9 家中医及中西医结合医院 4826 例冠心病住院病人的病史及中西医诊断信息，分析冠心病不同亚型及合并不同疾病病人的证候要素和中医证候分布特点，结果显示冠心病常见证候要素依次是血瘀、气虚、痰浊、阴虚、阳虚、气滞、血虚，其中血瘀证 3928(81.4%)，是冠心病基本的中医证型。在此基础上，采用前瞻性队列研究设计，系统采集全国 15 家医院的 1503 稳定型冠心病病人的临床信息，并进行 12 个月随访，采用复杂网络方法挖掘分析证候演变对心血管事件的影响，结果证实血瘀证与心血管事件的发生显著相关。因此，以血瘀证为切入点，开展冠心病血瘀证病证结合诊断标准研究，对预防心血管事件的发生具有重要临床价值。

A.1.3 定性研究

根据文献研究和真实世界研究结果设计标准化专家咨询问卷，选择相关领域有代表性的 80 位专家，通过信函及网络调查方式完成专家咨询。结果显示：胸痛位置固定、舌色紫暗、舌体瘀斑瘀点、冠状动脉 CT 血管造影(CTA)或冠状动脉造影显示任何 1 支血管闭塞等 37 个指标的专家意见集中程度 > 90%，可能作为冠心病血瘀证的主要诊断指标；胸痛呈刺痛等 27 个指标的专家意见集中程度位于 80%~90%，可能作为冠心病血瘀证的次要诊断指标，为冠心病血瘀证病证结合诊断标准的建立提供依据。

A.1.4 横断面研究

对 15 家分中心 4274 例经冠状动脉造影确诊至少 1 支冠状动脉血管狭窄 $\geq 50\%$ 或既往有陈旧性心肌梗死病史的冠心病病人进行流行病学调查，参照 1986 年血瘀证诊断标准，将病人分为血瘀证和非血瘀证两组，其中血瘀证组 3257 例，非血瘀证组 1017 例。通过单因素分析、Logistic 回归分析和逐步判别分析对诊断指标进行反复筛选和优化，根据病史、症状、体征、舌象、脉象、理化指标等不同变量的 OR 值判定其权重，结合临床实际情况，制订冠心病血瘀证病证结合诊断标准（草案）。

A. 1.5 病例对照研究

选择 450 例经冠状动脉造影确诊的冠心病患者为研究对象，将 4 名工作 5 年以上的心内科副主任医师分为相互独立的 A、B 两组，每组两名医师。A 组以 1986 年的血瘀证诊断标准为诊断依据，B 组以冠心病血瘀证病证结合诊断标准（草案）为诊断依据，分别在两个诊室，根据病历记录情况，相互独立对 450 例冠心病病人进行辨证，辨证结果有异议时，请第 3 名副主任医师进行辨证，3 名参与辨证的医师中有 2 名结果相同即可确立诊断。根据辨证结果计算诊断标准（草案）的敏感度为 94.36%，特异度为 89.38%，准确度为 93.11%，阳性似然比为 8.89，证实冠心病血瘀证病证结合诊断标准（草案）诊断准确可靠，具有临床实用性。

A. 1.6 德尔菲法

遵循权威性、代表性与地域性相结合的原则，采用德尔菲法对全国 24 个省、70 所临床、教学及科研机构的 110 位具有高级职称并从事相关领域工作 10 年以上的专家进行两轮问卷咨询。结果显示两轮咨询的专家积极系数分别为 99.1% 和 97.2%，专家权威程度 0.92，专家对冠心病血瘀证病证结合诊断标准（草案）的认可度为 99.1%，两轮专家咨询的 Kendall 协调系数为 0.664 和 0.849。根据专家咨询结果计算各项指标的权重系数，进而优化各项指标的赋分。

A. 1.7 病因学研究方法

选择全国 10 家医院就诊的经冠状动脉造影证实冠心病患者 3081 例，依据专家咨询法优化后的冠心病血瘀证病证结合诊断标准对病人进行冠心病血瘀证积分，绘制 ROC 曲线，选择 Youden 指数最大点对应的积分作为诊断界点，确定冠心病血瘀证诊断界值，最终建立冠心病血瘀证病证结合诊断标准。

