

本文引用: 袁祖贻. 2024 年《中国慢性冠脉综合征患者诊断及管理指南》更新要点和建议[J]. 中国动脉硬化杂志, 2024, 32(12): 1013-1019. DOI: 10.20039/j.cnki.1007-3949.2024.12.001.

[文章编号] 1007-3949(2024)32-12-1013-07

· 专家论坛 ·

2024 年《中国慢性冠脉综合征患者诊断及管理指南》 更新要点和建议

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[摘要] 2024 年发布的《中国慢性冠脉综合征患者诊断及管理指南》是由中华医学会心血管病分会动脉粥样硬化与冠心病学组和中华心血管病杂志编辑委员会牵头, 联合介入学组、腔内影像功能学组、心血管病影像学组和基础学组共同制定的。该指南是我国首部针对慢性冠脉综合征(CCS)患者诊断及管理的指导性文件, 全面介绍了 CCS 的定义、诊断流程、治疗策略以及长期管理。该指南旨在通过提供最佳诊断或治疗方法, 改善患者的预后和生活质量。该文聚焦于 CCS 患者抗栓治疗、降脂治疗以及特殊人群的管理, 对指南中的更新和建议进行进一步解读。

[关键词] 慢性冠脉综合征; 指南; 抗栓治疗; 降脂治疗; 特殊人群

[中图分类号] R5

[文献标识码] A

Key points and suggestions for the update of 2024 “Diagnosis and Management Guidelines for Chronic Coronary Syndrome Patients in China”

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[ABSTRACT] The “Diagnosis and Management Guidelines for Chronic Coronary Syndrome Patients in China” published in 2024 was led by the Atherosclerosis and Coronary Heart Disease Group of the Cardiology Branch of the Chinese Medical Association and the Editorial Board of the Chinese Journal of Cardiovascular Diseases, in conjunction with the Intervention Group, Intravascular Imaging and Functional Group, Cardiovascular Disease Imaging Group, and Basic Science Group. The guideline is the first in China to provide guidance for the diagnosis and management of patients with chronic coronary syndrome (CCS), comprehensively introducing the definition, diagnostic process, treatment strategies, and long-term management of CCS. The guideline aims to improve the prognosis and quality of life by providing the best diagnostic or treatment methods. This article focuses on the antithrombotic therapy, lipid-lowering therapy, and management of spe-

[收稿日期] 2024-09-20

[修回日期] 2024-11-28

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cial populations for patients with CCS, further interpreting the updates and recommendations in the guidelines.

[KEY WORDS] chronic coronary syndrome; guidelines; antithrombotic therapy; lipid-lowering therapy; special populations

2024年,由中华医学会心血管病学分会动脉粥样硬化与冠心病学组联合中华心血管病杂志编辑委员会及其他心血管相关学组共同发布了《中国慢性冠脉综合征患者诊断及管理指南》。这是国内首次针对慢性冠脉综合征(chronic coronary syndrome, CCS)患者推出的专业指南,涵盖了CCS的界定、诊断程序、治疗方针和长期照护策略。该指南涵盖了CCS患者的全生命周期,包括对合并症及特殊人群的最新管理建议。与2018版《中国慢性冠脉综合征患者诊断及管理指南》相比,2024版指南细化了CCS的定义、诊断流程、血运重建策略、生活方式的管理和调整,并新增和更新了多项重要推荐,例如CCS患者的部分检查方法推荐、P2Y₁₂抑制剂详细介绍及推荐、氯吡格雷/阿司匹林固定剂量复方制剂、抗凝药物缺血/出血风险分层评估、降脂药物中的前蛋白转化酶枯草溶菌素9(proprotein convertase subtilisin kexin 9, PCSK9)抑制剂、特殊人群管理等。此外,还强调了无创性检查、有创性检查、以患者为中心及医患共享决策的理念以及综合防治的重要性。

在治疗目标上,2024版指南着重于减轻CCS患者的症状、预防严重但非致命性心脏事件,并提升其长期生存的可能性。治疗策略囊括了药物治疗、血管重建手术及生活方式调整等多元化管理手段。2024版指南特别强调了对伴有心力衰竭、糖尿病或慢性肾脏病等并发症的CCS患者的细致管理,并给出了针对性的治疗指导。特别指出,血运重建的适用条件需清晰界定,并提倡基于全面评估患者状况后,制定个性化的治疗计划。此外,2024版指南亦着重于患者教育,鼓励其参与到决策过程中来,以实现更优的治疗效果。

