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膝下动脉闭塞腔内治疗热点问题——实践与思考

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【摘要】重症下肢缺血(CLI)是下肢动脉硬化闭塞症重度期表现,膝下动脉闭塞是导致 CLI 重要原因,保肢、提高生活质量是 CLI 治疗目标。随着技术和器械发展,腔内治疗成为膝下动脉病变的主要治疗方法。由于膝下动脉独特的解剖特点、治疗难度大、再狭窄发生率高,一系列争议性问题产生;首选腔内治疗还是传统旁路手术,膝下动脉治疗靶血管如何选择,膝下动脉腔内治疗入路如何选择,腔内治疗术式如何优化等。本文结合最新循证医学证据和临床治疗经验,就膝下动脉闭塞腔内治疗上述热点问题的实践与思考作一阐述。

【关键词】下肢动脉硬化闭塞症;膝下动脉闭塞;腔内治疗;重症下肢缺血

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【Abstract】Critical lower limb ischemia(CLI) is a severe manifestation of arteriosclerosis obliterans of lower extremity, infrapopliteal artery occlusion is an important cause of CLI. Both limb salvage and life quality improvement are therapeutic targets for CLI. With the development of technology and equipment, endovascular treatment has become the main means for infrapopliteal arterial occlusive diseases. Because of the unique anatomic features of infrapopliteal artery, great therapeutic difficulty and high incidence of restenosis, a series of controversial issues have been emerged. The main controversial issues are as follows: (1) Which should be taken as first choice of treatment, endovascular therapy or traditional bypass surgery? (2) How to select target vessels in treating infrapopliteal artery occlusion? (3) How to select optimal access in performing endovascular treatment of infrapopliteal artery? (4) How to optimize the endovascular surgical method for infrapopliteal arterial occlusive disease? Based on the latest advance in evidence-based medicine and on the clinical treatment experience, this paper aims to make a detailed description concerning the above mentioned hot issues in clinical practice as well as in academic consideration about endovascular treatment of infrapopliteal arterial occlusive diseases. (J Intervent Radiol, 2017, 26: 481-485)

【Key words】arteriosclerosis obliterans of lower extremity; infrapopliteal arterial occlusive disease; endovascular treatment; critical lower limb ischemia

重症下肢缺血(critical limb ischemia, CLI)是下肢动脉硬化闭塞症的重度期表现,可导致患者截肢和死亡。膝下动脉缺血性病变常见于长期患有糖尿病、慢性肾病或老年患者,是导致 CLI 的重要原因^[1]。

股腘动脉病变导致的 CLI 也常为多节段病变,多伴有膝下动脉病变,股腘动脉重建后同时开通膝下动脉已成为临床关注的热点。膝下动脉病变管腔细、病变节段广泛,治疗复杂。随着血管腔内治疗技术和器械日益成熟,膝下动脉腔内治疗近年来已有显著发展。慢性完全闭塞(chronic total occlusion, CTO)、休眠血管(hibernating vessel)、血管体区(angiosome)概念的引入,丰富了膝下血管腔内治疗的理论体系^[2]。

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膝下动脉腔内治疗后再狭窄和闭塞发生率高,也产生了一系列争议性问题。

1 腔内治疗还是传统旁路手术

膝下动脉开通的主要目标为减少静息痛,治疗溃疡和坏死,保肢,改善生活质量,次要目标为获得长期的通畅性。血管旁路手术包括大隐静脉、血管移植物、人工血管原位或转位移植术。血管腔内治疗包括经皮腔内血管成形术(PTA)、斑块旋切术和支架植入术。对 1 023 例 CLI 患者膝下病变分析后发现,PTA 组和外科旁路移植组 5 年保肢率和生存率差异无统计学意义^[3]。一项 98 例 CLI 患者膝下病变回顾性分析显示,PTA 组和静脉旁路移植组一期通畅率、二期通畅率、保肢率、术后 24 个月生存率差异无统计学意义^[4]。另一项对 500 例旁路手术和 2 066 例腔内介入治疗 CLI 患者膝下动脉病变的研究显示,腔内介入组 1 年一期通畅率显著优于旁路手术组,1 年保肢率、死亡率差异无统计学意义^[5]。BASIL 随机临床试验(RCT)研究显示,旁路移植术与 PTA 治疗 CLI 患者 5 年保肢率、死亡率相似,但旁路移植术较 PTA 治疗花费更高^[6]。