A. 2 标准证据

A. 2.1 主要指标

A. 2.1.1 胸痛位置固定

中医学认为血瘀证所导致疼痛性质主要为固定性疼痛，或刺痛、绞痛，冠心病血瘀证可见“胸刺痛”、“背刺痛”等症状，活血化瘀对改善心绞痛、头痛等固定性疼痛具有良好疗效。

A. 2.1.2 舌质紫或暗

舌质紫暗是瘀血舌象的重要特点。从现代医学角度来看，瘀血舌象是血液流变性异常改变至一定程度而导致舌微循环障碍的结果。

A. 2.1.3 舌有瘀斑、瘀点

舌有瘀斑、瘀点，舌尖微循环障碍，黏膜固有层中点状出血后的含铁血黄素以及各种刺激引起的黑色素沉积是舌上瘀斑、瘀点发生的病理基础。

A. 2.1.4 冠状动脉造影显示至少一支冠状动脉狭窄 $\geq 75\%$

徐浩等在探讨冠心病血瘀证与冠脉造影所示病变及介入治疗后再狭窄的相关性中发现，冠心病血瘀证与冠脉病变复杂程度有一定相关性，血瘀程度轻重是再狭窄发生与否的重要影响因素。Meta 分析显示，冠心病血瘀证型比非血瘀证型更易出现多支病变、75%以上狭窄和更高的 Gensini 积分，活血化瘀对降低 PCI 术后再狭窄率和再狭窄程度具有积极作用。

A. 2. 1. 5 超声或造影显示冠状动脉血栓或心腔内附壁血栓

冠心病血瘀证是指瘀血内阻，血行不畅，与现代医学的血栓形成、梗塞表现相同，血行不畅进而可导致脏器缺血，活血化瘀可以防止血栓形成，并对相关疾病具有良好疗效。

A. 2. 2 次要指标

A. 2. 2. 1 胸痛夜间加重

疼痛夜间加重是中医学中血瘀证重点体征，经活血化瘀治疗后发作频率、发作程度可明显改善。

A. 2. 2. 2 口唇或齿龈紫暗

冠心病血瘀证患者口唇、肢端紫绀为血中脱氧血红蛋白增多所致，经活血化瘀治疗后，冠心病血瘀证患者面部可视光血氧饱和度明显提高。

A. 2. 2. 3 舌下静脉曲张或色紫暗

血瘀证患者常存在静脉曲张现象，舌下静脉曲张或色紫暗，经活血化瘀治疗后常可获效。

A. 2. 2. 4 冠状动脉造影显示至少一支冠状动脉狭窄 $\geq 50\%$ ，但 $< 75\%$

马晓昌等在研究冠心病中医辨证分型与冠状动脉造影所见相关性发现冠状动脉血管狭窄程度越重，血瘀症候积分值越大，血瘀程度越重。

A. 2. 2. 5 部分凝血活酶时间（APTT）或凝血酶原时间（PT）缩短

张长军等研究发现，血流变指标、凝血指标等在不同血瘀证分型中能够提供实验依据，提高血瘀证诊断分型的客观性。活血化瘀可改善血液流变性、凝血、纤溶、微循环等理化指标，赤芍总苷可显著延长 PT、APTT 时间，降低全血黏度，减少血栓的生成；低剂量红花制剂能够改善大鼠血流变学，抑制血瘀证大鼠血栓形成。

A. 2. 3 辅助指标

A. 2. 3. 1 面色黧黑

徐凤芹等血瘀证证候特征要素权重系数的研究发现，面色黧黑是血瘀证较为重要的体征，但考虑个体存在差异，故将该条列在辅助指标中。

A. 2. 3. 2 脉涩

冠心病血瘀证脉涩患者血液流变学各项指标明显升高，血液呈高粘状态，揭示血瘀脉涩与血液流变呈一种“涩脉—高粘”的关系。根据中医传统文献，脉涩与血瘀关

系密切，但考虑到脉象的确定有一定主观性，故将该条列在辅助指标中。

A. 2. 3. 3 冠状动脉 CTA 或冠状动脉造影显示血管明显钙化或弥漫病变

影像学检查提示冠状动脉血管狭窄与冠心病血瘀证密切相关，但由于狭窄程度较轻，故列为辅助标准。

A. 2. 3. 4 纤维蛋白原升高

一项涉及 13 项研究 1073 人的 meta 分析显示：西药基础上加用活血化瘀中药注射液能够降低冠心病血瘀证患者纤维蛋白原水平。

A. 3 临床研究

A. 3. 1 诊断效能比较

与既往相关标准诊断效能比较为证实新建的冠心病血瘀证病证结合诊断标准与既往标准比较的优势，本研究分别选择 1986 年“血瘀证诊断标准”“冠心病血瘀证病证结合诊断标准（草案）”、新建的“冠心病血瘀证病证结合诊断标准”为试验标准，以综合诊断结果为参考标准，由甲、乙两名专家分别以上述 3 个试验标准为依据，通过回顾性病例研究，对 3081 例冠心病患者进行辨证诊断，进而比较 3 个诊断标准的敏感度、特异度、诊断比值比和阳性似然比，结果证实新建的“冠心病血瘀证病证结合诊断标准”较既往相关标准具有更高的诊断价值。

