

【 专家共识 】

芪参益气滴丸临床应用专家共识

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摘要: 芪参益气滴丸具有益气通脉、活血止痛之功, 是目前冠状动脉粥样硬化性心脏病临床治疗推荐用药, 但未经过系统整理、归纳, 缺乏相应的指导性文件。为进一步提高临床医生对该药的认识, 更好地指导其临床合理用药, 特邀请全国临床与科研一线专家制订本临床应用专家共识。本共识在系统检索梳理芪参益气滴丸上市以来的临床及基础研究证据的基础上, 采用国际临床医学专家共识研制方法, 对芪参益气滴丸疾病治疗的优势环节、用药方案与时机、剂量、疗效特点、用药安全及注意事项等问题等进行了推荐或建议, 通过了专家评审与论证, 为指导芪参益气滴丸的临床合理用药提供参考。该共识已通过中华中医药学会的审核, 并进行了发布, 编号为 GS/CACM 366—2024。

关键词: 芪参益气滴丸; 临床应用; 合理用药; 专家共识; 冠状动脉粥样硬化性心脏病

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Expert consensus on clinical application of Qishenyiqi Dropping Pills

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Abstract: Qishenyiqi Dropping Pills, renowned for their efficacy in replenishing *qi*, invigorating blood circulation, and mitigating pain, are presently advocated for the clinical management of coronary atherosclerotic heart disease. Despite their therapeutic promise, there has been an absence of comprehensive synthesis or summarization of their applications, alongside a dearth of authoritative guidelines. To deepen clinicians' comprehension of this pharmaceutical and to steer its judicious clinical utilization, we have convened a panel of frontline clinical and research experts nationwide to craft this Expert Consensus on Clinical Application. This consensus is the product of meticulous scrutiny and analysis of clinical and fundamental research evidence accrued since the market introduction of Qishenyiqi Dropping Pills. Employing internationally recognized methodologies for formulating clinical medical expert consensus, it delineates recommendations on the therapeutic advantages, medication protocols and timing, dosage, efficacy profiles, safety, and precautions associated with Qishenyiqi Dropping Pills. Having been meticulously reviewed and validated by experts, this consensus serves as a beacon for the rational clinical deployment of Qishenyiqi Dropping Pills. Endorsed by the China Association of Chinese Medicine (CACM), this consensus has been formally promulgated under the document identifier GS/CACM 366-2024.

Key words: Qishenyiqi Dropping Pills; clinical application; rational deployment; expert consensus; coronary atherosclerotic heart disease

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心血管疾病是我国人口主要死亡原因，其患病率和死亡率处于上升阶段，严重威胁着我国人民的健康安全^[1]。《中国心血管健康与疾病报告》^[2](2023版)指出，我国心血管疾病现患病人数3.3亿，农村和城市每5例死亡人口中就有2例死于心血管疾病，并且面临人口老龄化和代谢危险因素持续流行的双重压力，心血管疾病负担仍将持续增加。芪参益气滴丸具有益气通脉、活血止痛之功，是目前冠状动脉粥样硬化性心脏病(简称冠心病)临床治疗推荐用药，已被纳入《急性心肌梗死中西医结合诊疗专家共识》^[3]和《冠心病合理用药指南》(第二版)^[4]中，同时在全国多个省市各级临床医疗机构均有使用。芪参益气滴丸在临床中广泛应用，临床疗效显著，但未经过系统整理、归纳，缺乏相应的指导性文件。通过总结有关芪参益气滴丸的临床医师应用经验基础，梳理现有循证及临床研究证据，明确其在疾病治疗的优势环节、用药方案与时机、剂量、疗效特点、用药安全及注意事项等问题，促进临床规范合理应用，减少临床用药风险，特制订本临床应用专家共识指导临床

实践。本文件的制定历经梳理说明书，文献预检索，专家访谈，问卷设计及临床应用调研，临床问题确定，证据检索、综合及评价，形成推荐意见/共识建议，撰写共识草案，征求意见，同行评价等环节，并通过进一步的修改和完善，最终共同制定了《芪参益气滴丸临床应用专家共识》(以下简称“本共识”)。

