

药物球囊应用于支架内再狭窄患者临床疗效研究进展

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摘要

支架内再狭窄(In-Stent Restenosis, ISR)是冠状动脉介入治疗后常见且具有挑战性的并发症,严重影响患者的长期预后和生活质量。随着介入技术的发展,药物球囊(Drug-Coated Balloon, DCB)作为一种新兴的局部药物递送工具,因其无需再次植入支架且能有效抑制血管内膜增生,近年来在ISR治疗领域受到广泛关注与研究。当前大量临床试验和系统评价显示,药物球囊在改善血管通畅率、减少再狭窄发生及降低不良心血管事件方面表现出良好的临床疗效和安全性。然而,药物球囊的作用机制尚需进一步阐明,且不同患者群体的疗效差异及长期效果仍有待深入探讨。本综述着重药物球囊在ISR患者中的最新应用进展,系统分析其临床疗效与安全性评价,并对未来的研究方向进行了展望,旨在为临床治疗提供科学依据和实践指导,推动ISR治疗策略的优化升级。

关键词

药物球囊, 支架内再狭窄, 临床疗效, 冠状动脉介入, 局部药物递送

Research Progress on Clinical Efficacy of Drug Balloon in Patients with in-Stent Restenosis

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Abstract

In-Stent Restenosis, ISR) is a common and challenging complication after percutaneous coronary intervention, which seriously affects the long-term prognosis and quality of life of patients. With the development of interventional technology, Drug-Coated Balloon, DCB), as a new local drug delivery tool, has been widely concerned and studied in the field of ISR therapy in recent years because it does not need to implant stents again and can effectively inhibit intimal hyperplasia. At present, a large number of clinical trials and systematic reviews show that drug balloons show good clinical efficacy and safety in improving vascular patency rate, reducing restenosis and reducing adverse vascular events. However, the mechanism of action of drug balloon needs to be further clarified, and the difference of curative effect and long-term effect of different patient groups need to be further discussed. This review focuses on the latest application progress of drug balloon in ISR patients, systematically analyzes its clinical efficacy and safety evaluation, and looks forward to the future research direction, aiming at providing scientific basis and practical guidance for clinical treatment and promoting the optimization and upgrading of ISR treatment strategy.

Keywords

Drug Balloon, In-Stent Restenosis, Clinical Efficacy, Coronary Intervention, Local Drug Delivery

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1. 前言

支架内再狭窄(in-stent restenosis, ISR)是冠状动脉支架植入术后常见的血管重塑问题,主要表现为血管腔的再次狭窄,进而影响局部血流,增加心血管事件的风险。虽然药物洗脱支架(drug-eluting stents, DES)已显著减少了 ISR 的发生率,但这一并发症依然存在,且其治疗复杂[1][2]。ISR 的发生机制主要涉及血管平滑肌细胞(vascular smooth muscle cells, VSMCs)的异常增殖和迁移,以及血管内皮功能的损伤和修复失衡[3][4]。具体而言, VSMCs 的表型转换、炎症反应、细胞凋亡及自噬等细胞学过程参与了新生内膜的形成,这些病理改变最终导致血管腔狭窄[4][5]。此外,内皮细胞的修复不良和血管壁的机械刺激也是促使 ISR 形成的重要因素[3]。

传统的 ISR 治疗方法包括再次进行球囊扩张(plain balloon angioplasty, POBA)和重复植入支架,但这些方法存在一定局限性。重复支架植入虽然能机械性支撑血管,抑制新生内膜增生,但多层金属支架叠加可能引发更严重的血管炎症、纤维化反应及晚期支架血栓形成风险[3][6]。而传统球囊扩张往往因不能有效遏制 VSMCs 的增殖,导致高复发率[7]。此外,生物可吸收支架(bioresorbable vascular scaffolds, BVS)虽然提供了无永久异物的优势,但其机械强度不足、降解速度不理想及晚期安全性问题限制了广泛应用[8][9]。

近年来,药物球囊(drug-coated balloons, DCB)作为一种局部药物释放技术,因其“无支架植入”原则和有效抑制新生内膜增生的能力,成为 ISR 治疗的重要选择。DCB 通过在球囊扩张过程中将抗增殖药物(如紫杉醇、雷帕霉素)迅速递送至病变部位,抑制 VSMCs 异常增殖和迁移,同时避免了金属异物的长期留置带来的不良反应。自 2006 年首例使用紫杉醇涂层球囊治疗冠脉 ISR 成功报告以来,DCB 的临床应用逐渐增多,涵盖 ISR、小血管病变、分叉病变等多个复杂冠状动脉病变类型[10][11]。多项临床研究和

