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· 指南解读 ·

欧洲血管外科学会2024版《腹主动脉-髂动脉动脉瘤管理 临床实践指南》解读

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摘要

欧洲血管外科学会发布了2024版《腹主动脉-髂动脉动脉瘤管理临床实践指南》，对腹主动脉瘤和髂动脉病变的诊疗策略进行了全面而详细的介绍。该指南基于截至2023年8月的最佳证据，依据修改后的欧洲心脏病学会评分系统制定了160条建议，较2019年版本新增59项全新建议。新版指南针对质量控制、流行病学与诊断筛查、小型腹主动脉瘤管理、腹主动脉瘤择期修复、破裂及症状性腹主动脉瘤管理、复杂腹主动脉瘤管理等方面的重要内容进行了证据总结与分级推荐。该指南对于指导国内血管外科腹主动脉-髂动脉瘤临床工作具有重大借鉴意义，但同时也需注意结合本土患者的实际情况开展个体化诊疗。本文对指南中相关部分进行了解读，供学者们参考讨论。

关键词

主动脉瘤；腹；髂动脉瘤；诊疗指南
中图分类号：R654.3

Interpretation of the *European Society for Vascular Surgery (ESVS) 2024 Clinical Practice Guidelines on the Management of Abdominal Aorto-Iliac Artery Aneurysms*

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Abstract

The European Society for Vascular Surgery (ESVS) released the *ESVS 2024 Clinical Practice Guidelines on the Management of Abdominal Aorto-Iliac Artery Aneurysms*, providing a comprehensive and detailed overview of diagnostic and treatment strategies for abdominal aortic aneurysms and iliac artery lesions. Based on the best available evidence as of August 2023, the guidelines include 160 recommendations according to the revised European Society of Cardiology grading system. This new edition features 59 additional recommendations compared to the 2019 version. Key topics covered in the guidelines include quality control, epidemiology, and diagnostic screening, management of small abdominal aortic aneurysms, elective repair of abdominal aortic aneurysms, management of ruptured and symptomatic abdominal aortic aneurysms, and management of complex abdominal aortic aneurysms, with evidence-

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based summaries and graded recommendations provided. These guidelines are of significant value for guiding clinical practice in vascular surgery for abdominal aorto-iliac artery aneurysms in domestic settings. However, it is essential to tailor individualized diagnosis and treatment plans to the specific conditions of local patients. This article interprets relevant sections of the guidelines for academic reference and discussion.

Key words Aortic Aneurysm, Abdominal; Iliac Aneurysm; Diagnostic and treatment guideline
CLC number: R654.3

欧洲血管外科学会（European Society for Vascular Surgery, ESVS）2024版《腹主动脉-髂动脉瘤管理临床实践指南》（以下简称“2024版指南”）由来自12个欧洲国家的16名血管外科主动脉专家及1名血管病理学家组成的指南编写委员会在3年内共同制定。最终指南共由来自15个国家的23名审稿人历经三轮审查后提交，其中包含

11名来自ESVS指南指导委员会的成员及12名外部审稿人。通过总结和评估目前最佳的可用证据（参考文献截至2023年8月），并根据修改后的欧洲心脏病学会（European Society of Cardiology, ESC）评分系统^[1]进行分级（表1-2），制定了160条关于患者评估和治疗的建议。

表1 来自ESC证据分级系统的推荐等级

Table 1 Recommendation grades from the ESC evidence grading system

证据等级	定义	推荐措辞
I	证据和/或共识表明某一治疗或操作是有益/有效的	推荐
II	关于某一治疗或操作的有益性/有效性存在有争议的证据和/或不同意见	
IIa	证据/意见的权重倾向于有益/有效	应该考虑
IIb	有益性/有效性不太好由证据/意见确定	可以考虑
III	证据或共识表明某一治疗或操作无益/无效,在某些情况下可能有弊处	不推荐

表2 来自ESC证据分级系统的证据等级

Table 2 Levels of evidence from the ESC evidence grading system

证据等级	定义
A	数据来自多个随机试验或者随机试验的Meta分析
B	数据来自单个随机试验、大型非随机研究或非随机试验的Meta分析
C	专家共识和/或小型试验、回顾性研究或注册研究

