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• 临床研究 Clinical research •

准分子激光消融联合药物涂层球囊治疗下肢动脉硬化闭塞 20 例

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【摘要】 目的 评价准分子激光消融术(ELA)联合药物涂层球囊治疗下肢动脉硬化闭塞的安全性和有效性。**方法** 回顾性分析 2016 年 11 月至 2017 年 6 月收治的 20 例接受 ELA 联合药物涂层球囊治疗的下肢动脉硬化闭塞患者临床资料。**结果** 手术成功 19 例(95%), 症状消失, 静息痛症状缓解; 失败 1 例(伴发腹主动脉瘤、静息痛), 瘤腔内大量血栓多次脱落至远端动脉, 足部动脉完全闭塞, 且取栓后效果不佳, 终因剧烈疼痛予膝下截肢。1 例前半足截肢患者于术后第 7 日左下肢动脉形成血栓, 经溶栓后症状有所缓解。术后踝-肱指数(ABI)与术前比较, 7 例(36.8%)提升<0.3, 8 例(42.2%)提升 0.3~0.5, 4 例(21.0%)提升>0.5。18 例患者平均随访 4(1~8)个月, 症状均缓解, 未再次干预; 1 例足趾溃疡患者溃疡愈合。**结论** ELA 联合药物涂层球囊治疗下肢动脉硬化闭塞所致缺血安全、有效, 但仍需更大样本量和更长随访时间临床观察。

【关键词】 动脉闭塞性疾病, 下肢; 准分子激光消融术; 经皮腔内血管成形术

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Excimer laser ablation combined with drug-coating balloon angioplasty for lower extremity arteriosclerosis occlusive diseases: preliminary results in 20 patients GU Yongquan, GUO Lianrui, QI Lixing, CUI Shijun, GUO Jianming, LI Yang, GAO Xixiang, TONG Zhu, QI Yixia, ZHANG Chengchao, WU Zhongjian, YANG Shengjia, ZHANG Jian, WANG Zhonggao. Department of Vascular Surgery,

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【Abstract】 Objective To evaluate the efficacy and safety of excimer laser atherectomy (ELA) combined with drug-coating balloon angioplasty in treating lower extremity arteriosclerosis occlusive diseases. **Methods** The clinical data of 20 patients with chronic ischemia caused by arteriosclerosis occlusive diseases of lower limbs, who were admitted to authors' hospital to receive ELA therapy during the period from November 2016 to June 2017, were retrospectively analyzed. **Results** Successful ELA was accomplished in 19 patients (95%), their clinical symptoms disappeared and the symptoms of resting pain were improved. ELA procedure failed in one patient, who had abdominal aortic aneurysm and resting pain; the great quantity of thrombus within the aneurysmal lumen repeatedly fell off and floated to distal arteries, and the patient's foot arteries were completely occluded; finally, as the effect of thrombus removal treatment was poor, below-knee amputation had to be carried out due to unbearable severe pain. Another patient, who had received anterior half foot amputation, developed thrombosis of left lower extremity artery on the seventh day after ELA therapy, the clinical symptoms were relived to some extent after thrombolytic therapy. Compared with preoperative data, the postoperative ankle-brachial index (ABI) was improved; an increase of <0.3 was seen in 7 patients (36.8%), an increase of $0.3-0.5$ in 8 patients (42.2%), and an increase of >0.5 in 4 patients (21.0%). Eighteen patients were followed up for a mean of 4 months (1-8 months), the clinical symptoms were improved in all patients, no second intervention therapy was needed, and the skin ulcer healed up in one patient who had toe ulceration. **Conclusion** For the treatment of arteriosclerosis occlusive diseases of lower limbs, ELA combined with drug-coating balloon angioplasty is safe and effective, although more researches with large sample and long-term clinical follow-up observation are needed to further clarify its curative effect. (J Intervent Radiol, 2018, 27: 779-782)

【Key words】 arteriosclerosis occlusive disease, lower extremity; excimer laser ablation; percutaneous transluminal angioplasty

经皮腔内血管成形术(PTA)或/和支架成形术是目前我国治疗下肢动脉硬化闭塞所致慢性缺血的主要手段,但均可发生术后再狭窄而再次干预,甚至可能面临截肢风险。如何减少术后再狭窄,保持靶血管远期通畅是临床上面临的重大挑战。激光治疗的问世有可能解决或部分解决这一问题。本中心采用准分子激光消融术(excimer laser atherectomy, ELA)联合紫杉醇药物涂层球囊治疗 20 例下肢动脉硬化闭塞患者,近期效果满意,现报道如下。