随机对照试验显示, DCB 治疗 ISR 的目标病变再血管重建率(target lesion revascularization, TLR)显著降低, 且安全性良好[12]-[14]。相较于重复支架植入, DCB 在避免多层金属叠加、缩短双抗治疗时间及减少晚期支架相关事件方面具有明显优势[6] [15]。

此外, 药物球囊的药物类型及载体技术不断进步。紫杉醇涂层球囊因其高效的抗增殖作用被广泛采用, 而雷帕霉素涂层球囊以其均匀的药物分布和抗炎特性, 尤其适用于不稳定及炎症丰富的斑块病变[16]。两者在不同病理类型的斑块及 ISR 治疗中显示出可比甚至互补的优势, 成为个体化治疗策略的重要组成。当前, 更多新型药物球囊如 sirolimus 纳米载体球囊等正在临床研究阶段, 期待进一步提升治疗效果[6] [17]。

尽管药物球囊技术取得显著进展, 但仍存在一些挑战和不足。如药物在传递过程中的损失、均匀分布不足及对钙化严重病变的穿透力有限等问题[18]。此外, 针对不同类型 ISR (如裸金属支架 ISR 与药物洗脱支架 ISR)及不同病理机制的个体化治疗方案尚需深入探讨[6] [15]。影像学技术如光学相干断层扫描(optical coherence tomography, OCT)在 ISR 病理类型识别、治疗方案选择和效果评估中发挥越来越重要的作用, 辅助实现精准治疗[19] [20]。

综上所述, 支架内再狭窄作为冠状动脉介入治疗后的主要血管重塑问题, 给临床带来显著挑战。传统治疗方法虽有一定效果, 但复发率较高且存在局限性。药物球囊作为一种局部药物递送创新技术, 通过有效抑制 VSMCs 的异常增殖, 减少新生内膜形成, 逐渐成为 ISR 治疗的重要手段。近年来, 随着技术和药物载体的不断优化, 药物球囊在 ISR 治疗中的临床应用日益广泛, 疗效和安全性获得众多临床研究支持, 显示出良好前景。未来, 结合先进影像技术, 深入解析 ISR 的病理机制, 优化药物球囊设计与个体化治疗策略, 将进一步促进该领域的发展, 为临床决策提供科学依据和技术保障[3] [10] [16] [19]。

2. 正文

2.1. 药物球囊的作用机制及技术特点

2.1.1. 药物球囊的设计原理与药物递送机制

药物球囊(Drug-Coated Balloons, DCB)作为一种新兴的血管介入治疗技术, 主要通过在球囊表面涂覆抗增殖药物(如紫杉醇、依维莫司)实现局部药物递送。在扩张过程中, 球囊将药物迅速释放至血管内膜, 通过高浓度的局部药物递送抑制血管平滑肌细胞的增殖与迁移, 减少纤维组织形成, 从而降低支架内再狭窄(ISR)的发生率。紫杉醇(Paclitaxel)作为主要的药物涂层, 因其高脂溶性和快速细胞摄取特性, 在临床上广泛应用且效果显著[11]。然而, 紫杉醇可能引起部分不良血管重塑, 如冠状动脉瘤形成, 这提示其药物作用机制及安全性需进一步关注[21]。

依维莫司(Sirolimus)球囊作为另一种抗增殖药物选项, 具备更均匀的组织分布和抗炎特性, 适用于不稳定、富含脂质及炎症斑块, 促进斑块稳定性。初步临床研究表明, 依维莫司球囊在安全性和疗效上不逊于紫杉醇球囊[16] [22]。药物释放时间和剂量的精准控制对于治疗效果至关重要, 当前球囊涂层技术不断优化, 包括采用不同辅料和纳米技术, 提升药物的稳定性和释放效率[23] [24]。例如, 利用超声喷涂技术制备的可响应活性氧(ROS)降解的水凝胶涂层, 实现持续控制释放, 促进血管内皮屏障修复和局部抗炎, 增强血管愈合[25]。此外, 球囊表面微针结构的引入提高了药物传递效率, 通过物理穿透促进药物深入血管壁, 显示出优于传统涂层球囊的药物递送能力[26] [27]。药物球囊的设计基于快速且高效的局部药物释放, 结合药物的抗增殖作用及载体技术的优化, 旨在实现无支架植入的同时有效抑制血管再狭窄, 体现了介入治疗技术向精准药物递送方向的发展趋势。