A. 3. 2 相关性分析

为研究新建冠心病血瘀证病证结合诊断标准与冠状动脉病变程度的相关性，本研究选取 2011 年 3 月—2021 年 6 月于首都医科大学附属安贞医院经冠状动脉造影检查确诊且未经血运重建干预的冠心病患者 209 例，进行临床观察。将每例病人依据“冠心病血瘀证病证结合诊断标准”计算冠心病血瘀证积分，同时根据冠状动脉造影结果进行 Gensini 评分。结果显示冠心病血瘀证积分与 Gensini 评分明显呈正相关（Pearson 相关系数为 0.72， $P=0.0054$ ）。由此证实冠心病血瘀证积分可反映冠状动脉病变的严重程度。

A. 3. 2 真实性检验

采用多中心、随机、双盲、安慰剂对照的研究方法，选取 4 家医院就诊的根据冠心病血瘀证病证结合诊断标准辨证为冠心病血瘀证病人 460 例，治疗组在西药常规治疗基础上加服冠心丹参滴丸，对照组在常规西药治疗基础上加服同样剂量冠心丹参滴丸模拟剂，“以药测证”，对冠心病血瘀证病证结合诊断标准进行临床验证。结果显示：经药物治疗后两组冠心病血瘀证总积分较治疗前均明显降低，但与对照组比较，治疗组冠心病血瘀证总积分降低更明显，差异有统计学意义（ $P<0.01$ ）。与治疗前相比，治疗组冠心病血瘀证病证结合诊断标准的主要指标、次要指标、辅助指标对应的积分均显著降低（ $P<0.05$ ）。由此证明冠心病血瘀证病证结合诊断标准及其主要指标、次要指标、辅助指标均可反映血瘀证轻重程度的变化和活血化瘀药物的治疗效果。

为了进一步评价冠心病血瘀证病证结合诊断标准对血瘀证诊断的敏感性，本研究将冠心病血瘀证病证结合诊断标准与 1986 年的“血瘀证诊断标准”和“冠心病血瘀证病证结合诊断标准（草案）”进行比较。在双盲情况下对每例病人分别依据 1986 年的

“血瘀证诊断标准”计算血瘀证积分，依据“冠心病血瘀证病证结合诊断标准（草案）”计算冠心病血瘀证草案积分，依据“冠心病血瘀证病证结合诊断标准”计算冠心病血瘀证积分，试验前、试验结束时各评分 1 次。分析比较 3 个诊断标准的计分减少率。结果显示冠心病血瘀证积分较 1986 年“血瘀证诊断标准”积分和“冠心病血瘀证病证结合诊断标准（草案）”积分减少率更大($P < 0.05$)。由此证实冠心病血瘀证病证结合诊断标准不仅具有良好的临床实用性，且较既往标准更敏感，可灵敏反映血瘀证轻重程度变化。

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Foreword

Please note that some of the contents of this document may be covered by patents. The issuing organization of this document assumes no responsibility for identifying patents.

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The drafting process of this document follows the SCM 1.1-2021 *Directives for Standardization-Part 1: Procedures or Standard Development, Revision and Publication*, issued by the World Federation of Chinese Medicine Societies.

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Introduction

The World Health Organization has released Global Health Estimates 2022 report, stating that 73.6% of global deaths in 2019 were attributed to non-communicable diseases, with coronary heart disease (CHD) being the leading cause of death, accounting for 16% of all global deaths. Since 2000, the largest increase in deaths has also been from coronary heart disease, which in 2019 reached 8.9 million people. In the U.S., coronary heart disease accounts for 1 in 7 deaths, and the direct and indirect cost of treating heart disease exceeds \$200 billion, and the burden of care continues to rise. "Annual Report on Cardiovascular Health and Disease in China (2020)" points out that the number of people suffering from coronary heart disease in China can reach 11.39 million, and the annual number of deaths from coronary heart disease is close to 2 million. Lipid-lowering, anti-platelet and other treatments are the main means of intervening in coronary heart disease, and play a role in improving the prognosis of patients with coronary heart disease, but the residual risk of patients with coronary heart disease is still high.

According to the theoretical understanding of traditional Chinese medicine on blood stasis, the combination of disease and syndrome, the main pathological aspects of coronary heart disease, such as thrombosis, platelet activation, vascular stenosis, spasms, etc., and blood stasis, etc., to understand the etiology of coronary heart disease in traditional Chinese medicine, and believe that regardless of whether coronary heart disease is real or imaginary, "stasis of the heart's blood and blood vessels and the lack of circulation is painful," is always an important aspect of the cause and mechanism of coronary heart disease. It is believed that coronary heart disease, no matter whether it is real or imaginary, "stagnation of heart blood vessels, pain if they do not circulate" is always an important aspect of its causes. The group firstly advocated the use of blood circulation and stasis removing prescription for the treatment of angina pectoris and myocardial infarction of coronary heart disease, the clinical efficacy of which was significantly improved compared with the traditional method of declaring paralysis and passing the yang method, and the mechanism of blood circulation and stasis removing prescription for the treatment of coronary heart disease was revealed from the molecular level of the blood biorheology, platelet function, cellular bioactivity factor and gene protein expression, which makes blood circulation promoting and blood stasis removing the main stream and the first choice of the treatment of coronary heart disease in the clinical treatment of modern traditional Chinese medicine. The study was the first to advocate the use of randomized, double-blind trials. At the same time, it firstly advocated the adoption of randomized, double-blind, double-simulation, multi-center clinical research method to objectively evaluate the safety and

effectiveness of the formula of activating blood circulation and removing blood stasis in the treatment of coronary heart disease, which significantly improved the scientific level of clinical research of Chinese medicine.