1 共识结构

本共识共由8部分内容构成，分别为：推荐意见/共识建议概要表、范围、药物基本信息、药物研究基础、临床应用建议(包括适应证、用法用量、联合用药、不良反应、禁忌、注意事项)、研究进展、利益冲突说明、共识说明。

2 推荐意见/共识建议概要

本共识针对芪参益气滴丸临床实践应用，通过名义组法共形成了16条指导性意见，其中11条为有证据支持，其证据等级和推荐强度的形成选用GRADE标准^[5]，另外5条为证据不充分所形成的共识建议，具体见表1、2。超说明书但有临床证据支持的内容放于本共识“研究进展”中。

表1 推荐意见

Table 1 Recommendations

序号	共识条目	证据等级	推荐强度
1	在西医规范化治疗基础上，联合应用芪参益气滴丸，可用于治疗稳定型心绞痛患者，以改善临床症状和心电图表现	A级	强推荐
2	在西医规范化治疗基础上，联合应用芪参益气滴丸，能够改善稳定型心绞痛患者中医证候积分	B级	强推荐
3	在西医规范化治疗基础上，联合应用芪参益气滴丸，可用于治疗稳定型心绞痛患者，以减少心绞痛发作次数	C级	强推荐
4	在西医规范化治疗基础上，联合应用芪参益气滴丸，可用于治疗稳定型心绞痛患者，以减少硝酸甘油使用量	B级	强推荐
5	在西医规范化治疗基础上，联合应用芪参益气滴丸，可用于治疗不稳定型心绞痛患者，以改善临床症状和心电图表现	B级	强推荐
6	在西医规范化治疗基础上，联合应用芪参益气滴丸能够降低冠心病不稳定型心绞痛患者总胆固醇(TC)水平	B级	弱推荐
7	在西医规范化治疗基础上，联合应用芪参益气滴丸能够降低冠心病不稳定型心绞痛患者三酰甘油(TG)和低密度脂蛋白胆固醇(LDL-C)水平	C级	强推荐
8	在西医规范化治疗基础上，联合应用芪参益气滴丸，可用于冠心病经皮冠状动脉介入治疗(PCI)术后心绞痛治疗，以提高临床有效率，改善中医症状积分和中医血瘀证候积分	C级	强推荐
9	在西医规范化治疗基础上，联合应用芪参益气滴丸，可用于冠心病PCI术后心绞痛治疗，以减少心绞痛复发率	A级	强推荐
10	在西医规范化治疗基础上，联合应用芪参益气滴丸，可用于冠心病PCI术后心绞痛治疗，以改善患者心绞痛发作情况(SAQ量表)	B级	强推荐
11	在西医规范化治疗基础上，联合应用芪参益气滴丸，可用于冠心病PCI术后心绞痛治疗，以改善患者躯体受限程度、提升心绞痛稳定状况和治疗满意程度(SAQ量表)	C级	强推荐

表 2 共识建议
Table 2 Consensus recommendations

序号	共识条目	建议情况
1	芪参益气滴丸适用气虚血瘀型胸痹心痛患者，以减轻心前区刺痛、胸闷、心悸、气短等中医临床症状	建议
2	芪参益气滴丸可用于治疗冠状动脉微血管心绞痛，以减轻胸闷胸痛等临床症状，但需要更多高质量随机对照试验（RCT）研究提供证据	建议
3	孕妇及过敏体质者慎用芪参益气滴丸	建议
4	极个别患者服用芪参益气滴丸期间可出现胃肠道不适、低血压、头晕头痛等不良反应	建议
5	芪参益气滴丸不良反应的处理方式主要采用停药及对症处理	建议

3 范围

本共识规定了芪参益气滴丸的临床关键问题清单、疾病诊断、临床应用建议等，并说明了其临床应用的安全性和注意事项。本共识适用于全国三级医院、二级医院、一级医院、基层医疗卫生机构的临床医师（中医、西医、中西医结合专业），为其合理使用芪参益气滴丸提供指导和参考。