2.1.2. 药物球囊与传统治疗方法的比较

药物球囊相较于传统的再次支架植入, 具有避免多层金属支架叠加带来的机械问题和血管壁损伤的

优势。多层支架不仅会增加血管壁的机械负担, 导致血管弹性减弱, 还可能加重内膜增生, 促发更严重的再狭窄[28]。相比之下, 药物球囊通过局部药物释放抑制平滑肌细胞增生, 且不留置永久支架, 减少了慢性炎症反应及支架相关并发症(如迟发性支架血栓)的风险[11] [29]。

与普通球囊扩张相比, 药物球囊因其药物抑制机制显著降低了再狭窄率。多项随机对照试验显示, 药物球囊治疗的目标病变再狭窄率明显低于普通球囊组, 改善了血管再通率和临床症状[30] [31]。此外, 药物球囊操作相对简便, 不需额外植入物, 减少了手术时间和并发症风险。在复杂病变的处理上, 药物球囊亦表现出较好的适应性, 如小血管病变、分叉病变等, 且术后抗血小板治疗时间较短, 有利于高出血风险患者的管理[11] [32]。

在周围血管介入领域, 药物球囊与修复性装置如旋磨术联合使用, 显示出对难治性病变的协同效应, 改善临床终点[31] [33]。然而, 药物球囊的药物释放效率及均匀性仍受球囊设计、药物涂层微观结构及血管壁特性的影响, 限制了其疗效的一致性[34] [35]。药物球囊通过结合机械扩张与药物抑制相较传统治疗展现出多方面优势, 尤其在避免多层支架叠加及降低再狭窄方面表现突出, 成为临床治疗支架内再狭窄及部分新病变的有效选择。

2.2. 药物球囊在支架内再狭窄患者中的临床疗效评价

2.2.1. 临床试验数据综述

多项随机对照试验(RCT)已系统评估药物球囊(Drug-Coated Balloon, DCB)治疗支架内再狭窄(In-Stent Restenosis, ISR)的临床疗效, 结果显示相较于普通球囊扩张, 药物球囊显著降低了血管再狭窄率。主要终点通常涵盖血管内径减少率、目标病变再血管化率(Target Lesion Revascularization, TLR)及无事件生存率等关键指标。例如, PACCOCATH ISR 试验和 PEPCAD II 试验均证实了药物球囊在 ISR 治疗中的优势。PACCOCATH ISR 试验指出, 使用药物球囊治疗 ISR 时, TLR 率显著较低, 临床事件发生率亦有所减少[37]。另有一项多中心随机对照研究比较了药物球囊与重复植入新一代药物洗脱支架(DES)治疗支架边缘再狭窄(Stent Edge Restenosis, SER), 结果发现药物球囊组在初期随访中 TVR 风险较低, 但经倾向性匹配后, 两组临床事件无显著差异, 显示药物球囊为治疗 SER 的有效替代方案[41]。

此外, 多项 RCT 显示, 对于复发性 DES-ISR, 药物球囊治疗在降低 MACE (主要不良心脏事件)和 TLR 方面优于重复植入 DES, 尤其在三层及以上金属支架的 ISR 患者中, 药物球囊显著改善了无事件生存率[42]。DAEDALUS 研究汇总 10 项 RCT 数据, 分析了药物球囊对裸金属支架(BMS)及 DES ISR 的疗效, 结果表明在 BMS-ISR 患者中, 药物球囊与重复 DES 植入效果相当; 而在 DES-ISR 患者中, 药物球囊的 TLR 风险较重复 DES 植入高, 但其安全性指标相似。此外, 药物球囊在治疗冠状动脉 ISR 显示了良好的血管内径维持和较低的晚期狭窄发生率, 支持其作为一种有效的治疗策略[43] [44]。