Blood stasis syndrome for coronary heart disease is the most active area in the study of blood stasis syndrome. The results of previous studies show that blood stasis syndrome for coronary heart disease has its own particularities in terms of macro characterization, physicochemical index, chemical indexes, characteristics of TCM syndromes and the evolution of TCM syndromes. Therefore, it is of great significance to carry out research on the diagnosis and efficacy evaluation criteria of blood stasis syndrome by combination of disease and syndrome using coronary heart disease as an entry point. Based on research methods of modern epidemiology and Etiology, screening diagnostic indexes of blood stasis syndrome for coronary heart disease through literature research; To observing the clinical characteristics and the evolution of TCM syndromes of coronary heart disease in blood stasis syndrome through a multi-center, large-sample and real-world study; To determine the position and weight of diagnostic indicators and establish a diagnostic index system for coronary heart disease in blood stasis syndrome through prospective, multi-center, and large-sample etiological study; To optimize the diagnostic index system for coronary heart disease blood stasis syndrome through expert consultation studies and diagnostic tests with large samples; Clinical disproof of the diagnostic criteria using the methods of "measuring TCM syndrome by medicine" and "measuring TCM syndrome by efficacy", through prospective, randomized, double-blind controlled clinical studies"; To establish sensitive, reliable and clinically practical diagnostic criteria for blood stasis syndrome in coronary heart diseases.

For a long time, the lack of international diagnostic standards for blood stasis syndrome in coronary heart disease. Seriously limiting the development of research on blood stasis syndrome and promoting blood circulation to remove blood stasis, affecting the objective evaluation of the clinical efficacy of traditional Chinese medicine in major diseases such as cardiovascular and cerebrovascular diseases, in which blood stasis is the main syndrome, and restricting international exchanges and cooperation in the research on promoting blood circulation to remove blood stasis.

With the globalization of traditional Chinese medicine, to formulate an international diagnostic guideline for blood stasis syndrome that adapts the modern clinical research needs, which is of positive significance in guiding the diagnosis and treatment of common diseases and major diseases worldwide in which blood stasis syndrome is the main symptom. The *SCM*

standard of Diagnostic guidelines for Blood Stasis Syndrome for Coronary Heart Disease, which is based on the Diagnostic Criteria for Coronary Heart Disease of Blood Stasis Syndrome, was developed by inviting 16 experts from Hong Kong, Taiwan, Macao, South Korea, America, Britain, Germany, Canada, Australia, Singapore, and Malaysia as the members of the Guidelines Working Group. Then further soliciting the opinions of experts from both at home and abroad after the SCM standard of Diagnostic guidelines for Blood Stasis Syndrome for Coronary Heart Disease was revised and perfected. It is characterized by concise diagnostic entries, wide coverage, simple judgment criteria, conformity to clinical practice, and strong operability.

This document is primarily intended for use by medical clinicians and scientific researchers.

WFECMS

International Diagnostic Guidelines for Integrating Blood Stasis in Coronary Heart Diseases

1 Scope

This document specifies the primary indicators, secondary indicators and auxiliary indicators for the diagnosis of coronary heart disease with blood stasis.

This document applies to the clinical and research work on blood stasis in coronary heart disease.

2 Normative references

"The contents of the following documents constitute indispensable provisions of this document by means of normative references in the text. Where a document is cited with a date, only the version corresponding to that date applies to this document; where a document is cited without a date, the latest version (including all change orders) applies to this document.

In 1986, China Society of Integrated Chinese and Western Medicine releases *Diagnostic standards for blood stasis syndrome*

In 2011, Chinese Society of Integrative Medicine Professional Committee on Activating Blood Stasis issued the Consensus on Integrative Diagnosis and Treatment of Blood Stasis Evidence.

In 2016, Chinese Society of Integrative Chinese and Western Medicine Professional Committee on Activating Blood Stasis issued *the Diagnostic Criteria for Coronary Heart Disease of Blood Stasis Syndrome*

3 Terms and definitions

The following terms and definitions apply to this document.

3.1

Coronary heart disease

Heart disease caused by atherosclerosis of the coronary arteries that results in myocardial ischemia, hypoxia or necrosis due to narrowing or occlusion of the lumen of the coronary arteries is collectively known as coronary atherosclerotic heart disease, or coronary heart disease for short, which is categorized as an

ischemic heart disease, and it is the most common type of atherosclerosis-induced organ lesions.