1 材料与方法

1.1 一般资料

2016 年 11 月至 2017 年 6 月收治的 20 例下肢动脉硬化闭塞患者中男 19 例,女 1 例,平均年龄 66.3(48~85)岁;15 例间歇性跛行(行走距离 50~200 m),3 例静息痛,1 例足趾溃疡,1 例足部坏疽行半足截肢创面不愈合;平均踝-肱指数(ABI)为 0.44(0~1.10);伴高血压 11 例,糖尿病 11 例,高脂血症 10 例,脑梗死后遗症 5 例,冠心病 3 例,吸烟 12 例。CTA 检查显示股腘动脉原发闭塞 10 例,股浅

动脉支架术后再闭塞 5 例,膝下动脉闭塞 5 例。

1.2 治疗方式

对 10 例股腘动脉原发闭塞和 5 例股浅动脉支架术后再闭塞,予以 ELA 联合普通球囊扩张预防 ELA 后管腔回缩(巩固管腔获得)、紫杉醇涂层球囊扩张靶病变管腔持续 4 min 治疗(10 例闭塞病变通过对侧股动脉穿刺翻山到达开通,3 例股腘动脉原发闭塞和 2 例股浅动脉支架术后再闭塞病变通过穿刺病变远端逆向开通),其中 1 例支架术后再闭塞和 3 例股腘动脉原发闭塞患者在紫杉醇涂层球囊扩张后出现严重动脉夹层,遂以补救性植入支架。对 5 例膝下动脉闭塞患者(小腿胫后动脉病变 4 例,胫腓干动脉和腓动脉病变 1 例),予以 ELA 联合紫杉醇涂层球囊扩张靶病变管腔持续 3 min 治疗,其中通过真腔开通和假腔开通各 2 例,1 例为多段重度狭窄病变。

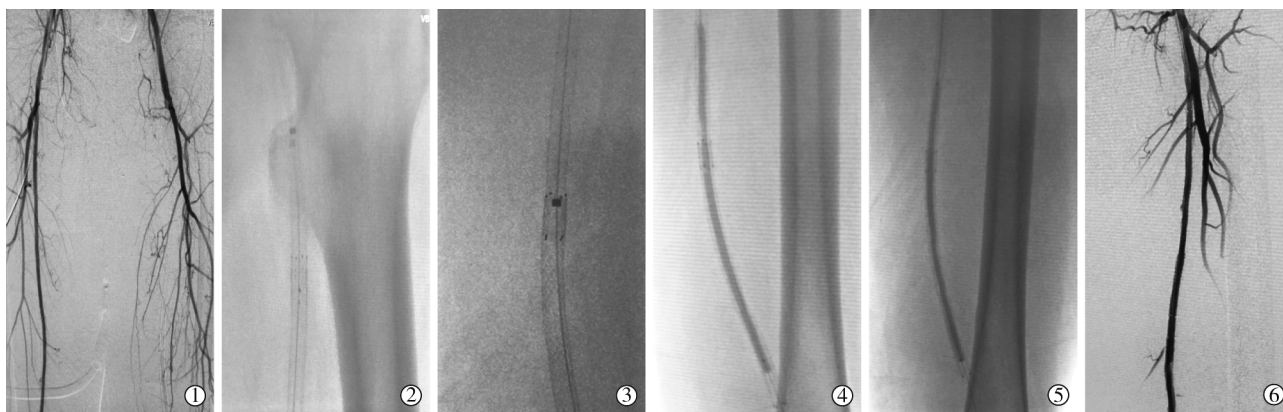
ELA 方法:采用 CVX-300 型氯化氙准分子激光发生系统(美国 Spectranetics 公司,波长 308 nm,脉冲式发射),将 0.018 英寸导丝送达靶动脉远端真腔,沿导丝送入 Turbo-Elite 激光导管(管径 2.3 mm

用于股腘动脉病变,1.7 mm 用于膝下动脉病变),从患侧股浅动脉起始端向远端以 1 mm/s 速度缓慢移动消融(频率 40 Hz,40 mJ/mm²)至远端动脉真腔段;再次自近端病变以高频率 50 Hz 和高能量 50 mJ/mm² 激光向远端缓慢消融,造影显示血流通畅。

2 结果

手术成功 19 例(95%),症状消失,静息痛症状缓解(图 1);失败 1 例(伴有腹主动脉瘤、静息痛),

瘤腔内大量血栓多次脱落至远端动脉,足部动脉完全闭塞,且取栓后效果不佳,终因剧烈疼痛予膝下截肢。1 例前半足截肢患者于术后第 7 日左下肢动脉形成血栓,经溶栓后症状有所缓解;复查造影发现股浅动脉重度狭窄,患者拒绝进一步介入治疗自动出院。术后 ABI 与术前比较,7 例(36.8%)提升<0.3,8 例(42.2%)提升 0.3~0.5,4 例(21.0%)提升>0.5。18 例患者平均随访 4(1~8)个月,症状均缓解,无再次干预;1 例足趾溃疡患者溃疡愈合。