与2019年的旧版本相比，2024版指南新增了160项建议，其中59项为全新建议（包括7项I级建议），对49项建议进行了重分级或有显著的措辞修改，意义在一定程度上有所变化，仅有52项建议保持不变。这些更新反映了对腹主动脉瘤知识的增长以及该领域技术和医疗水平的快速进展，迫切需要从2019年的指南中更新信息。本文拟对2024版指南中的重要信息进行详细解读，以供学者们参考讨论。

1 质量控制

首先，2024版指南重新强调并更新了关于血管外科手术质量控制的内容。推荐的最低年手术量已提高至每个血管外科中心每年至少完成30台标准腹主动脉瘤修复手术（开放手术和血管内修复各不少于15台），并增加了关于复杂腹主动脉瘤修复手术的最低年手术量的共识建议^[2-5]。更新的章节还强调了模拟培训的重要性。同时，随着开放式主动脉手术数量的减少和住院医生接触机会的降低，开放式手术修复可能需要在手术量较大的中心进行额外的培训轮换。在研究生阶段接受复杂的腔内和开放式主动脉手术方面的专科培训，可能有助于培养未来一代主动脉外科医生^[6]。

2 流行病学、诊断与筛查

超声仍然是小型腹主动脉瘤诊断和随访的推

荐首选方法,但目前尚无法确定使用哪种测量参照点更为合适。关于这一点的背景及不同测量点放置的临床后果,在2024版指南的第3章和去年的一篇系统综述^[7]中展开了详细讨论。在英国国家腹主动脉瘤筛查计划(National Abdominal Aortic Aneurysm Screening Programme, NAAASP)中使用了“内膜至内膜”(inner to inner, ITI)方法,而瑞典的筛查计划则采用了“前缘至前缘”(leading edge to leading edge, LELE)方法^[8]。不同的测量参照在不同的筛查场景下会影响诊断与治疗决策,需根据患者个体情况进行判断,且一旦超声检查达到择期腹主动脉瘤修复术的前后径阈值,建议进行计算机断层扫描血管造影(computed tomography angiography, CTA)用于治疗计划和破裂诊断(1C)。

此外,鉴于腹主动脉瘤流行病学的显著变化,主要是其流行率的下降,对筛查的建议是进行彻底的重新评估。在2024版指南本章更新后的第3节中,仍强烈推荐对高风险群体进行筛查(1A),但目标群体未像以前那样在建议中定义,而应根据当地条件,如疾病的流行率、预期寿命和医疗体系结构等决定筛查的目标群体^[8-9]。

3 小型腹主动脉瘤的管理

关于小型腹主动脉瘤的管理与诊疗在2024版指南中进行了较大改动与补充。在更新的第4章中明确了小型腹主动脉瘤性别特定的监测间隔^[10-12],男性患者主动脉直径25~29 mm的小型腹主动脉瘤每5年1次,直径30~39 mm的每3年1次,直径40~49 mm的每年1次,腹主动脉瘤直径>50 mm的每6个月1次;女性患者主动脉直径为25~29 mm的小型腹主动脉瘤每5年1次,直径30~39 mm的每3年1次,直径40~44 mm每年1次,腹主动脉瘤直径≥45 mm每6个月1次。并且发布了一项新的建议,即小型腹主动脉瘤的患者,如果预估在其预期寿命内无法达到修复的直径阈值、或不适合修复、或倾向于保守治疗,则应考虑停止监测。

此外,基于对现有证据的全面分析,如之前美国食品药品监督管理局(Food and Drug Administration, FDA)和欧洲药品管理局(European Medicines Agency, EMA)所建议的限制在小型腹主动脉瘤的患者中使用氟喹诺酮类抗生素的意见,2024版指南认为是没有根据的^[13-15]。同

样,2024版指南建议不限制腹主动脉瘤患者的运动和性活动^[16],暂无足够的证据证明需限制此类运动。

第4节中关于腹主动脉瘤择期修复的指征也进行了重大修订,现已明确不推荐对男性患者直径<55 mm和女性患者直径<50 mm的腹主动脉瘤进行修复。修复可考虑的直径阈值仍维持为男性55 mm、女性50 mm;然而,由于缺乏支持的高质量证据,这些建议已被降级^[17-19]。