3.2

Blood stasis certificate

The symptoms caused by poor blood circulation, stagnation of blood flow, or blood overflowing out of the veins and stagnation in the body, with pain, lumps, bleeding, purple or cyanosis of the face or lips and tongue, and astringency or knotting of the pulse as the main clinical manifestations.

4 Diagnostic Criteria

4.1 Key Indicators

4.1.1 Chest pain position fixation (10 points).

4.1.2 Purple or dark tongue color (10 points).

4.1.3 Petechiae and ecchymoses on the tongue (10 points).

4.1.4 Coronary arteriography showing $\geq 75\%$ stenosis in at least one coronary artery (9 points) .

4.1.5 Ultrasound or imaging showing coronary thrombus or intramural wall thrombus (8 points).

4.2 Minor index

4.2.1 Chest pain worsens at night (6 points) .

4.2.2 The dull purple of lip and gum (7 points) .

4.2.3 Varicose or dull purple sublingual veins (7 points) .

4.2.4 Coronary angiography showing Stenosis $\geq 50\%$ but $< 75\%$ in at least one coronary artery (6 points) .

4.2.5 Shortened activated partial thromboplastin time (APTT) or prothrombin time (PT) (5 points) .

4.3 Auxiliary index

4.3.1 Darkish complexion (2 points) .

4.3.2 Hesitant pulse (4 points) .

4.3.3 Coronary artery CT angiography or coronary angiography showing Significant vascular calcification or diffuse lesions(3 points) .

4.3.4 Elevated fibrinogen (3 points) .

5 Judgment criterion

Meets diagnostic criteria for coronary heart disease, and Scientific research needs to satisfy:

a) Coronary angiography showing Stenosis $\geq 50\%$ in at least one coronary artery .

b) Blood stasis syndrome for coronary heart disease can be diagnosed with a score of ≥ 19 , and the degree of blood stasis syndrome for coronary heart disease can be evaluated by the level of the score;

c) The diagnosis of coronary heart disease in blood stasis syndrome must include at least 1 macro-index among the primary and secondary index, and simple biochemical indicators cannot be diagnosed.

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ANNEX A
(Normative)
Guide to the research process

A.1 Research Methodology

A.1.1 Literature Research

A standardized step of systematic evaluation was used to organize ancient and modern literature, and 22 clinical manifestations related to blood stasis syndrome of coronary heart disease in ancient Chinese medicine were found by searching the Chinese ancient literature database, including chest fullness, chest pain, chest tightness, cardiac pain, dysarthria, blue tongue, and astringent pulse. We searched CNKI, CBM, VIP, full text database of important conference papers in China, and PubMed, and used the search terms of "coronary heart disease" and "blood stasis syndrome" were used as the search terms, and the combination of subject words, key words and free words were used according to the characteristics of each database.

The English databases were searched using the corresponding translations. A total of 1825 studies related to blood stasis in coronary heart disease were detected, and 74 diagnostic tests, including the study on the correlation between blood stasis in coronary heart disease and high-sensitivity C-reactive protein (hs-CRP), were finally included in the analysis after repeated screening, and meta-analysis showed that a total of 122 indicators, such as hs-CRP, Hcy, D-dimer, etc., were significantly correlated with blood stasis in coronary heart disease. indicators were significantly correlated with blood stasis in coronary heart disease.

A.1.2 Real World Research

We collected the medical history and Chinese and Western medicine diagnostic information of 4826 coronary heart disease inpatients from 9 Chinese medicine and combined Chinese and Western medicine hospitals in Beijing and Tianjin, and analyzed the diagnostic elements of different subtypes of coronary heart disease and patients with combinations of different diseases and the characteristics of the distribution of Chinese medicine evidence, which showed that the common diagnostic elements of coronary heart disease were, in order of magnitude, blood stasis, qi deficiency, phlegm, yin deficiency, yang deficiency, qi stagnation, and blood deficiency, with blood stasis evidence of 3928(81.4%), which is the the basic

Chinese medicine evidence type of coronary heart disease. On this basis, a prospective cohort study design was used to systematically collect clinical information on 1503 patients with stable coronary heart disease from 15 hospitals across China with 12-month follow-up, and a complex network approach was used to mine and analyze the effect of the evolution of the syndrome on cardiovascular events, and the results confirmed that the blood stasis syndrome was significantly associated with the occurrence of cardiovascular events. Therefore, taking blood stasis syndrome as an entry point, carrying out research on the diagnostic criteria for blood stasis syndrome for coronary heart diseasesyndrome is of great clinical value for the prevention of cardiovascular events.