4 药物基本信息

芪参益气滴丸是提取黄芪、丹参、三七、降香中的有效成分精制而成的滴丸制剂（国药准字 Z20030139），主要用于心血管疾病的治疗。该药于 2003 年上市销售，是《中华人民共和国药典》（2020 版）、《国家基本药物目录》（2018 版）、《国家医保目录》（2024 版）纳入品种，先后进入多项诊疗指南和专家共识。芪参益气滴丸药品说明书载该药具有益气通脉、活血止痛功效。用于气虚血瘀型胸痹。症见胸闷胸痛，气短乏力、心悸、面色少华、自汗，舌体胖有齿痕、舌质暗或紫暗或有瘀斑，脉沉或沉弦。适用于冠心病、心绞痛见上述症状者。

5 药物研究基础

5.1 芪参益气滴丸基础研究

5.1.1 改善能量代谢 芪参益气滴丸主要成分黄芪甲苷、三七皂苷和丹参素等的协同作用，能够显著改善心肌缺血再灌注损伤中失常的能量代谢。可通过改善线粒体复合物 V 的亚基 ATP5D 低表达，抑制 RhoA 的活性和线粒体复合物 I 的亚基 NDUFA10 的降低，调节 ATP5D mRNA（ATP 合酶 δ 亚基）水平，提高心肌组织 ATP 含量，综合改善心脏能量代谢^[6]。

5.1.2 减轻心肌损伤，抑制胶原沉积 缺血再灌注大鼠模型给予芪参益气滴丸后，可抑制大鼠心肌断裂、抑制线粒体肿胀、减少组织间水肿；可以显著保护心肌，改善心肌结构。在抑制胶原沉积方面，

芪参益气滴丸主要通过 TGF β 1/Smad 信号通路抑制胶原沉积^[6]。

5.1.3 抑制心肌纤维化 缺血再灌注损伤 3 h 组中，核糖体蛋白 S19 (RPS19) 二聚体的蛋白含量提高，并且再灌注 6 d 后进一步增加；芪参益气滴丸给药后，显著抑制了 RP S19 二聚体的异常上调；通过 S19 途径抑制单核细胞分泌促纤维化因子进入受损的心肌组织，从而抑制心肌纤维化^[7]。

5.1.4 抑制心肌肥厚 芪参益气滴丸的主要成分黄芪甲苷、丹参素、三七皂苷 R₁，单独给药可以抑制心肌肥厚。主要机制是促进腺苷三磷酸/腺苷二磷酸 (ATP/ADP)、腺苷三磷酸 / 腺苷一磷酸 (ATP/AMP) 间的转化，改善心肌能量代谢，并抑制过氧化物产生，减少氧化应激损伤。在主动脉夹闭 4 周后给药不仅可抑制 8 周后的肥厚，还可逆转心肌肥厚^[8]。同时可显著减轻左室后壁舒张末期厚度和动物的全心质量指数 (HW/BW)，增加左室射血分数 (LVEF) 和左室缩短分数。能降低心肌纤维化程度，CD68 和转化生长因子 β -1 的表达明显下降^[7]。

5.1.5 调控一氧化氮-环磷酸鸟苷酸-环磷酸鸟苷酸依赖的蛋白激酶 (NO-cGMP-PKG) 信号通路 NO-cGMP-PKG 通路受抑制，导致心肌纤维化，心室重构，心室僵硬度增加，舒张功能减退等，是射血分数保留型心衰 (HFpEF) 发生的重要机制之一。通过 HFpEF 小鼠模型进行实验发现，芪参益气滴丸可能通过下调心肌细胞钙转运或释放的关键蛋白 RyR2 的表达，调控 NO-cGMP-PKG 信号通路，减少内皮一氧化氮合酶 (eNOS) 解耦联，抑制内皮细胞炎症反应，减轻 HFpEF 的氧化应激损伤等途径延缓心肌纤维化，改善舒张功能，改善 HFpEF^[9]。

5.1.6 抗动脉粥样硬化 芪参益气滴丸通过促进动脉粥样硬化病变中调节性 T 细胞、抑制斑块、脾脏中辅助 Th17 细胞、肝脏胆固醇排泄来发挥抗动

脉粥样硬化作用^[10]。可降低血清肿瘤坏死因子- α (TNF- α)、血管细胞黏附分子-1 (VCAM-1)、白细胞介素 6 (IL-6) 水平, 抑制 TNF- α 、VCAM-1 在斑块部位表达, 抑制斑块局部炎症反应从而达到稳定斑块的作用^[11]。同时可以显著降低超敏 C 反应蛋白 (hs-CRP) 水平, 具有抗炎作用, 从而延缓和抑制动脉粥样硬化的进展^[12]。

