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·文献综述·

可降解支架治疗下肢动脉疾病的研究进展

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摘　要　下肢动脉疾病（LEAD）指因动脉粥样硬化斑块形成导致的下肢动脉狭窄或闭塞。据估算，全世界25岁以上人群中约有2.37亿例罹患LEAD，我国的LEAD患者约有4 530万例，疾病负担重。腔内血运重建为缓解保守治疗效果不佳的LEAD患者下肢缺血症状的首选治疗方式。但是，受限于内膜增生等支架植入后反应，腔内血运重建术后的中远期初级通畅率仍逊于开放手术，且再干预率更高。作为血管腔内永久性金属支架植入的新型替代治疗方案，可降解支架（BRS）指由聚合物或金属材料制成的，可在体内被逐步分解、吸收并降解，降解产物可被完全排出人体的支架。BRS植入后可为狭窄段血管提供临时管壁支撑，理想状态下可在血管重塑后完全降解，恢复生理性血管反应性和内皮功能。有望避免支架内再狭窄等远期并发症，进一步提升LEAD腔内血运重建疗效。目前，REMEDY、ABSORB、AMS等BRS已被用于LEAD治疗。其中，REMEDY支架治疗下肢动脉闭塞性病变的疗效欠佳，其治疗狭窄性病变的效果与内膜切除和镍钛合金支架植入相比并无明显优势。ABSORB治疗膝下动脉病变的术后1年通畅率高，靶病变再干预率较低。与经皮球囊血管成形术相比，AMS支架植入后6个月的初级通畅率显著更低，无法达到有效性评价指标。此外，目前尚无高质量循证医学证据说明LEAD患者BRS植入后应如何开展抗血栓治疗。未来，应开发具备更佳材料性能、更优结构设计的新一代BRS，并将其与各类LEAD腔内治疗方式结合，有效提升LEAD医疗质量。

关键词　闭塞性动脉硬化；下肢；可吸收性植入物；支架；综述
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Progress in bioresorbable stents for the treatment of lower extremity artery disease

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Abstract　Lower extremity arterial disease (LEAD) refers to the stenosis or occlusion of lower limb arteries caused by atherosclerotic plaque formation. It is estimated that approximately 237 million people worldwide,

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aged 25 and above, suffer from LEAD. In China, there are around 45.3 million LEAD patients, imposing a significant disease burden. Endovascular revascularization is the preferred treatment method for alleviating lower limb ischemic symptoms in LEAD patients with poor response to conservative therapy. However, due to reactions such as intimal hyperplasia after stent implantation, the mid- to long-term primary patency rates of endovascular revascularization remain inferior to open surgery, with a higher rate of reintervention. As a novel alternative treatment for the permanent metallic stent implantation, bioresorbable stents (BRS) are stents made from polymers or metal materials that can gradually decompose, degrade and eventually be completely eliminated from the body. After BRS implantation, temporary wall support is provided to the narrowed vascular segment, ideally degrading completely after vascular remodeling to restore physiological vasomotor activity and endothelial function. BRS holds the potential to avoid long-term complications such as in-stent restenosis, thereby further improving the efficacy of endovascular revascularization for LEAD. Currently, BRS such as REMEDY, ABSORB, and AMS have been used in the treatment of LEAD. REMEDY stent treatment for occlusive lesions of lower limb arteries shows suboptimal efficacy, with no apparent advantage over endarterectomy and nitinol stent implantation in treating stenotic lesions. ABSORB demonstrates a high 1-year patency rate for infrapopliteal lesions and a lower rate of target lesion reintervention. In comparison to percutaneous balloon angioplasty, AMS stent implantation has a significantly lower primary patency rate at six months and fails to meet efficacy evaluation criteria. Moreover, there is currently no high-quality recommendations of evidence-based medicine to guide anti-thrombotic treatment after BRS implantation in LEAD patients. In the future, efforts should be directed towards developing the next generation of BRS with superior material properties and optimal structural design. These advancements should be integrated with various endovascular treatment modalities for LEAD to effectively improve the quality of medical care for LEAD patients.