A.1.3 Qualitative research

A standardized expert consultation questionnaire was designed based on literature studies and real-world findings, and 80 representative experts in the relevant fields were selected to complete the expert consultation by letter and online surveys. The results showed that 37 indicators, such as fixed location of chest pain, purplish tongue color, petechiae on the tongue, coronary artery CT angiography (CTA) or coronary artery angiography showing occlusion of any one blood vessel, had a concentration of >90% of experts' opinions, which might be used as the main diagnostic indicators for coronary heart disease blood stasis; and 27 indicators, such as stabbing pain in the chest, had a concentration of experts' opinions in the range of 80% to 90%, which might be used as the secondary diagnostic indicators for coronary heart disease blood stasis. The concentration of 27 indicators, such as chest pain with stabbing pain, is between 80% and 90%, which may be used as the secondary diagnostic indicators of coronary heart disease blood stasis, and provides the basis for the establishment of the diagnostic standard of coronary heart disease blood stasis.

A.1.4 Transect studies

An epidemiological survey was conducted on 4,274 patients with coronary heart disease diagnosed with stenosis of $\geq 50\%$ in at least 1 coronary artery vessel confirmed by coronary angiography or with a history of previous old myocardial infarction in 15 sub-centers, and with reference to *diagnostic standards for blood stasis syndrome* in 1986, the patients were divided into two groups of blood stasis and non-blood stasis, with 3,257 cases in the group of blood stasis and 1,017 cases in the group of non-blood stasis. The diagnostic indexes were repeatedly screened

and optimized by one-way analysis, logistic regression analysis and stepwise discriminant analysis, and the weights of different variables such as history, symptoms, signs, tongue, pulse, physical and chemical indexes were determined according to their OR values, and the draft diagnostic criteria for the combination of disease and evidence of coronary heart disease with blood stasis syndrome were formulated by combining with the actual clinical situation.

A.1.5 Case-control studies

450 coronary artery disease patients diagnosed by coronary angiography were selected for the study, and 4 deputy chief physicians of the Department of Cardiology who had been working for more than 5 years were divided into two independent groups, A and B, with two physicians in each group. group A took the 1986 diagnostic criteria for blood stasis as the diagnostic basis, and group B took the combined diagnostic criteria for coronary artery disease blood stasis as the diagnostic basis, and respectively identified 450 cases of coronary artery disease patients independently of each other in the two clinics according to the records of medical records. In Group B, the diagnosis of 450 coronary heart disease patients was conducted independently of each other, and if there was any disagreement about the results of the diagnosis, the third deputy chief physician was asked to conduct the diagnosis, and the diagnosis could be established if the results of two of the three physicians involved in the diagnosis were the same. The sensitivity of the draft diagnostic criteria (94.36%), specificity (89.38%), accuracy (93.11%), and positive likelihood ratio (8.89) were calculated based on the identification results, confirming that the draft diagnostic criteria (draft) for combining diagnostic criteria of coronary heart disease with blood stasis is diagnostically accurate and reliable, and clinically useful.

A.1.6 The Delphi Method

Following the principles of authority, representativeness and regionality, the Delphi method was used to conduct two rounds of questionnaire consultation with 110 experts with senior titles who have been working in the related fields for more than 10 years in 70 clinical, teaching and scientific research institutions in 24 provinces across China. The results showed that the positive coefficients of the experts in the two rounds of consultation were 99.1% and 97.2% respectively, the degree of authority of the experts was 0.92, the degree of acceptance of the experts to the draft diagnostic criteria of coronary heart disease with blood stasis, and the

Kendall coordination coefficients of the two rounds of consultation were 0.664 and 0.849. The weight coefficients of the indicators were calculated according to the results of the experts' consultation, and the scores assigned to the indicators were then optimized. indicators' assigned scores.

A.1.7 Etiologic research methods

We selected 3081 patients with coronary artery disease confirmed by coronary angiography from 10 hospitals in China, and based on the optimized diagnostic criteria of coronary blood stasis evidence combined with expert consultation method, we made the points of coronary blood stasis evidence, drew the ROC curve, and chose the points corresponding to the maximal point of Youden's index as the diagnostic boundary point to determine the diagnostic boundary value of coronary blood stasis evidence, and finally set up the diagnostic criteria of coronary blood stasis evidence. Finally, the diagnostic standard of blood stasis syndrome of coronary heart disease was established.

A.2 Standard Evidence

A.2.1 Key Indicators

A.2.1.1 Chest pain position fixation

According to Chinese medicine, the pain caused by blood stasis is mainly fixed pain, or stabbing pain, colic, coronary heart disease blood stasis can be seen in "chest pain", "back pain" and other symptoms, promoting blood circulation and removing blood stasis to improve angina pectoris, headache and other fixed pain has a good therapeutic effect.

A.2.1.2 Purple or dark tongue

Purple and dark tongue texture is an important feature of Stasis Blood Tongue Symptoms. From the point of view of modern medicine, stasis of blood on the tongue is the result of abnormal changes in blood rheology to a certain extent, leading to microcirculatory disorders of the tongue.