2024版指南为国内心血管医疗工作者提供了一套规范化、专业化的临床操作指南,对提高CCS患者的整体管理标准具有深远的临床及社会影响。本文将深入探讨2024版指南中关于抗栓治疗、降脂治疗及特殊人群管理的更新要点和建议。

1 抗栓治疗

CCS的治疗中,抗栓治疗扮演着至关重要的角色^[1-2]。抗栓治疗包括抗凝和抗血小板治疗,尤其

在动脉粥样硬化性疾病中具有特定疗效^[3-4]。然而,抗栓治疗也与出血风险相关。制定抗栓治疗策略时,应特别关注患者是处于急性期还是稳定期或慢性期。不同阶段的血栓风险并不一致,应特别讲究平衡:对于每一个需要抗栓治疗的患者,都需要评估缺血和出血风险有多高,从而制定合理的、个体化的抗栓治疗方案。

抗血小板治疗是冠心病CCS患者治疗的基石,其中环氧合酶1(cyclooxygenase-1, COX-1)抑制剂和P2Y₁₂受体抑制剂在长期使用中占据重要地位。对于经皮冠状动脉介入治疗(percutaneous coronary intervention, PCI)患者,双联抗血小板治疗(dual antiplatelet therapy, DAPT)的时长需综合考虑缺血与出血风险,以实现个体化治疗。阿司匹林作为经典的抗血小板药物,在二级预防中仍有一定获益,但其高出血风险不容忽视^[5-8]。吲哚布芬停药后24h即可恢复血小板功能,出血风险较低,即使发生出血也较易控制,与阿司匹林心血管疾病死亡、全因死亡、心肌梗死发生率差异无统计学意义^[9-10]。与阿司匹林相比,氯吡格雷在降低缺血风险的同时,胃肠道出血发生率更低。研究证实,氯吡格雷相较于阿司匹林在降低主要临床不良事件风险、缺血复合终点及出血风险方面均有显著优势。对于合并出血和缺血双高危的急性冠脉综合征(acute coronary syndrome, ACS)行PCI患者,继续氯吡格雷单一治疗相较于DAPT能显著降低临床相关出血和主要不良心脑血管事件风险^[11-16]。此外,氯吡格雷/阿司匹林固定剂量复方制剂可减少胃肠道不良反应,提高患者依从性^[17-21]。高危PCI患者行替格瑞洛联合阿司匹林治疗后3个月,单用替格瑞洛相较于替格瑞洛DAPT降低1年出血事件风险达44%($P < 0.001$),且缺血事件达非劣效性终点,但其相较于氯吡格雷在围术期心肌梗死和心肌损伤方面的效果并无显著差异,且轻微出血事件更为频繁^[22-26]。

抗凝药物在凝血与血小板活化中扮演关键角色,尤其在行PCI的CCS患者治疗中尤为重要。以往多依赖华法林,但临床研究显示新型口服抗凝药(novel oral anticoagulant, NOAC)具有更高的安全性。COMPASS研究表明,低剂量利伐沙班(2.5 mg,每日两次)联合阿司匹林(100 mg,每日一

次)相比阿司匹林单药显著降低 CCS 和(或)外周动脉疾病患者的缺血风险,可作为 CCS 患者抗栓的一种替代选择^[27]。

高出血风险患者行 PCI 后,通常建议使用 P2Y₁₂ 受体抑制剂联合阿司匹林治疗,但考虑到出血风险(如胃肠道出血、颅内出血等),可考虑缩短治疗时间或选择单药治疗^[25,28-30]。新型支架技术的应用及腔内影像学指导的 PCI 可降低不良事件的发生率^[31-32]。另一种策略是起始联合用药 1 个月后降阶为阿司匹林联合氯吡格雷,能降低出血风险,提高临床净获益^[33-34]。高缺血风险患者如血栓风险高而出血风险低,可考虑延长 DAPT 疗程^[35-36]。中国医学科学院阜外医院证实,对无保护左主干病变患者个体化评估后延长 DAPT 效果更佳^[37]。