4 腹主动脉瘤的择期修复

术前评估方面,基于目前CTA分析技术的不断进展与市面上大量后处理软件的迭代更新,2024版指南新增了明确考虑在腹主动脉瘤择期修复术前进行CTA成像并使用后处理软件分析以建立详细的手术计划^[20-21]。但现存文献较少、年份较老,且证据级别不高,本推荐主要根据共识总结得出,缺乏高级别证据。

主动脉瘤腔内修复术(endovascular aneurysm repair, EVAR)的可行性及其早期和长期成功依赖于可靠的基线评估,包括固定和封堵的锚定区主动脉形态学评价,以及适当支架选择的正确测量^[22]。根据现有器械制造商定义的使用说明(instruction for use, IFU),已经建立了多个标准来定义患者是否适合EVAR^[20]。尽管目前还没有关于最佳影像评估方式的随机对照试验(randomized control trial, RCT),但现有共识是,薄层(1 mm)CTA包括多平面和曲面的三维血管重建,是EVAR术前首选的影像评估方式^[21]。

第5章同时更新了关于腹主动脉瘤择期修复术中肝素使用和静脉血栓预防的部分,新增推荐使用活化凝血时间(activated clotting time, ACT)以测量肝素对个体患者的影响并指导额外的肝素给药^[23-25]。所有接受择期EVAR并被认为存在术后静脉血栓栓塞风险的患者均应考虑进行血栓预防,但现存文献数量较少,且其结论力度不强,其中得到的结论仅为倾向于血栓预防但无统计学意义的趋势,各中心应根据患者的个体情况加以决策^[26-28]。

鉴于EVAR手术相关的器械失败的报告,2024版指南建议使用经过耐久性验证的器械^[29],并反对在择期手术中超出IFU范围进行EVAR^[30-31],

尤其目前在复杂腹主动脉瘤中使用分支支架和开窗支架的比例越来越高，更加要求遵照IFU范围使用以进行质控。

目前针对腔内修复有越来越多的新器械上市，需要更为谨慎的评估。对于新一代支架而言，建议继续对基于已建立平台的改进器械在前瞻性注册研究中进行长期随访^[32-35]，且对10年的耐久性数据要求有所增加，这一点与FDA近期关于器械效能的监测推荐一致（I C）。

此外，由于缺乏临床相关获益的证据，不建议在EVAR前常规进行侧支血管的预防性栓塞或非选择性动脉瘤囊栓塞^[36-39]。

正如2024版指南第5章所述，EVAR作为大多数患者腹主动脉瘤的首选治疗方式的趋势依然保持，尤其对于有合适解剖学条件及适当预期寿命的患者^[40-42]。

5 破裂及症状性腹主动脉瘤的管理

在破裂及症状性腹主动脉瘤的治疗过程中，由于其效果的不确定性，主动脉球囊阻断用于近端控制的建议被降级（IIb C）^[43]；

近年来新增的RCT和大型队列研究已经证明了EVAR在治疗破裂性腹主动脉瘤中的益处，因此EVAR作为破裂性腹主动脉瘤首选治疗方案的建议依然有效，同时将其证据水平升级为A级^[44-47]。

针对破裂性腹主动脉瘤开放或腔内修复术后出现的腹间隔综合征，开放减压中使用真空辅助开放腹部闭合系统的建议被升级，并增加了网片牵引的使用推荐^[48]。其他更新内容包括新增了破裂性腹主动脉瘤修复术后结肠缺血的诊断过程；术后，所有破裂性腹主动脉瘤患者应密切监测结肠缺血的迹象；当怀疑诊断时，建议进行频繁的临床评估、监测腹腔内压（IAP，已发现其与结肠缺血有强烈相关性）、广泛使用乙状结肠镜检查以及早期探查性剖腹手术，以确认诊断并改善整体管理^[49-50]。

6 腹主动脉瘤修复术后的长期结局及随访

2024版指南第7章关于腹主动脉瘤修复术后随访的内容进行了全面更新。与围手术期病死率逐渐下降不同，腹主动脉瘤修复术后的远期病死

率仍然很高，过去20年中并没有显著改善。最常见的死亡原因是心血管疾病（尤其是缺血性心脏病）、肺癌和肺部疾病。2024版指南仍推荐腹主动脉瘤手术患者应接受术后心血管风险管理包括他汀类药物、抗血小板药物和血压控制（I B）^[51-53]。