A.2.1.3 Petechiae and ecchymoses on the tongue

Petechiae and petechiae on the tongue, impaired microcirculation at the tongue tip, iron-containing hemosiderin after punctate hemorrhage in the lamina propria of the mucosa, and melanin deposition caused by various stimuli are the pathological

basis for the occurrence of petechiae and petechiae on the tongue.

A.2.1.4 Coronary angiography showing $\geq 75\%$ stenosis in at least one coronary artery

Xu Hao et al, in exploring the correlation between coronary blood stasis and coronary angiographic lesions and post-interventional restenosis, found that there was a correlation between coronary blood stasis and the complexity of coronary lesions, and that the degree of blood stasis was an important factor in the occurrence of restenosis. Meta-analysis showed that coronary blood stasis was more likely to present with multibranched lesions, stenosis of more than 75%, and higher Gensini scores than the non-blood stasis type. Meta-analysis showed that coronary artery disease with blood stasis was more likely to have multibranch lesions, more than 75% stenosis, and higher Gensini score than non-coronary artery disease with blood stasis.

A.2.1.5 Ultrasound or imaging showing coronary thrombus or intramural wall thrombus

Blood stasis in coronary heart disease refers to the internal obstruction of blood stasis and poor blood circulation, which is the same as the performance of thrombosis and infarction in modern medicine, and the poor blood circulation can lead to ischemia of organs, promoting blood circulation and removing blood stasis can prevent thrombosis and have good curative effect on related diseases.

A.2.2 Minor index

A.2.2.1 Chest pain worsens at night (6 points) .

Nocturnal aggravation of pain is the key sign of blood stasis syndrome in Chinese medicine, and the frequency and extent of attacks can be significantly improved after treatment of activating blood circulation and removing blood stasis.

A.2.2.2 The dull purple of lip and gum (7 points) .

Cyanosis of lips and limbs in patients with coronary heart disease with blood stasis is caused by the increase of deoxyhemoglobin in the blood, after the treatment of activating blood circulation and removing blood stasis, the oxygen saturation level of facial visualization light in patients with coronary heart disease with blood stasis was significantly improved.

A.2.2.3 Varicose or dull purple sublingual veins (7 points) .

Patients with blood stasis syndrome often have varicose veins, with varicose veins under the tongue or purplish color, which are often effective after treatment of activating blood circulation and removing blood stasis.

A.2.2.4 Coronary angiography showing Stenosis $\geq 50\%$ but $< 75\%$ in at least one coronary artery (6 points) .

Ma et al. found that the greater the degree of coronary artery stenosis, the greater the value of the blood stasis symptom score, and the greater the degree of blood stasis in their study of the correlation between Chinese medical diagnosis and coronary artery disease and coronary angiography.

A.2.2.5 Shortened activated partial thromboplastin time (APTT) or prothrombin time (PT) (5 points)

Zhang et al. found that blood rheology indexes and coagulation indexes can provide experimental basis in different blood stasis syndrome typing and improve the objectivity of blood stasis syndrome diagnosis typing. Activating blood circulation and removing blood stasis can improve blood rheology, coagulation, fibrinolysis, microcirculation and other physicochemical indexes, and total paeony glycoside can significantly prolong the time of PT, APTT, reduces whole blood viscosity and the generation of thrombus; low-dose safflower preparation can improve the blood rheology of the rats, and inhibit the thrombus formation in rats with blood stasis evidence.

A.2.3 Auxiliary index

A.2.3.1 darkish complexion

Xu Fengqin et al.'s study of the weight coefficient of the characteristic elements of blood stasis syndrome found that darkish complexion is a more important sign of blood stasis syndrome, but considering the differences in individuals, this article is listed in the auxiliary index.

A.2.3.2 pulse hesitant

In patients with blood stasis syndrome and hesitant pulse in coronary heart disease, hemorrheological index are significantly elevated and the blood is highly viscous, revealing that blood stasis and hesitant pulse have a

"hesitant pulse-high viscosity" relationship with Hemorrheology. According to traditional Chinese medical literature, hesitant pulse is closely related to blood stasis, but considering that the determination of the pulse condition is subjective, this article is listed among the auxiliary index.

A.2.3.3 Coronary artery CT angiography or coronary angiography showing Significant vascular calcification or diffuse lesions

Imaging examination suggests that coronary artery stenosis is closely related to coronary heart disease with blood stasis syndrome, because the degree of stenosis is mild, this article is listed among the auxiliary index.

A.2.3.4 Elevated fibrinogen

A meta-analysis involving 13 studies with 1073 participants showed that the addition of blood-activating and activating microcirculation and removing stasis medicinal herbal injections on the basis of Western medicine was able to reduce fibrinogen levels in patients with coronary heart disease with blood stasis syndrome.