2024 版指南在抗血小板治疗部分更新了 7 条 I 类推荐,根据有/无口服抗凝指征对患者区分推荐,进一步明确了 DAPT(简称双抗)疗程和适用人群,并将双抗后 P2Y₁₂ 抑制剂单药抗血小板治疗(简称单抗)方案写入指南,以氯吡格雷为代表的 P2Y₁₂ 抑制剂在单抗治疗阶段中的地位大幅提高。此外,鉴于氯吡格雷在糖尿病和老年患者中有明确的获益,对于合并糖尿病和老年 CCS 患者,2024 版指南明确推荐 P2Y₁₂ 抑制剂使用氯吡格雷。

2 降脂治疗

CCS 患者作为极高危的动脉粥样硬化性心血管疾病群体,降脂治疗尤为关键。低密度脂蛋白胆固醇(low density lipoprotein cholesterol, LDLC)是降脂治疗的主要靶点,其降低幅度和达标率是预防不良心血管事件的核心。LDLC 的目标值应低于 1.8 mmol/L,并在基线水平上降低超过 50%,以达到血脂双达标,从而逆转动脉粥样硬化斑块并降低主要不良心血管事件(major adverse cardiovascular events, MACE)风险。对于评估为超高危动脉粥样硬化性心血管疾病的 CCS,LDLC 靶目标为<1.4 mmol/L 且较基线降低幅度>50%^[38]。需强调的是,LDLC 较基线降低幅度>50%是动脉粥样硬化斑块逆转的前提,可进一步降低 MACE 风险^[39]。

降脂药物的选择中,他汀类是基石,能够显著降低患者的 MACE 风险^[40-42],但单药使用往往难以达到理想效果。因此,常需联合其他药物如胆固醇吸收抑制剂或 PCSK9 抑制剂来进一步提高降脂疗效。胆固醇吸收抑制剂如依折麦布,可在他汀类的

基础上进一步降低 LDLC^[43]。而他汀类与胆固醇吸收抑制剂的固定剂量复方制剂则兼具疗效和安全性^[44-45]。PCSK9 抑制剂作为新型降脂药物,可显著降低 LDLC 水平达 50%~70%,显著降低 MACE 风险,其安全性和耐受性良好,为临床降脂治疗提供了新的选择^[46-52]。此外,小干扰 RNA 英克司兰^[53-55]和新型降甘油三酯药物二十碳五烯酸乙酯(icosapent ethyl, IPE)也展现出了良好的降脂前景^[56-57]。

3 特殊人群的管理

2024 版指南新增了对 CCS 特殊人群的管理,从疾病综合防治的角度对糖尿病、慢性肾脏病等 7 类特殊人群进行了介绍,旨在提高临床对这些患者的重视,以加强合理用药,且重点讨论了高龄、晚期慢性肾脏病、心力衰竭、癌症及合并瓣膜病等高危因素显著增加冠状动脉疾病及 MACE 发生风险,但此类患者常被大型临床研究排除或样本量极低,导致研究结果代表性不足^[58-63]。心血管代谢性疾病由代谢危险因素累积造成,以动脉粥样硬化和心脑血管事件为主要特征,干预代谢紊乱对预后积极影响。心血管病和慢性肾脏病有共同的危险因素和病理生理机制,互为影响。2024 版指南关注特殊人群的综合防治,特别是合并心力衰竭、糖尿病、慢性肾脏病、高血压、瓣膜性心脏病和癌症的老年患者。

3.1 糖尿病合并 CCS 患者的治疗

同时合并糖尿病和冠状动脉疾病的患者被认为具有极高的 MACE 风险,糖尿病又使冠状动脉疾病的风险增加约 2 倍。近年,新型降糖药钠-葡萄糖协同转运蛋白 2(sodium-glucose cotransporter protein 2, SGLT2)抑制剂和胰高糖素样肽 1(glucagon-like peptide-1, GLP-1)受体激动剂可显著降低 MACE 风险,有强大的心血管保护益处^[4]。抗栓药物选择方面,2 型糖尿病患者存在广泛的血栓前状态,更容易形成血栓,与单用阿司匹林相比,单用氯吡格雷可降低心血管风险,且不显著增加出血风险^[6]。