Key words　Arteriosclerosis Obliterans; Lower Extremity; Absorbable Implants; Stents; Review

CLC number: R654.3

下肢动脉疾病（lower extremity arterial disease，LEAD）指因动脉粥样硬化斑块形成导致的下肢动脉狭窄或闭塞。若以踝–肱指数≤0.90 为诊断标准，全世界 25 岁以上人群中约有 2.37 亿例罹患 LEAD，占世界总人口的 5.56%[1]。据估算，我国的 LEAD 患者约有 4 530 万例，且随着人口老龄化的进展，LEAD 疾病负担有可能进一步加重[2]。

腔内血运重建已成为缓解保守治疗效果不佳的 LEAD 患者下肢缺血症状的首选治疗方式[3]。但是，球囊扩张和支架植入造成的机械损伤和炎症反应可导致血管内膜增生，进而造成支架内再狭窄等并发症[4]。受限于此，腔内血运重建术后的中远期初级通畅率仍逊于开放手术，且再干预率更高[5-6]。作为血管腔内永久性金属支架植入的新型替代治疗方案，可降解支架（bioresorbable stent，BRS）有望避免支架内再狭窄等远期并发症，进一步提升 LEAD 腔内血运重建疗效[7]。

BRS 指由聚合物或金属材料制成的，可在体内被逐步分解、吸收并降解，降解产物可被完全排出人体的支架[8]。BRS 植入后可为狭窄段血管提供临时管壁支撑，理想状态下可在血管重塑后完全降解，恢复生理性血管反应性和内皮功能。本文将就 BRS 治疗 LEAD 的临床应用现状作一综述。

1　BRS 治疗 LEAD 的疗效

目前已被用于 LEAD 治疗的 BRS 主要由聚左旋乳酸（poly-L-lactic acid，PLLA）和镁合金制成。植入人体后，PLLA 聚合物链逐渐降解为水溶性低聚物，进而降解为左旋乳酸单体。巨噬细胞将吞噬直径<2 μm 的聚合物颗粒并最终通过三羧酸循环将其降解为水和 CO_2[9]。但是，PLLA 材料的张力模量

　

远低于不锈钢或钴铬合金。为提供相似的径向支撑力，PLLA支架的厚度需较常规金属支架增加约240%[10]。镁合金则在体内被降解为离子形式排出。本文所述BRS均为球扩式裸支架。

1.1 REMEDY支架

Igaki-Tamai支架是首款被植入人体的BRS，REMEDY支架（Kyoto Medical Planning Co，Ltd，日本）在Igaki-Tamai支架基础上发展而来并被用于治疗外周动脉疾病[11]。

REMEDY支架治疗髂动脉病变的1年初级通畅率为88.6%，术后1、5年后分别有95.8%和85.4%的患者无需接受靶病变再干预（target lesion revascularization，TLR），其疗效逊于现有金属支架[12]。另有研究[13]比较了REMEDY支架植入和内膜切除术治疗股总动脉慢性动脉粥样硬化闭塞的效果。结果显示，虽然两组间术后30 d的踝–肱指数无显著差异，但REMEDY支架组术后30 d及术后1年的初级通畅率均显著低于内膜切除组（92.5% *vs.* 100.0%；80.0% *vs.* 100.0%，均$P<0.05$）。若被用于治疗股腘动脉闭塞性病变，REMEDY支架术后1年初级通畅率为58.1%，TLR率为32.5%，且存在术中球囊–支架粘连和胫腓干血栓形成等并发症发生风险[11]。

REMEDY支架治疗股浅动脉狭窄术后1、3年的初级通畅率分别为82.8%、77.1%。超声随访结果显示，术后30个月所有支架均无法被超声探及[14]。前瞻性的GAIA研究[15]则探究了REMEDY支架治疗无钙化股浅动脉狭窄的有效性，术后1年初级通畅率为32.1%，再狭窄率为67.9%。组织病理学分析显示，REMEDY支架植入股浅动脉后的再狭窄主要由内膜增生导致。在此基础上，GAIA-DEB研究[16]尝试利用药物洗脱球囊（drug-eluting balloon，DEB）扩张股浅动脉狭窄段后植入REMEDY支架，术后1年再狭窄率为57.9%。

上述研究结果提示，REMEDY支架治疗下肢动脉闭塞性病变的疗效欠佳[11]，其治疗狭窄性病变的效果与内膜切除和镍钛合金支架植入相比并无明显优势[12-14]。此外，单纯应用DEB并不足以避免该支架降解过程中的内膜增生[16]。在单纯聚合物BRS基础上发展而来的药物涂层BRS可更有效地抑制内膜增生，可能进一步提升BRS疗效。

1.2 ABSORB支架

ABSORB支架（Abbott Vascular，美国）是一款冠状动脉支架，其依维莫司药物载量为100 μg/mm^2，在LEAD治疗中主要被用于无严重钙化的局限性膝下动脉病变。