A.3 Clinical research

A.3.1 Comparison of diagnostic effectiveness

Comparison of the diagnostic effectiveness of the previous standards to confirm the advantages of the newly constructed diagnostic standards for the combination of blood stasis syndrome and coronary heart disease.

This study selected the 1986 "*Diagnostic standards for blood stasis syndrome*", "*Diagnostic standards for the combination of blood stasis syndrome and coronary heart disease (draft)*" and the newly constructed "*Standard of Diagnostic guidelines for Blood Stasis Syndrome for Coronary Heart Disease*" as the test criteria, and the comprehensive diagnostic results as the reference standards. Then two experts, A and B, respectively, based on the above three test criteria, through retrospective studies, diagnosed 3081 patients with coronary heart disease based on syndrome, and compared the sensitivity, specificity, diagnostic odds ratio and positive likelihood ratio of the three diagnostic criteria, and the results confirmed that the newly constructed "*Standard of Diagnostic guidelines for Blood Stasis Syndrome for Coronary Heart Disease*" has a higher diagnostic value than the previous relevant criteria.

A.3.2 Relativity analysis

In order to study the correlation between the newly constructed *Standard of Diagnostic guidelines for Blood Stasis Syndrome for Coronary Heart Disease* and severity of coronary artery disease, 209 coronary heart disease patient without intervention of revascularization in the Beijing Anzhen Hospital of Capital Medical University from March 2011 to June 2021 are selected for clinical observation in this study. Calculated the points of blood stasis syndrome in coronary heart disease according to the "*Standard of Diagnostic guidelines for Blood Stasis Syndrome for Coronary Heart Disease*". And calculate the Gensini score according to the results of coronary angiography. The results showed that there was a positive correlation between the score of coronary heart disease blood stasis syndrome and the Gensini score (Pearson's correlation coefficient was 0.72, $P=0.0054$). This confirms that the score of coronary heart disease blood stasis syndrome can reflect the severity of coronary artery lesions.

A.3.3 Authenticity identification

Used the multi-center, randomized, double-blind, and placebo-controlled study method ,to select 460 patients diagnosed as coronary heart disease blood stasis syndrome according to the *Standard of Diagnostic guidelines for Blood Stasis Syndrome for Coronary Heart Disease* in four hospitals. Treatment group was treated with Guanxin Dangshen Drip Pill on top of the conventional treatment of western medicines, and the control group was treated with the same dose of Guanxin Dangshen Drip Pill simulant on top of the conventional treatment of western medicines, "measuring syndrome with medicine", to clinically validate the *Standard of Diagnostic guidelines for Blood Stasis Syndrome for Coronary Heart Disease*.

The results showed that the total points of coronary heart disease blood stasis syndrome in both groups were significantly reduced after drug treatment compared with those before treatment, but compared with the control group, the total points of coronary heart disease blood stasis syndrome in the treatment group were reduced more significantly, and the difference was statistical significance ($P < 0.01$). Compared with the pre-treatment, the points corresponding to the primary, secondary, and auxiliary indexes of the *Standard of Diagnostic guidelines for Blood Stasis Syndrome for Coronary Heart Disease* in the treatment group were all significantly reduced ($P < 0.05$). This proves that the *Standard of Diagnostic guidelines for Blood Stasis Syndrome for Coronary Heart Disease* and its major, minor and auxiliary indicators can reflect the changes in the degree of blood stasis syndrome and the therapeutic effect of the drugs for activating blood circulation and removing blood stasis. In order to further evaluate the sensitivity of the *Standard of Diagnostic guidelines for Blood Stasis Syndrome for Coronary Heart Disease* to diagnose blood stasis syndrome, this study compared the *Standard of Diagnostic guidelines for Blood Stasis Syndrome for Coronary Heart Disease* with the "Diagnostic standards for blood stasis syndrome" and the "Diagnostic standards for the combination of blood stasis syndrome and coronary heart disease (draft)" in 1986. In a double-blind situation, calculate the points of blood stasis syndrome according to the 1986 "Diagnostic standards for blood stasis syndrome", calculate the draft points of blood stasis syndrome according to the "Diagnostic standards for the combination of blood stasis syndrome and coronary heart disease (draft)", calculate the points of blood stasis syndrome according to the *standard of Diagnostic guidelines for Blood Stasis Syndrome for Coronary Heart Disease*", and grate the score of coronary heart disease blood stasis

syndrome before the test and at the end of the test. Compared the reduction rates of the points of the three diagnostic criteria. The results showed that the points of blood stasis in coronary heart disease were reduced more than the points of *"Diagnostic standards for blood stasis syndrome" in 1986 and "Diagnostic standards for the combination of blood stasis syndrome and coronary heart disease (draft)"* ($P < 0.05$). This confirms that the *Standard of Diagnostic guidelines for Blood Stasis Syndrome for Coronary Heart Disease* not only have good clinical applicability, but also are more sensitive than the previous criteria, and can sensitively reflect the changes in the severity of blood stasis.

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