5.1.7 调节血脂 茜参益气滴丸可降低 TC、LDL-C 水平从而抑制动脉粥样硬化的进展^[11]。减轻脂毒性对血管内皮细胞的毒害效应; 防止高脂血症对内皮细胞/一氧化氮合成酶/一氧化氮 (EC/NOS/NO) 途径的损伤, 改善血管内皮依赖性舒张功能障碍^[13]。

5.1.8 安全性研究 茜参益气滴丸小鼠单次 ig 给药的半数致死量 (LD_{50}) 为浸膏 $25.807\text{ g}\cdot\text{kg}^{-1}$ (相当于滴丸 $103.225\text{ g}\cdot\text{kg}^{-1}$), 为临床剂量的 4 129 倍。在 GLP 实验室完成了大鼠 6 个月重复给药毒性试验结果显示, ig 给予 0 、 500 、 $1\,500$ 、 $4\,000\text{ mg}\cdot\text{kg}^{-1}$ 的茜参益气滴丸, 各剂量组动物的一般观察、体质质量、摄食量、眼科检查、血液学、血凝学、血液生化学、尿液分析、脏器系数及组织病理学检查均未见与供试品相关的异常改变, 重复给药后无蓄积, 大鼠 6 个月重复给药未观察到临床不良反应的剂量 (NOAEL) 为滴丸 $4\,000\text{ mg}\cdot\text{kg}^{-1}$, 为临床剂量的 160 倍。

5.2 茜参益气滴丸临床研究

5.2.1 茜参益气滴丸治疗冠心病心绞痛(气虚血瘀证)II期临床试验 既往在中国中医科学院西苑医院等 5 家医疗机构开展的 II 期临床试验 (内部试验), 共观察患者 209 例, 试验组给予茜参益气滴丸 0.5 g , 餐后半小时服用, 同时服用养心氏片模拟剂 1.8 g (3 片), 每日 3 次; 对照组予养心氏片 1.8 g , 餐后半小时服用, 同时服用茜参益气滴丸模拟剂 0.5 g , 每日 3 次, 观察 4 周。结果显示: 试验组治疗心绞痛显效率为 43.27% , 总有效率为 86.53% ; 对照组显效率为 22.86% , 总有效率为 73.33% , 组间比较具有显著性差异 ($P<0.01$)。试验组中医症状总有效率 92.31% , 对照组为 79.05% , 组间比较具有显著性差异 ($P<0.01$)。临床试验中通过对血、尿、粪常规及肝、肾功能实验室检查, 未发现明显不良反应。未见治疗前正常, 治疗后出现异常者。未见明显不良反应。

5.2.2 茜参益气滴丸治疗冠心病心绞痛(气虚血瘀证)III期临床试验 既往在中国中医科学院西苑医

院等 5 家医疗机构开展的 III 期临床试验 (内部试验), 共观察患者 421 例, 试验组予茜参益气滴丸 0.5 g , 餐后半小时服用, 每日 3 次; 对照组予养心氏片 1.8 g , 餐后半小时服用, 每日 3 次, 观察 4 周。结果显示: 试验组治疗冠心病心绞痛显效率为 46.00% , 总有效率为 88.33% , 中医症状总有效率 89.00% ; 对照组显效率为 25.62% , 总有效率为 75.20% , 中医症状总有效率 82.64% 。组间比较具有显著性差异 ($P<0.01$)。心电图疗效: 试验组总有效率为 60.67% , 对照组为 52.89% , 组间比较具有显著性差异 ($P<0.01$)。茜参益气滴丸能明显减少冠心病心绞痛患者心绞痛发作次数, 并能有效地改善胸痛、胸闷、气短、乏力等各项中医症状。其治疗前后各项中医症状改善比较, 具有显著性差异 ($P<0.01$)。与对照组比较, 胸痛症状改善方面具有显著性差异 ($P<0.01$)。