2015年，Varcoe等[17]率先将ABSORB支架用于膝下动脉病变治疗，术后6个月初级通畅率为90.5%。于同一中心进行的中期随访结果提示，ABSORB治疗膝下动脉狭窄患者术后1、2年的初级通畅率分别为96.0%、84.6%[18]，术后5年的初级通畅率为72.3%，再狭窄率为15.5%，TLR率为9.3%[19]。

Dia等[20-21]的回顾性结果研究显示，术后1、2年的初级通畅率分别为96.7%、87.1%，无需接受TLR的患者比例分别为95.1%、93.5%。针对亚洲人群的DISAPEAR注册研究[22]中，术后1年的初级通畅率为86.0%，TLR率为7.0%。荟萃分析[23]结果显示，ABSORB支架治疗膝下动脉病变的1年初级通畅率为90.0%，96.0%的患者无需TLR。

Giordano等[24]则进一步回顾性分析了BRS（ABSORB支架）和药物涂层支架（drug eluting stent，DES）治疗膝下动脉病变的结果差异。初步对比结果显示BRS组的TLR率明显高于DES组（35.5% *vs.* 9.2%，$P=0.001$），死亡、截肢等主要不良事件发生率亦相对高于DES组，但差异无统计学意义（41.9% *vs.* 23.0%，$P=0.104$）。经倾向性评分分析校正后，两组间TLR率、主要不良事件发生率的差异均无统计学意义。

上述研究结果提示，虽然现有研究病例数较少且证据级别较低，但ABSORB治疗膝下动脉病变的术后1年通畅率高，TLR率较低[23]。但是，5年随访分析中纳入的48例患者中有22例于随访期间去世，末次分析仅15.5%（11/71）的病变数据未脱漏[19]，故应谨慎评价ABSORB治疗膝下动脉病变的长期疗效。目前仍缺乏对比ABSORB支架和其他膝下动脉病变腔内治疗方式的高质量研究。

1.3 其他BRS

ESPRIT BVS支架（Abbott Vascular，美国）与ABSORB支架设计相似，主体亦由PLLA制成并附有依维莫司药物涂层。该支架针对外周动脉疾病而设计，试验阶段标称长度、直径分别为58 mm和6 mm[25]。ESPRIT BVS支架于首次人体研究中被用于治疗股浅动脉与髂外动脉狭窄，术后2年88.2%的患者无需TLR[25]。

印度的CREDENCE BtK-1试验[26]则将一款新型

西罗莫斯涂层BRS用于膝下动脉病变治疗。术后1年的初级通畅率为88.9%，且所有患者均无需TLR。

AMS支架（Biotronik，德国）则由镁合金制成。2006年，Peeters等[27]率先尝试利用AMS支架治疗膝下动脉病变，术后3个月初级通畅率为89.5%，超声随访提示几乎所有支架均在术后6周内完全降解。AMS INSIGHT试验[28]则对比了AMS支架和经皮球囊血管成形术（percutaneous balloon angioplasty，PTA）治疗膝下动脉病变的疗效。术后6个月动脉造影结果提示，AMS组的初级通畅率显著低于PTA组（31.8% *vs.* 63.4%，*P*=0.005），TLR率则显著更高（31.9% *vs.* 10.9%，*P*=0.004）。该研究作者指出AMS支架无法达到有效性评价指标，不建议继续将AMS支架用于膝下动脉病变治疗[28]。部分研究进一步指出，镁合金降解过程中释放的氢离子可能抑制血管内膜修复，且较快的降解速度可能造成血管早期回缩，最终导致再狭窄[29]。

2　BRS植入后的抗血栓治疗

以抗血小板治疗为基础抗血栓治疗是LEAD治疗的重要组成部分，但目前关于LEAD腔内血运重建术后抗血栓策略的证据有限且异质性大[30]。指南[31]推荐LEAD患者腔内治疗术后每日口服阿司匹林75~325 mg或氯吡格雷75 mg以提升通畅率，但双联抗血小板治疗（dual antiplatelet therapy，DAPT）降低心脑血管不良事件的效果尚不明确。

目前尚无确切证据指明BRS治疗LEAD术后的最佳抗血小板策略。Varcoe等[17]曾报道1例下肢动脉BRS植入后支架内血栓形成，并发症发生时患者尚未接受抗血小板治疗并立即接受了金属支架植入以恢复血运。现有研究中均推荐患者终身服用阿司匹林，且多于术后开始DAPT。DAPT持续时间包括4周[11, 14, 28]、3个月[13, 20]、6个月[16–17, 19]或1年[24]。尚无研究分析不同DAPT持续时间对BRS治疗LEAD疗效的影响。