综合当前研究,血管腔内治疗与血管旁路术 3 年保肢率(82.4%对 82.3%)相当^[7-8]。关于膝下动脉腔内治疗和自体静脉旁路移植治疗效果的比较,普遍观点认为腔内治疗效果不劣于旁路移植,期待分别于 2014 年、2015 年启动的 BEST-CLI 和 BASIL-2 两项多中心 RCT 研究能够给出更加确切的证据^[9-10]。

2 膝下动脉治疗靶血管选择及意义

CLI 几乎仅见于膝下动脉闭塞患者,约占全部外周动脉疾病的 10%。膝下动脉单支病变很少引起 CLI,无严重症状患者不推荐介入再通治疗^[11]。腔内治疗应选择相对简单的操作,减少并发症风险,并提高所选治疗的经济效率。医师经验、技术及器材条件在靶血管选择方面起着重要作用。应综合考虑患者对疗效的预期、病变位置解剖结构特点、肢体缺血程度、全身并发症情况等选择靶血管^[12]。

目前膝下动脉病变缺乏能够指导腔内治疗的临床分型。2015 年泛大西洋学会联盟(TASC)Ⅱ指南推出特别文件,对膝下动脉病变分型作出重要补充^[11]。A 型:目标血管存在单节段局部狭窄(≤ 5 cm),其它胫动脉存在程度类似或更加严重的狭窄或闭塞;B 型:目标血管存在多处狭窄(单节段 ≤ 5 cm 或总长度 ≤ 10 cm),其它胫动脉存在程度类似或更加

严重的狭窄或闭塞;C 型:目标血管存在多处狭窄和/或闭塞(总长度 > 10 cm),其它胫动脉存在程度类似或更加严重的狭窄或闭塞;D 型:目标血管存在多处狭窄和/或闭塞(总长度 > 10 cm),或分支存在严重钙化或闭塞,其它胫动脉闭塞或严重钙化。由于缺乏临床证据,以上补充分型并未像 TASC Ⅱ股腘动脉分型一样,给出相对应的治疗决策指导,但对临床上患者预后判断具有重要意义,也为 TASC Ⅲ指南的颁布作出重要铺垫。

关于 CLI 患者膝下动脉干预顺序,Mustapha 等^[13]提出“Jenali 小腿流出道分级及干预方案”,针对具体缺血区域,优先开通相应动脉,为精确治疗提供了可量化的操作流程。若流入道造影足部无连续性血流灌注,则可通过“Jenali 侧支评分系统”判定缺血程度。“Jenali 小腿分区”有助于术者精确描述膝下病变血管段及其位置,借助造影显像分别描述小腿,尤其是缺血或坏死区域血供状况。把膝下 3 条流出道、侧支情况及小腿区域灌注进行统筹考虑,对于 CLI 精确诊断及腔内治疗相当有意义。

“血管体区”理论对于 CLI 患者腔内治疗十分重要。血管体区指由同一动脉供血的一组三维组织结构,包括皮肤、皮下组织、筋膜、肌肉和骨骼,由无数交通支和链接动脉相互连通,即使某血管体区主干闭塞,大的动脉-动脉连接血管和侧支仍可给该血管体区提供血流。研究显示血管体区指导下的直接供血区开通后 4 年期保肢率为 86%,2 年期伤口愈合率为 91%,1 年期伤口愈合率为 92%;间接开通后 4 年期保肢率为 69%,2 年期伤口愈合率为 62%,1 年期伤口愈合率为 73%^[14-15]。与直接开通血管体区血管相比,间接开通组溃疡愈合速度显著减慢,但两组保肢率差异无显著统计学意义^[16]。同时,也应重视非血管体区指导下腔内治疗,如缺血程度仅表现为间歇跛行,一般不行膝下介入治疗。轻度静息痛,也可不考虑腔内治疗,或仅开通 1 支到达足部的血管即可达到缓解症状的目的。开通靶血管后造影显示侧支能到达缺血区,或仅有 1 支小腿动脉通畅,但对足背动脉弓完整的患者,或技术上难以达到,开通时会影响已建立的良好侧支患者,均可行非血管体区指导下靶血管开通^[17]。