6 临床应用建议

6.1 适应证

茜参益气滴丸适用气虚血瘀型胸痹心痛患者, 以减轻心前区刺痛、胸闷、心悸、气短等中医临床症状 (共识建议)。临床适应证包括: 冠心病稳定型心绞痛、不稳定型心绞痛、冠心病 PCI 术后胸闷胸痛临床症状及冠状动脉微血管心绞痛, 以下分条目详细阐述各个疾病的专家推荐意见、共识建议及临床研究证据。

6.1.1 稳定型心绞痛 西医规范化治疗基础上, 联合应用茜参益气滴丸, 能够改善稳定型心绞痛患者的临床症状和心电图疗效 (A 级证据, 强推荐)、中医证候积分 (B 级证据, 强推荐), 减少硝酸甘油使用量 (B 级证据, 强推荐) 和心绞痛发作次数 (C 级证据, 强推荐)。证据概要: 对包含 3 044 例患者的 26 项 RCT 研究进行 Meta 分析^[14-39], 结果显示, 在西医规范化治疗基础上, 联合应用茜参益气滴丸能够改善临床疗效 ($P<0.01$)、心电图变化 ($P<0.01$)、中医证候积分 ($P<0.01$)、LVEF ($P<0.01$)、和心排血量 ($P<0.01$); 减少硝酸甘油使用量 ($P<0.05$) 和心绞痛发作次数 ($P<0.01$)。

6.1.2 不稳定型心绞痛 在西医规范化治疗基础上, 联合应用茜参益气滴丸, 能够改善不稳定型心绞痛患者临床症状和心电图表现 (B 级证据, 强推荐), 降低 TC 水平 (B 级证据, 弱推荐), 降低 TG 和 LDL-C 水平 (C 级证据, 弱推荐)。证据概要: 对包含 1 779 例患者的 18 项 RCTs 研究进行 Meta

分析^[40-57],结果显示,在西医规范化治疗基础上,联合应用芪参益气滴丸可以显著改善患者心绞痛临床疗效($P<0.01$)、心电图变化($P<0.01$)、LVEF ($P<0.01$);能够降低 TG ($P<0.01$)、TC ($P<0.01$) 和 LDL-C 水平 ($P<0.01$)。

6.1.3 冠心病 PCI 术后胸痹心痛临床症状 在西医规范化治疗基础上,联合应用芪参益气滴丸,可用于冠心病 PCI 术后心绞痛治疗,以提高临床有效率,改善中医症状积分和中医血瘀证候积分水平(C 级证据,强推荐)。在西医规范化治疗基础上,联合应用芪参益气滴丸,可用于冠心病 PCI 术后心绞痛治疗,以减少心绞痛复发率(A 级证据,强推荐),改善心绞痛发作情况(SAQ 量表,B 级证据,强推荐)、患者躯体受限程度,提升心绞痛稳定状况和治疗满意程度(SAQ 量表,C 级证据,强推荐)。证据概要:对包含 4 876 例患者的 41 项 RCTs 研究进行 Meta 分析^[45,51,58-96],结果显示,在西医规范化治疗基础上,联合应用芪参益气滴丸显著提高冠心病 PCI 术后心绞痛患者的临床有效率($P<0.01$)。芪参益气滴丸治疗 6 个月后可显著降低中医症状积分($P<0.01$)和血瘀证候积分($P<0.05$)。芪参益气滴丸可用于治疗冠心病 PCI 术后心绞痛患者,减少心绞痛复发率($P<0.01$)。在西雅图心绞痛评分(SAQ 量表)方面,芪参益气滴丸可显著改善躯体受限程度(PL, $P<0.01$)、心绞痛稳定状况(AS, $P<0.01$)和心绞痛发作情况(AF, $P<0.01$),提高治疗满意程度(TS, $P<0.05$)。