总体而言, 临床试验数据一致支持药物球囊治疗 ISR 患者能有效减少血管再狭窄及再干预需求, 且在部分患者群体中, 药物球囊治疗的临床结局优于或不逊于重复植入 DES, 成为 ISR 治疗的重要手段之一[45] [46]。

2.2.2. 长期疗效与安全性分析

药物球囊治疗 ISR 患者的长期随访数据显示, 患者复发率较低, 晚期血栓形成事件相对较少, 安全性良好。长期数据来自包括瑞典冠状动脉造影及血管成形注册(SCAAR)数据库等大型队列分析, 显示药物球囊较普通球囊扩张可显著降低目标病变再血管化率(TLR)和全因死亡率[47]。IN.PACT Global 研究对复杂患者的长期随访(最长达 36 个月)表明, 药物球囊治疗股腠动脉病变具有持续的临床有效性和较低的再干预率, 显示其在现实世界中的安全性和有效性[48] [49]。

针对不同药物涂层的球囊, 疗效和安全性存在一定差异。近期多项研究比较了紫杉醇(paclitaxel)与西

罗莫司(sirolimus)涂层球囊的临床表现。一项前瞻性观察研究指出,两种涂层均安全有效,且结合影像学指导(如 IVUS)可优化治疗效果。另外,多项随机试验显示,西罗莫司涂层球囊在部分患者中表现出非劣效性,但仍需更大规模及长期临床试验进一步验证。创新型涂层如依维莫司(everolimus)涂层球囊在动物模型中显示出良好的安全性和疗效,为未来临床应用提供潜力[50]-[53]。

长期安全性方面,药物球囊治疗未见显著增加出血事件或其他严重不良反应。基于大规模数据库和多中心研究,药物球囊与第二代 DES 相比,在 1 年至 3 年的随访中均未显示显著的死亡率差异,且在部分研究中药物球囊组的全因死亡率及出血入院率更低,进一步确认其安全性。然而,关于药物剂量及涂层成分对长期安全性的影响,目前仍存在争议,需持续关注后续研究[54][56]。药物球囊在 ISR 治疗中展现出良好的长期疗效和安全性,为患者提供了无需植入额外金属支架的治疗选择,特别适用于多层支架 ISR 或高出血风险患者[57]。

2.2.3. 药物球囊的影响因素、局限性及对策

药物球囊目前主要适用于支架内再狭窄(ISR)患者,尤其是早期 ISR 和小直径血管病变。大量临床研究证实,药物球囊在 ISR 治疗中可有效降低靶病变再血管化率,并在小血管病变中显示出与药物洗脱支架相当的疗效[36][37]。此外,药物球囊在分叉病变、急性冠脉综合征、高出血风险患者等特殊群体中也获得了一定的应用认可[29][38]。然而,对于复杂病变如重度钙化、长期病变的疗效仍需进一步验证。钙化斑块可能阻碍药物的有效穿透和均匀递送,影响治疗效果。同时,长病变区域的均匀药物递送存在技术挑战,部分研究建议联合旋磨术等预处理手段以改善效果[31][33][39]。药物球囊的成本较传统普通球囊显著增加,且药物选择受限,目前临床主要应用紫杉醇和依维莫司两种药物,其他新药物涂层仍处于早期研究阶段,限制了其广泛推广。此外,药物球囊的药物释放过程存在药物损失和递送效率不稳定的问题,影响疗效[18][40]。

药物球囊治疗 ISR 的疗效受到多种临床因素的影响。首先,病变长度是影响治疗效果的重要指标。研究显示,较长的病变长度与较高的复发率相关,尤其是在股膝动脉 ISR 中,病变长度越长,复发狭窄率越高[58][59]。其次,支架类型对疗效亦有显著影响。DAEDALUS 研究指出,药物球囊在裸金属支架 ISR (BMS-ISR)与重复 DES 植入效果相当,但在 DES-ISR 患者中,药物球囊的疗效劣于重复植入 DES。同时患者基础疾病,尤其是糖尿病,对治疗结局有重要影响。糖尿病患者术后 MACE 风险显著提高,是药物球囊治疗效果的独立预测因素。此外,术前影像学评估及术中操作技术对疗效保障至关重要。光学相干断层扫描(OCT)和血管内超声(IVUS)等影像技术可帮助明确 ISR 机制、优化球囊选择及膨胀策略,从而提高治疗成功率和降低复发率。结合影像学指导的药物球囊治疗显示出更大内径、较低的残余狭窄和更佳的临床结局[11][19][42]。