①术前 DSA 造影显示左股浅动脉支架后闭塞;②③术中 2.5 mm 激光导管逐段消融;④普通球囊扩张;⑤药物涂层球囊扩张;⑥复查造影显示病变动脉通畅

图 1 ELA 联合普通球囊和紫杉醇涂层球囊扩张治疗下肢动脉硬化闭塞患者影像

3 讨论

血管腔内治疗已成为目前临床干预下肢动脉硬化闭塞症的主流手段。在股腘动脉闭塞病变腔内治疗方面,支架成形术应用最普遍、疗效最确切;在膝下动脉闭塞病变方面,球囊扩张是最普遍选择^[1-2]。但支架植入或球囊扩张相关问题也一直存在:①单纯球囊扩张动脉后很易出现弹性回缩;②球囊扩张增加夹层风险,普通球囊难以充分扩张钙化病变,血流改善有限;③支架植入后金属异物持续刺激动脉致血栓形成或内膜增生,造成再狭窄;④受邻近髌膝关节反复屈曲影响,股腘动脉近关节区域植入支架易出现金属疲劳,随访 1 年断裂率达 15%~44%,从而增加血管闭塞风险,造成缺血症状复发^[3-5];⑤支架植入增加二次手术难度,使部分患者失去手术机会。因此,找到可避免支架植入、疗效确切的新型腔内治疗手段是临床上迫切需要解决的实际问题。

血管减容手术在直接消除硬化闭塞组织的同时避免了支架植入,为进一步提高远期通畅率带来可能。作为减容术主要代表,ELA 术原理为光化学作用,斑块组织通过吸收 308 nm 激光能量引起分子键断裂,碎化成直径<25 μm 碎片。因此,ELA 术可安全地消融溶解血管内血栓、斑块等。ELA 术治

疗下肢动脉硬化闭塞原发病变的安全性和有效性已得到多项多中心临床试验研究证实,手术成功率为 93.5%~96.7%,12 个月通畅率为 54.0%~64.4%,术后患者均无严重不良事件及并发症发生^[6-8]。有临床研究发现 ELA 术去除硬化斑块组织后辅以药物涂层球囊扩张,会使球囊附带药物更有效地接触内膜并传递至平滑肌,提高抑制内膜增生效果^[9]。Gandini 等^[10]对比分析 ELA 术联合药物涂层球囊和单纯药物涂层球囊治疗股浅动脉支架内再狭窄效果,结果发现前者明显优于后者,术后 6 个月、12 个月一期通畅率均显著提高(91.7%对 66.7%,58.3%对 37.5%)($P=0.01$)。本研究选择 ELA 术开通闭塞下肢动脉,然后以普通球囊扩张并以药物涂层球囊紧密贴附动脉内膜,以期获得满意的通畅率。

ELA 术在国内开展较晚,本中心 2017 年报道采用 ELA 术联合药物球囊治疗下肢动脉慢性缺血 3 例,取得良好效果^[11]。本组 20 例下肢动脉硬化闭塞病变包括股腘段和膝下段原发病变和支架术后再闭塞病变,目前 18 例平均随访 4 个月通畅率为 100%,短期临床疗效理想。临床操作中发现 ELA 技术安全性较高,也可应用于内膜下开通,例如激光作用半径稍超越导管直径,动脉破裂穿孔风险低;

术中仅需间歇性地在 X 线透视下看一下导管头端位置,辐射时间非常短,且激光本身无放射性;激光发出后呈一圆形,与导丝共轴,不需调整角度。对原发性闭塞及支架术后再闭塞病变,尤其是内膜下开通闭塞病变,建议选择 ELA 术。ELA 术应用于血栓组织等质地柔软病变和严重钙化病变需格外慎重,血栓组织对 208 nm 激光能量吸收差,会导致疗效欠佳,Turbhawk 斑块切除系统切割开通严重钙化病变效率更高、更有针对性^[12]。为降低开通过程中远端栓塞事件发生,ELA 术中需注意:①操作中应慢速通过病变,建议速率 <1 mm/s;②术后普通球囊和药物球囊扩张时间应比常规时间延长。本组患者中发生截肢事件由近端主动脉瘤腔内血栓脱落造成栓塞所致。但本研究随访时间较短,仍需更长观察时间、更大样本量临床研究结果验证。

总之,ELA 联合药物涂层球囊治疗下肢动脉硬化闭塞原发病变和支架术后再闭塞病变安全可行,可取得满意短期疗效,但仍需更大样本量和更长随访时间临床观察。

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