6.1.4 冠状动脉微血管心绞痛 芪参益气滴丸可用于治疗冠状动脉微血管心绞痛,以减轻胸闷胸痛等临床症状,但需要更多高质量 RCTs 研究提供证据(共识建议)。

6.2 用法用量

餐后半小时服用,1 次 1 袋(每袋装 0.5 g; 薄膜衣滴丸每袋装 0.52 g),每日 3 次,4 周为一疗程或根据临床实际状况调整。

6.3 联合用药

与其他中药或中成药联合使用时,应注意辨证施治原则,关注用药安全性。

6.4 不良反应

芪参益气滴丸不良反应的处理方式主要采用停药及对症处理(共识建议)。

共 4 篇文献^[59,68,73,76]报告了西医常规治疗联合芪参益气滴丸出现的不良反应,低血压、过敏、头

痛、急性肾损伤、恶心、呕吐、腹泻、胃脘部疼痛、牙龈出血累计 26 例。

6.5 禁忌

孕妇及过敏体质者慎用芪参益气滴丸(共识建议)。

6.6 注意事项

极个别患者服用芪参益气滴丸期间可出现胃肠道不适、低血压、头晕头痛等不良反应(共识建议)。

7 研究进展

7.1 冠心病急性 ST 段抬高型心肌梗死(STEMI)

研究表明,在西医规范化治疗基础上,联合应用芪参益气滴丸,能够改善冠心病 STEMI 患者 LVEF、左心室舒张末期内径(LVEDD)、左心室收缩末期内径(LVESD),降低氨基末端脑钠肽前体(NT-proBNP)指标水平(C 级证据)。证据概要:对包含 616 例患者的 6 项 RCTs 研究进行 Meta 分析^[58-62,96],结果显示,在西医规范化治疗基础上,联合应用芪参益气滴丸能够改善冠心病 STEMI 患者 LVEF ($P<0.01$);降低 NT-proBNP 指标水平($P<0.01$);改善 LVEDD ($P<0.05$) 和 LVESD ($P<0.05$)。

7.2 冠心病心肌梗死后二级预防

研究表明,芪参益气滴丸在冠心病心肌梗死后二级预防上与阿司匹林有相似的作用,但需要更多高质量 RCTs 研究提供证据(A 级证据)。证据概要:一项包含 3 505 例患者的 RCT 研究^[97],结果显示芪参益气滴丸与阿司匹林相比,在治疗 12 个月,并观察 6 个月后芪参益气滴丸组在 12 个月和 18 个月主要结局的估计发生率分别为 2.98% 和 3.67%,阿司匹林组分别为 2.96% 和 3.81%,两组间无显著差异,芪参益气滴丸在冠心病心肌梗死二级预防方面具有与阿司匹林相似的效果,且不良反应更少。基础实验表明,芪参益气滴丸具有血小板抑制作用、稳定动脉粥样硬化斑块及心肌保护作用。

7.3 冠心病合并心力衰竭

研究表明,芪参益气滴丸可以提高冠心病合并心力衰竭患者 6 min 步行距离,改善 LVEF、左心室收缩末期容积(LVESV)和 LVESD,降低 NT-proBNP 水平(C 级证据)。芪参益气滴丸可以改善冠心病合并心力衰竭患者心功能分级(NYHA 分级,A 级证据)和心室舒张功能(C 级证据)。证据概要:对包含 3 703 例患者的 32 项 RCT 研究进行 Meta 分析^[98-129],结果显示,在西医规范化治疗

基础上,联合应用芪参益气滴丸可以进一步提高患者6 min步行距离($P<0.01$)、改善患者心功能NYHA分级水平($P<0.01$)、LVEF($P<0.01$)、心室舒张功能(E/A值)($P<0.01$)、LVESV($P<0.01$)、LVESD($P<0.01$)水平;进一步降低患者NT-proBNP指标水平($P<0.01$)。一项研究纳入640例慢性缺血性射血分数降低型心力衰竭(HFrEF,LVEF≤40%)患者,常规抗心衰药物治疗基础上联合芪参益气滴丸治疗,可以显著提高患者6个月时的6 min步行距离($P<0.01$),改善患者的生活质量($P<0.01$)^[129]。