此外,术中合理的病变预处理(如切割球囊、旋磨术、激光消融等)联合药物球囊能够改善复杂 ISR 的治疗效果。如在 Tosaka III 型复杂股膝动脉 ISR 中,联合减容术和药物球囊治疗显示出更高的一年原发通畅率。病变分型(局灶型与非局灶型 ISR)也影响药物球囊疗效,局灶型 ISR 患者术后复发率明显较低,提示病变形态应作为治疗选择的参考因素[60]-[63]。

2.3. 药物球囊应用的最新研究进展与未来展望

2.3.1. 新型药物球囊材料与药物组合的研发

近年来,药物球囊(drug-coated balloon, DCB)技术不断革新,尤其是在涂层材料和药物载体方面取得了显著进展。新型涂层材料如聚合物载体和纳米技术的应用,显著提升了药物的稳定性和释放的可控性。例如,纳米胶体、脂质体等纳米封装技术已被用于载药,能够实现靶向精准药物释放,减少药物在传递过程中的损失,提高治疗效果。此外,聚合物载体不仅起到保护药物的作用,还能调控药物释放速率,

从而实现更持久的抗增殖效果[22] [23]。

多药物联合涂层球囊的研究也逐渐展开,旨在通过协同作用增强抗增殖和抗炎效果。例如,在传统抗增殖药物紫杉醇(paclitaxel)基础上,加入抗炎药物或免疫调节剂,能够有效降低血管壁炎症反应,促进血管修复[27]。这种多药物组合策略为解决单一药物疗效有限的问题提供了新的思路。

生物降解材料的应用为药物球囊的材料研发带来了新的方向。生物降解材料不仅能够减少局部毒性,还能促进血管壁的正常修复过程。例如,通过调控材料降解速率,实现药物的持续释放,同时避免长期植入物带来的慢性炎症和血栓风险[23]。此外,创新的高顺应性聚合物膜技术,也有助于球囊与血管壁的良好接触,提升药物递送效率[64]。

综合来看,新型药物球囊材料与药物组合的研发正朝向更高效、安全及个性化治疗方向发展。未来,随着纳米技术和生物材料学的进一步融合,药物球囊的药物递送能力和治疗效果将持续提升,为支架内再狭窄(ISR)患者提供更优的治疗方案[27]。

2.3.2. 联合治疗策略的探索

药物球囊的临床应用不仅局限于单一介入手段,联合治疗策略逐渐成为研究热点。例如,药物球囊联合支架置入技术(hybrid strategy),通过在病变部位精准选择使用药物球囊或支架,既减少了支架使用量,又保证了血管的支撑效果,有助于降低再狭窄率和支架相关并发症[65]。该策略在复杂高危患者(CHIP)中表现出良好的临床前景。

基因治疗和干细胞治疗与药物球囊的结合也处于初步研究阶段。基因治疗可通过药物球囊实现局部基因递送,调控血管平滑肌细胞的增殖和迁移,防止ISR的发生。干细胞治疗则借助药物球囊作为递送载体,促进血管内皮功能恢复和重塑,为血管修复提供新思路。

多模式治疗整合了药物球囊、基因治疗、干细胞治疗及支架技术,可能进一步降低ISR复发率,改善患者预后[38]。当前,多项临床试验正在评估联合治疗的安全性和有效性,试图为不同病变类型和患者群体构建个性化的治疗方案[66]。这些联合治疗策略预示着未来支架内再狭窄的干预将更加精准和多元。

2.3.3. 临床应用中的挑战、解决方案与未来展望

尽管药物球囊在临床上的应用日益广泛,但其适应症的扩展和个体化治疗方案的制定仍面临诸多挑战。一方面,缺乏大规模、长期、高质量的临床数据限制了其在复杂病变和特殊患者中的推广应用[67]-[69]。因此,开展随机对照试验和真实世界研究,积累数据支持,成为当前的重点任务。

此外,术者经验和技术培训是保证药物球囊治疗效果的重要因素。在操作技术、病变选择、术中影像指导等方面,均需有规范化培训和标准化操作流程,减少术中并发症,提高术后成功率[70][71]。随着临床经验的积累和技术的进步,药物球囊的操作安全性和疗效将进一步提升。