近年来,足底动脉环路(pedal-plantar loop,PPL)技术得到广泛关注。足底动脉弓连接足背动脉和足底外侧动脉,腓动脉远端发出的前交通动脉 90%与胫后动脉远端连接,10%与胫前动脉远端连接。开通 PPL 将加快足部溃疡愈合速度,显著提高足部灌注,

这对溃疡坏疽患者有重要意义。足背动脉开通后溃疡愈合率显著优于非开通组,但保肢率差异无明显统计学意义^[18]。但 PPL 技术操作费时费力,有大量射线暴露,对于膝下动脉闭塞的 CLI 患者远期效果尚不明确,是否应广泛应用存在争议。膝下动脉多支病变患者保肢率,随重建膝下血管支数增加而提高,应首先处理易开通的动脉,保证至少 1 支血管供血至足部,一般可避免截肢^[19]。糖尿病患者侧支循环差,3 支主干应尽可能多地再通。充分利用小腿动脉侧支循环,主干动脉无法开通时开通侧支循环血管,使导丝和导管达到主干。多种入路与技术结合,顺行入路无法开通时,可采用足部逆行穿刺技术、远端小腿动脉或足背动脉切开法,提高成功率。对膝下动脉病变需保肢患者,不应追求造影影像完美,达到目标疗效即可。膝下病变多伴有膝上动脉病变,建立良好流入道具有重要意义。

3 膝下动脉腔内治疗入路如何选择

膝下动脉腔内治疗入路主要有顺行腔内开通、顺行内膜下开通、经足部血管穿刺逆向开通(trans-pedal access)、经侧支/交通作顺行或逆向开通、顺逆行双向内膜下血管成形(SAFARI)以及经足部/足底顺行或逆行开通。当前临床上首选同侧顺行入路,次选对侧翻山入路,路程短,易于操作^[20]。足部动脉逆向入路具有独特优势,胫动脉分支多,进入分支及滋养血管概率小;顺行入路导丝易进入分支,导致血管破裂。胫动脉并非完全闭塞,多为“休眠血管”,足部动脉管径小,可直接穿刺,但需要有通畅的动脉中远段,穿刺难度大,未能开通病变时有可能加重远端缺血。一项纳入 1 035 例 CLI 患者的研究显示,30.7%经足部顺逆行双向开通,16.1%为足背动脉逆向开通,24.2%接受 PPL 技术,29%经侧支开通,12%因经股动脉顺行入路失败而采用其它入路,手术成功率为 96%;联合多种入路开通膝下动脉患者 6 个月溃疡愈合率及保肢率显著优于未采用其它入路患者^[21]。足部逆向开通是一种安全有效的膝下动脉开通方法,尤其适合顺行开通困难的挑战性患者。逆行导丝不能进入胫前动脉或胫后动脉真腔时,可考虑 SAFARI 技术,这为无法行旁路手术或病变广泛、涉及股浅和三分叉处动脉的 CTO 患者保肢带来新选择^[22]。以此入路发展而来的顺行-逆行双球囊对吻技术,用于治疗膝下动脉闭塞安全有效,可提高分叉处病变治疗效果,减少腔内治疗并发症^[23]。

4 腔内治疗术式如何优化

膝下动脉直径细小,硬化严重,易出现夹层或血管被导丝穿破。小血管病变多发生于糖尿病下肢动脉硬化,斑块比一般动脉硬化斑块坚硬,不易扩张。距离心脏远,动脉压力小,远端流出道差,小动脉扩张后易形成血栓,一旦远端流出道无法打通,即面临截肢可能。当前,普通球囊 PTA、药物洗脱球囊(DES)PTA、金属裸支架、药物洗脱支架(DES)、斑块旋切治疗等,均广泛应用于膝下动脉闭塞腔内治疗,靶血管开通模式的优化具有重要临床意义。