7.4 冠心病合并高血压

研究表明,芪参益气滴丸可以降低冠心病合并高血压患者的舒张压水平(A级证据)。证据概要:对包含1152例患者的2项RCTs研究进行Meta分析^[68,130],结果显示,在西医规范化治疗基础上,联合应用芪参益气滴丸可以降低患者的舒张压($P<0.05$)。针对冠心病合并高血压患者的西雅图心绞痛评分(SAQ量表),在西医规范化治疗基础上,联合应用芪参益气滴丸可以改善躯体受限程度(PL, $P<0.01$)。

7.5 冠心病合并2型糖尿病

研究表明,芪参益气滴丸可以降低冠心病合并2型糖尿病患者糖化血红蛋白(HbA1c)、TC和TG水平,提升高密度脂蛋白胆固醇水平(HDL-C)(C级证据)。芪参益气滴丸可降低冠心病合并2型糖尿病患者餐后2 h血糖水平(B级证据)。证据概要:对包含432例患者的7项RCTs研究进行Meta分析^[76,80,106,131-134],结果显示,在西医规范化治疗基础上,联合应用芪参益气滴丸可显著改善患者糖化血红蛋白水平($P<0.01$);显著降低冠心病合并2型糖尿病患者的餐后2 h血糖($P<0.01$)、血清TC水平($P<0.01$)、血清TG水平($P<0.01$);提升HDL-C水平($P<0.05$)、LVEF($P<0.01$)和LVEDD($P<0.01$)。

7.6 冠心病合并期前收缩

研究表明,芪参益气滴丸能够改善冠心病合并室性期前收缩和房性期前收缩患者病情,但需要更多高质量RCTs研究提供证据。证据概要:共纳入2篇RCTs^[135-136]、280例患者,因结局指标差异大,未能进行合并分析,仅进行系统综述。在临床有效率方面,一项研究^[135]将房性、室性、交界性心律失常一起统计,研究结果显示,在西医规范化治疗

基础上,联合应用芪参益气滴丸治疗优于对照组,差异具有统计学意义($P<0.05$);另一项研究^[136]将室性期前收缩和房性期前收缩一起统计,结果显示,在西医规范化治疗基础上,联合应用芪参益气滴丸治疗优于对照组,差异具有统计学意义($P<0.05$)。

7.7 冠心病PCI术后不良事件

研究表明,在西医规范化治疗基础上,联合应用芪参益气滴丸,可用于治疗冠心病PCI术后患者,减少主要心脏不良事件(MACE)整体发生率(B级证据),其中可减少心肌梗死发生率(A级证据)、心源性死亡发生率(B级证据),同时具有提升患者心功能水平、改善血脂指标功效。芪参益气滴丸治疗稳定型心绞痛、不稳定型心绞痛、慢性心力衰竭和急性心肌梗死PCI术后半年内不良反应发生率低,安全性较高(D级证据)。证据概要:对包含4876例患者的41项RCTs研究进行Meta分析^[45,52,58-73],结果显示,在MACE方面,芪参益气滴丸治疗后MACE整体发生率显著降低($P<0.01$),其中,心肌梗死发生率($P<0.05$)、心源性死亡发生率($P<0.05$)均显著降低。在心功能指标方面,结果显示芪参益气滴丸可降低BNP水平($P<0.01$)和LVEDD($P<0.01$);提高LVEF($P<0.01$),降低LVEDV($P<0.01$)、LVESD($P<0.01$)以及LVESV($P<0.05$)。其他结局指标方面,芪参益气滴丸可显著降低血清TC($P<0.05$)和提升HDL-C($P<0.05$),降低hs-CRP($P<0.01$)、肌酸激酶同工酶MB(CK-MB, $P<0.05$)。

7.8 其他临床应用

有研究报道芪参益气滴丸对于糖尿病肾病^[137]、糖尿病周围神经病变^[138]、亚临床甲状腺功能减退^[139]、慢性阻塞性肺疾病^[140]、急性脑卒中^[141]、慢性乙型肝炎^[142]、主动脉夹层^[143]等疾病具有一定临床疗效。

8 利益冲突说明

所有参与制定的成员均正式签署了利益冲突声明书,声明无利益冲突。在本共识的制定过程中,所有相关参与者均无利益冲突。企业人员主要负责组织、服务等事务性工作,不参与任何共识决策。

9 共识说明

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利益冲突 所有作者均声明不存在利益冲突

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