3.2 慢性肾脏病合并 CCS 患者的治疗

慢性肾脏病是冠状动脉疾病的独立危险因素,超过 30%的冠状动脉疾病患者存在中至重度慢性肾脏病,越来越多接受 PCI 的患者同时患有慢性肾脏病^[64]。随着肾小球滤过率的降低,心血管疾病死亡的风险呈线性增高。血液透析患者的死亡率每年为 20%,其中约 50%可归因于心血管疾病^[7]。心血管病和慢性肾脏病具有共同危险因素和病理生理机制,两者紧密联系,其中一个器官急性或慢性

障碍易诱发另外一个器官的功能障碍即慢性心肾疾病(心肾功能障碍)。目前观点认为,应该将肾脏并列作为心脏和代谢性疾病(心肾代谢性疾病)进行综合性防治。合并慢性肾脏病患者接受介入治疗和药物治疗较少,预后较差,建议对慢性肾脏病患者采用与肾功能正常患者相同的诊断和治疗策略,但需结合患者肾功能调整药物剂量。

3.3 高血压合并 CCS 患者的治疗

高血压是冠状动脉疾病的主要危险因素之一,且许多 CCS 患者同时患有高血压。目前对于近期有心肌梗死的高血压患者,推荐使用对心血管系统有益的降压药物肾素-血管紧张素系统抑制剂(renin-angiotensin system inhibitor, RASI)和 β 受体阻滞剂;对于同时患有高血压、糖尿病、左心室射血分数(left ventricular ejection fraction, LVEF) $\leq 40\%$ 或慢性肾脏病的 CCS 患者,建议使用血管紧张素转化酶抑制剂(angiotensin-converting enzyme inhibitor, ACEI)、血管紧张素 II 受体阻滞剂(angiotensin receptor blocker, ARB)以减少 MACE;对于合并高血压、糖尿病和慢性肾脏病的患者优先推荐 ARB(厄贝沙坦)/ACEI 降低尿蛋白及微量白蛋白,改善肾功能及远期预后。

3.4 心力衰竭合并 CCS 患者的治疗

中国前瞻性心衰注册研究显示 49.4% 的心力衰竭患者合并冠心病^[8]。有症状的心力衰竭患者应充分利尿,优选袪利尿剂,同时建议加用新四联药物,包括肾素-血管紧张素-醛固酮系统(renin-angiotensin-aldosterone system, RAAS)抑制剂[ACEI、ARB、血管紧张素受体脑啡肽酶抑制剂(angiotensin receptor neprilysin inhibitor, ARNI)等]、 β 受体阻滞剂、盐皮质激素受体拮抗剂及 SGLT2 抑制剂。SGLT2 抑制剂可通过增加酮体的生物利用度来改善心力衰竭患者的心脏能量供应,具有潜在的心血管保护作用。心力衰竭的治疗不再强调用药顺序,而是建议尽早应用新四联药物,然后再逐步滴定剂量,在此过程中应关注肾功能的变化。另外,对于已接受指南指导的药物治疗但仍发生心力衰竭加重事件或射血分数降低的心力衰竭患者,可考虑口服可溶性鸟苷酸环化酶激动剂。

3.5 癌症合并 CCS 患者的治疗

癌症合并 CCS 的患者发生 MACE 的风险高,癌症治疗常用的化疗和放疗可能有心脏毒性。管理合并癌症的 CCS 患者具有挑战性,包括虚弱、血小板减少、高出血和高血栓形成风险增加。对于预期生存 ≥ 6 个月的高危癌症患者,可采用有创策略。

对于癌症预后较差(预期生存期 < 6 个月)和(或)出血风险非常高的患者,应考虑采用保守的无创策略。同时抗栓药物选择方面应基于预期寿命、合并症(如血小板减少症、血栓形成风险)以及治疗 CCS 的药物与抗肿瘤药物之间的潜在相互作用。

3.6 老年 CCS 患者的特点与管理挑战

老年 CCS 患者主要包括年龄相关的生理变化,对治疗的响应差异等。需要对老年患者进行个体化治疗,以适应其特定健康状况和需求,并且需要考虑药物的不良反应,因为老年患者可能对某些药物更为敏感^[65]。

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- (此文编辑 文玉珊)