此外，近期发布的关键研究促使主动脉移植物和支架移植物感染的治疗建议得到了更新。在存在感染的情况下，应考虑完全移除移植物并进行感染组织清创。首选的动脉移植物感染治疗方法是使用抗感染材料（如自体深静脉、冷冻保存的同种异体移植物或异种心包移植物）进行原位重建，并广泛清创感染组织。与自体重建相比，假体移植物替换的再感染风险更高，而浸渍了银和/或抗生素的假体移植物比标准假体移植物表现更好^[35, 54-57]。目前没有具体证据说明如何对感染性主动脉移植物处理后的患者进行随访。ESVS血管移植物和内支架感染管理临床实践指南^[58]建议，对于腹主动脉血管移植物或内支架感染，使用冷冻保存的同种异体移植物进行原位重建后应终生随访，以检测同种异体移植物的退变（I C）。但其他专家组报告了不同的策略，或未提及监测方案，大多数专家建议采用个性化的策略。由于证据不足和方案的异质性，目前无法提出普遍性的建议。

第7章同时介绍了多项新增和更新的内漏管理建议。EVAR后锚定区不满意但无影像可见内漏的患者可考虑进行干预以改善封闭，主要通过血管腔内方法^[59]。而对于近端锚定区不满意的患者，相较于其他血管腔内技术，应优先考虑使用开窗型和分支器械进行近端延伸^[60-62]。同时也突出强调了必要时采用支架移植物取出的开放手术修复选项^[60, 63]。

7 复杂腹主动脉瘤的管理

2024版指南第8章关于复杂腹主动脉瘤的内容进行了显著扩展，以反映自2019年以来的技术进步，涵盖了近肾和旁肾腹主动脉瘤、肾上腹主动脉瘤以及IV型胸腹主动脉瘤的管理。基于越来越全面的知识体系，包括最近的英国复杂动脉瘤研究^[64]（UK COMPASS试验）的初步数据更新了治疗建议。对于具有高手术风险和复杂解剖结构的患者，使用带有开窗和分支的内支架进行血管内修

复被认为有一定益处并受到推荐。现有数据^[65-67]显示,复杂腹主动脉瘤的分支和开窗血管内修复(fenestrated and branched endovascular aortic repair, f/b-EVAR)具有可接受的耐久性和并发症发生率,但需要再干预的比例在24%~39%之间。美国Zenith试验^[65]的5年结果,包括67例接受开窗血管内修复(fenestrated endovascular aortic repair, f-EVAR)治疗的近肾腹主动脉瘤患者,报告的30 d病死率为1.5%,5年无动脉瘤相关病死率为97%,无二次干预率为64%。没有出现动脉瘤破裂或转为开放手术的情况。在最近的一项来自美国Fenestrated and Branched Aortic Research Consortium的多中心研究^[67]中,包括1 681例接受复杂腹主动脉瘤f/b-EVAR治疗的患者,二次干预的发生率很高(1年随访时为18%,5年随访时为41%),其中大多数是腔内干预(84%),且主要为小型(70%)和低强度(根据生理效应)手术(81%)。这些数据突显了密切、终生随访的重要性,并表明如果二次干预得到充分处理,不会对生存率产生负面影响。

更新的章节还包括关于肾功能保护、预防脊髓缺血以及新技术的应用,包括现成的分支设备、医生改良的开窗内支架(physician-modified endograft, PMEG)、并行支架和原位开窗技术等。

8 髂动脉瘤的管理

此外,关于髂动脉瘤的修复阈值,鉴于其自然病程,考虑其增长速度缓慢且直径<40 mm时破裂风险极低,2024版指南认为将手术直径阈值从2011年ESVS指南中的30 mm提高到2019年ESVS指南中的35 mm,到现在进一步提高到40 mm是合理的^[68-69]。目前没有数据表明修复指征需要区分性别。然而,正如前文对待腹主动脉瘤的修复指征一样,可考虑将性别和体型纳入决策。

关于髂动脉瘤随访问隔的数据有限,最新建议是:对于直径20~25 mm的髂动脉瘤,每3年随访1次;对于直径25~29 mm的髂动脉瘤,每2年随访1次;对于直径≥30 mm的髂动脉瘤,每年随访1次。已知的髂动脉瘤随访最好使用超声进行,对于较大动脉瘤或超声可见度较差的患者,建议使用CTA^[69]。