此外,联合治疗策略的探索也为药物球囊技术的应用带来了新的视角。例如,将药物球囊与生物可降解支架或新型抗炎药物相结合,可能进一步提升治疗效果并延长血管通畅时间。同时,术者的操作技术和经验对治疗效果有着关键影响,术者培训成为推动药物球囊技术广泛应用的重要环节。规范化的培训和技术标准能够减少操作风险,提高治疗成功率,促进技术的普及和临床应用的规范化。

同时针对下一代药物球囊应用从多维度突破严重钙化病变的药物渗透屏障,① 炎症微环境响应型智能涂层设计: pH 敏感释药体系: 采用聚组氨酸-聚乙二醇共聚物(His-PEG)作为涂层基材,确保在正常血管组织(pH 7.4)中保持结构稳定,避免药物提前泄露。活性氧(ROS)响应交联网络: 在涂层中引入含硫醚键的可降解聚合物(如聚三亚甲基碳酸酯-硫醚共聚物),形成“释药-抗炎”双功能协同。24 小时药物释放率可达 85%,显著高于生理条件下的 12%。炎症细胞靶向肽修饰: 在涂层表面接枝 CXCR4 受体靶向肽(如 CTCE-9908),修饰后的涂层对 THP-1 巨噬细胞的靶向效率提高 3.2 倍,且可减少对正常血管内

皮细胞的非特异性黏附。② 钙化屏障穿透增强策略, 微纳米复合涂层结构: 构建“纳米粒-微针”复合涂层可使钙化模型的斑块钙化面积减少 35%, 同时增强 PTX 的渗透效率。超声响应空化增效: 采用聚多巴胺包裹的液态氟碳纳米滴(PDA-FCNDs)作为涂层组分, 使药物渗透效率提升 2.1 倍, 且未观察到对血管壁的机械损伤。③ 长效药物滞留与缓释调控; 双相释药动力学设计: 采用“快速释放-缓慢缓释”双相系统: 有效覆盖血管再狭窄的关键窗口期。细胞外基质锚定修饰: 在药物分子上接枝多巴酚基团(DOPA), 延长药物在病变部位的滞留时间。通过上述设计, 下一代智能药物球囊可实现“炎症微环境响应-钙化屏障穿透-长效精准释药”的协同作用, 有望突破严重钙化病变的治疗瓶颈。

综上所述, 解决临床应用中的挑战需要多方面协同推进, 包括临床研究、政策完善、经济评估及人才培养, 形成完整的支持体系, 推动药物球囊技术在支架内再狭窄患者中的广泛应用[67]-[70]。

3. 结论

药物球囊作为治疗支架内再狭窄(ISR)的一种创新手段, 近年来在临床实践中展现出显著的治疗优势。其通过局部高效递送抗增殖药物, 有效抑制血管内膜的过度增生, 从而显著降低了再狭窄的发生率。这一机制不仅避免了传统治疗中多层支架叠加所带来的复杂性及潜在风险, 还减少了患者对长期抗血小板治疗的依赖, 提高了治疗的安全性和耐受性。多项临床研究和随机对照试验均支持药物球囊在改善临床结局方面的积极作用, 为 ISR 患者提供了更为理想的治疗选择。

药物球囊技术的发展体现了介入心脏病学领域对精准治疗的不断追求。当前的研究主要集中在药物释放的优化、球囊材料的改进以及药物种类的创新上。不同研究在药物类型(如紫杉醇、雷帕霉素及其衍生物)、释放剂量和释放时间等方面存在一定差异, 这反映了学术界对于最佳治疗方案尚未形成完全统一的共识。然而, 综合现有证据可见, 个体化的药物球囊治疗策略更能满足不同患者的病理特征和临床需求。未来研究应进一步探讨如何结合患者的遗传背景、病变特点以及合并症状况, 制定个体化的治疗方案, 以实现最大疗效和最小副作用的平衡。

综上所述, 药物球囊作为治疗支架内再狭窄的有效手段, 已在临床上取得了令人瞩目的成绩。未来的发展方向应注重新型药物和材料的研发、联合治疗策略的创新以及个体化治疗方案的完善, 提升 ISR 患者的长期预后和生活质量。

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