有研究[32]汇总了接受冠状动脉ABSORB支架植入的患者个体数据，并指出术后1年内中止DAPT会增加支架内血栓形成风险，术后1至3年内继续DAPT则无显著获益。荟萃分析[33]结果显示，于冠状动脉植入BRS后各类支架内血栓形成事件发生风险显著高于DES组（*OR*=2.93，95% *CI*=1.37~6.26，*P*=0.01），该现象可能和BRS降解过程中导致的炎症反应相关。

可见，目前尚缺乏关于下肢动脉BRS植入术后抗血栓治疗方案的高级别循证医学证据，术者应综合考虑患者出血风险、血栓形成风险和BRS降解特性并为患者制定个体化用药方案。

3　新一代BRS的改进方向

植入BRS的初衷是为狭窄段血管提供临时管壁支撑，保留血管舒缩活性和生理性血管内皮功能，并避免支架植入相关长期并发症[34]。新一代BRS应同时具备以下特性：(1) 支架骨架足够薄且能提供充足的径向支撑力；(2) 支架降解速度与血管重塑程度相匹配；(3) 支架植入及降解过程中应尽可能减少组织损伤[35–37]。因此，可从以下三个方面进一步提升BRS性能。

3.1　提升支架材料性能

早期研究指出，BRS材料应能在3~6个月内为血管壁提供足够的径向支持力以避免弹性回缩，并在植入后12~24个月内完全降解[29,38–39]。现有镁合金BRS降解速度过快，再狭窄率高[28]。PLLA制成的BRS则可能因降解过程中炎性产物堆积以及支架内皮化不充分导致支架内血栓形成[34,40]。因此，有必要开发新型BRS材料。

已有研究[41–43]探索了利用锌合金、铁合金等材料制备BRS的可行性，但锌合金BRS强度仍需提升，铁合金BRS强度及塑性达标但降解速度过慢。本研究团队则通过金属注射成型技术制备了Fe-Mn-C合金BRS以同时实现制备效率、支架强度和降解速率的平衡。动物实验结果提示，该支架生物相容性好，与管壁贴合紧密，并在植入1个月后即为血管内皮覆盖[44]。目前，针对新型BRS材料的研究仍相对有限。

3.2　创新支架结构设计

作为支架结构的基础，支架构型应可保证支架在压握、输送及释放过程中均可展现出合格的力学性能[45]。现有的ABSORB及ESPRIT BVS支架均在PLLA支架骨架上增加了药物涂层[24–25]。基于AMS裸金属BRS发展而来的DREAMS系列冠状动脉BRS也在支架镁合金骨架上增加了聚合物药物涂层[46]。药物涂层包裹BRS骨架仍为当前BRS的主流结构设计。

在此基础上，已有研究者尝试将可降解材料

与不可降解材料结合并设计了复合型BRS。Lee等[47]尝试将PLLA与镍钛合金骨架编织连接，共同组成支架骨架，PLLA骨架可在降解前为支架提供充足的径向支持力。Dynam X支架则创新性地通过PLLA黏合钴铬合金制成的支架支撑环，PLLA完全降解后各个支撑环之间将“解锁”，令支架顺应血管走行，实现适应性血管重塑[48]。

3.3 改进腔内手术方式

最早期的Igaki-Tamai支架需要在使用时将球囊加热至70 ℃并保持30 s后方可撤除球囊，操作繁琐，并发症发生率高[49]。现临床应用的BRS均为球扩式支架，但已有研究尝试制造自膨胀式聚合物BRS以减少输送系统尺寸并增加管腔稳定性[50]。目前，LEAD治疗领域BRS产品有限，在我国也尚未开始大规模临床应用。随着BRS性能的提升，未来BRS可与载药球囊、减容器械、震波导管等相结合，成为LEAD治疗的有效措施。

4 小 结

综上所述，BRS的价值为支撑狭窄段血管并在血管重塑后降解，以避免支架内再狭窄等远期并发症。在LEAD治疗中，无药物涂层的REMEDY与AMS支架疗效欠佳，而ABSORB支架的整体效果令人满意。目前尚无高质量循证医学证据指导LEAD患者BRS植入术后抗血栓治疗方案。未来，具备更佳材料性能、更优结构设计的新一代BRS有望成为LEAD腔内治疗的有力工具。

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