9 其他主动脉疾病

在2024版指南第11章中,更新了有关炎性腹主动脉瘤诊疗的推荐。CTA能够检测出炎性腹主动脉瘤典型的解剖特征,即外套征(mantle sign);这种特征表现为由慢性炎性细胞和致密的动脉瘤周围纤维化导致的增厚壁层,同时保留后壁,可能会累及邻近结构如十二指肠、输尿管、左肾静脉和下腔静脉。然而,对于如何测量炎性腹主动脉瘤的直径尚无共识,是否应包括增厚的主动脉壁仍存在争议,这使得决定是否需要手术变得复杂。包括主动脉周围炎症或管壁水肿在内的测量方法有可能严重高估直径,从而迫使实际上较小的腹主动脉瘤进行手术修复。由于手术并发症风险增加且破裂风险没有增加,因此2024版指南考虑在确定炎性腹主动脉瘤修复适应证时,不应包括主动脉周围炎症区域或管壁水肿^[70]。

最后,第11章还讨论了在腹主动脉瘤环境中共同决策的证据,并提供了其应用的具体建议。应与患者对话讨论腹主动脉瘤筛查、监测和正在考虑修复的大型无症状腹主动脉瘤的管理,促进共同决策。同时建议考虑使用决策支持工具来帮助患者决定是否考虑修复腹主动脉瘤^[71-73]。

10 总结

尽管2024版指南更新并补充了大量关于腹主动脉-髂动脉瘤自2019年以来的研究证据及推荐意见,在此领域仍有很多亟待解决的问题与需补充的研究数据、共识等。2024版指南中引入了2019—2023年间发布的474篇新参考文献,包括16项RCT的初级或次级分析、106项系统综述或Meta分析以及84项基于血管登记册或质量倡议计划的研究。然而,在160项建议中,只有10项(占6%)建议基于A级证据,其中5项为I级建议,2项为III级建议;高达112项(占70%)建议仅限于C级证据或共识,这反映出主动脉领域的证据整体上仍然较为薄弱,常只能依赖回顾性、单中心的数据,因此许多推荐意见是基于C级证据,更像是专家共识推荐。这类数据的解读面临诸多挑战。单中心报告通常存在发表和确认偏差,而行业参与也可能会带来商业特殊利益,进一步影响数据的客观性。因此,产生无偏、高质量数据在腹主动脉

瘤领域成为普遍优先事项。

人工智能技术，如机器学习，具有巨大的潜力来管理、分析和利用大型数据集，从而在医疗保健领域开发应用程序。这包括自动成像分析、诊断、规划和随访。对新型EVAR设备进行连续监测，以便早期检测故障，或许是近期最值得关注的领域。长期来看，笔者预测其影响会更加深远且广泛，因此血管外科医生参与这一领域的持续发展至关重要^[74]。

在近肾、旁肾或IV型胸腹主动脉瘤的修复指征上，比标准的肾下腹主动脉瘤更不明确。虽然破裂风险被认为相似，但尚未得到充分证明，而手术风险普遍较高。需要更高质量的证据来支持治疗决策。虽然应优先考虑定制的腔内修复解决方案，但这些可能不易获得，off-label方案可能是开放手术之外的唯一选择。这些手术的作用、持久性和特定并发症需要更多证据支持。从长远来看，在择期手术情况下，摆脱耗时且昂贵的定制解决方案也是理想的方向，开发通用且耐用的现货解决方案是有必要的。复杂腹主动脉瘤修复，尤其是使用特制支架移植物的复杂腔内修复的成本效益问题也同样需要进一步分析。需要更多研究来更好地理解f-EVAR报告的长期生存率差的原因。这仅仅是由于患者选择偏差未补偿的研究方法学现象，还是腔内治疗与尚未知的长期不良影响相关，目前还无法得出定论。

此外，虽然中国血管外科领域近10余年的发展中已形成了越来越多高证据级别的腹主动脉-髂动脉瘤相关临床研究结果，但被国际指南纳入的仍然所占比重相对较小。因此在参照2024版指南的同时，应注意结合国内患者的实际情况，开展个体化诊疗流程。未来亟须进一步在此领域开展更多高水平临床试验，以形成更具中国特色的腹主动脉-髂动脉瘤诊疗共识。

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