InPeria II 研究显示,膝下动脉闭塞分别经裸支架植入和 PTA 治疗,两组 3 个月和 9 个月疗效差异无统计学意义^[24]。PaRADISE 研究发现,DES 植入与其它治疗方式相比,可有效改善临床症状,提高保肢率^[25]。YUKON-BTX 研究发现,西罗莫司 DES 治疗膝下动脉闭塞的远期生存率、保肢率、Rutherford-Becker 分级改善,均显著优于裸支架治疗^[26]。DESTINY 研究显示,依维莫司 DES 与 BMS 相比,能够显著降低术后再狭窄率和二次介入治疗率^[27]。ACHILLES 研究显示,西罗莫司 DES 治疗膝下动脉闭塞的靶血管通畅率、1 年保肢率显著优于普通球囊 PTA^[28]。IDEAS 研究发现,DES 治疗长段膝下病变与 DES 相比,显著降低术后近期再狭窄率、术后 6 个月再狭窄血管数^[29]。IN.PACT DEEP 研究发现,DES 与传统 PTA 相比,近期和 1 年临床疗效相当,1 年保肢率更优^[30]。LEVANT 2 研究显示,紫杉醇 DES 治疗膝下病变 1 年一期通畅率显著优于普通球囊 PTA^[31]。DEBATE-BTK 研究也显示,DES 与传统 PTA 相比,能够显著降低伴有糖尿病膝下病变 CLI 患者 1 年再狭窄率和目标血管闭塞率^[32]。BIOLUX P-II 研究则发现,紫杉醇 DES 治疗膝下病变安全有效,但 1 年随访结果与普通球囊 PTA 相比未显示明显优势^[33]。

值得注意的是,上述 RCT 研究中多将严重钙化病变排除,而钙化斑块是导致球囊扩张失败和药物难以弥散的重要阻碍,斑块切除装置在这些复杂病变治疗中显示出良好前景。目前临床上主要有 SilverHawk/TurboHawk 斑块旋切、JetStream XC 斑块切除、准分子激光斑块消融、Diamondback 360 斑块旋磨等系统。OASIS 研究中膝下病变患者 55%有严重钙化,Diamondback 360 斑块旋磨治疗 6 个月整体死亡、截肢和靶血管再狭窄占 10.4%^[34]。COMPLIANCE 360°研究也显示,斑块旋磨联合 PTA 治疗伴严重钙化膝下动脉闭塞 CLI 患者的临床效果显著优于单纯 PTA^[35]。斑块旋磨系统还可经足背动脉逆向开通

严重钙化的膝下闭塞动脉^[36]。DEFINITIVELE 研究显示, SilverHawk 斑块旋切治疗 189 例膝下动脉闭塞患者、CLI 患者的 1 年一期通畅率为 78%, 保肢率为 93.1%^[37]。应用 0.9 mm 和 1.4 mm 导管的准分子激光斑块消融治疗, 能够有效开通轻中度钙化的闭塞膝下动脉^[38], 对 TASC D 型及旁路手术失败的严重膝下动脉闭塞患者有良好疗效^[39]。目前尚无 JetStream XC 斑块切除治疗膝下动脉闭塞的 RCT 临床研究, 但对股浅静脉钙化斑块移除显示出良好的临床效果^[40]。理论上, JetStream XC 斑块切除可用于膝下动脉斑块去除, 尤其是膝下钙化血管治疗。当前尚无确切证据证实斑块旋切系统优于其它腔内治疗, 仍需要进一步扩大临床应用, 深入研究。

膝下动脉病变所致 CLI 治疗仍是临床处理难点, 首选 PTA 或支架植入存在争议。裸支架植入较普通球囊 PTA 并未显示出明显优势, DES 显示出良好应用前景, 仍需要更多证据支持。DEB、斑块旋切装置发展有望进一步提高膝下病变治疗效果。EUROCanal 研究已于 2010 年春天启动, 将对比 DEB 和普通球囊治疗膝下动脉病变的临床效果, 结论值得期待。

5 结语

膝下动脉流出道细长, 压力低、流速慢, 易继发血栓, 腔内治疗时应积极防止远端动脉栓塞发生, 注意术中抗凝剂和血管解痉剂药物应用, 并配合少量镇静、止痛剂。膝下动脉病变的介入治疗方法很多, 但目前尚无一种十全十美的术式及技术, 临床上可根据患者具体情况和手术经验, 选择最适合患者的治疗方式。由于篇幅所限, 本文仅能对膝下动脉闭塞腔内治疗部分热点问题的最新进展进行有限阐述, 有关支架内再狭窄、膝下动脉支架选择、无症状或间歇跛行的膝下病变患者的管理等均需要进一步研究。期待更多循证医学证据和新 TASC 指南, 为膝下动脉闭塞治疗决策带来更多帮助。

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