

球囊导引导管在大血管闭塞急诊血管内机械取栓术中的应用

罗雷雷 赵建斌 魏铭

【摘要】 血管内机械取栓术是经严格筛选的急性大血管闭塞一线治疗方案,是提高预后良好率的有效方法。越来越多的循证医学证据证明,球囊导引导管因其近端血流阻断作用,可以缩短血管再通时间,增加首次再通率,减少远端血栓逃逸风险,但目前球囊导引导管在急诊机械取栓术中应用仍受限。本文综述球囊导引导管的临床应用进展,以为其在急诊机械取栓术中的应用提供理论依据。

【关键词】 缺血性卒中; 血栓切除术; 球囊导引导管(非 MeSH 词); 综述

Application of balloon guide catheter in emergency endovascular thrombectomy for large vessel occlusion

LUO Lei-lei¹, ZHAO Jian-bin², WEI Ming¹

¹Department of Neurosurgery, Tianjin Huanhu Hospital; Clinical College of Neurology, Neurosurgery and Neurorehabilitation, Tianjin Medical University, Tianjin 300350, China

²Department of Neurology, Lulong County Hospital, Qinhuangdao 066400, Hebei, China

Corresponding author: WEI Ming (Email: drweiming@163.com)

【Abstract】 Endovascular thrombectomy is a first-line treatment option for acute large vessel occlusive ischemic stroke after strict selection, which is an effective method to improve the good prognosis rate of patients. More and more evidence-based medicine proves that balloon guide catheter (BGC) can shorten the reperfusion time, increase the rate of initial reperfusion, and reduce the risk of distal embolism due to its proximal blood flow occlusion, but the application of BGC in emergency endovascular thrombectomy is still limited. This review summarizes the clinical application progress of BGC to provide theoretical basis for its application in emergency endovascular thrombectomy.

【Key words】 Ischemic stroke; Thrombectomy; Balloon guide catheter (not in MeSH); Review

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多项研究建议,将血管内机械取栓术作为经严格筛选的急性大血管闭塞患者的首选治疗方法^[1-5]。

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作者单位:300350 天津市环湖医院神经外科 天津医科大学神经内外科及神经康复临床学院(罗雷雷,魏铭);066400 秦皇岛,河北省卢龙县医院神经内科(赵建斌)

通讯作者:魏铭,Email:drweiming@163.com

随着神经介入技术和器械的发展,机械取栓术可达 80% 以上的血管再通率,但仅约 50% 的急性大血管闭塞患者能实现术后 90 天预后良好^[6]。球囊导引导管(BGC)因其近端血流阻断作用,可提高首次再通率,降低远端栓塞风险,提高预后良好率^[7-8]。基于此,本文拟综述球囊导引导管的临床应用进展,以为其在急诊机械取栓术中的应用提供理论依据。

一、球囊导引导管的临床应用历程

颈动脉支架成形术(CAS)是脑卒中预防的有效手段,狭窄或闭塞近端和远端栓塞保护装置的应用有效降低围手术期脑卒中发生率。球囊导引导管

设计的初衷是为实现颈动脉的逆向血流,减少颈动脉闭塞开通或颈动脉支架成形术中栓塞风险,是目前最常用的近端栓塞保护装置。

早在 2001 年,Ohki 等^[9]探索近端阻断导管(POC)在预防颈动脉支架成形术中栓塞事件的有效性,发现单纯应用 PAEC(Parodi Anti-Embolization Catheter, 美国 ArteriA 公司)导管阻断颈总动脉(CCA)时,由于甲状腺动脉-颈外动脉(ECA)逆向血流的存在,并不能有效预防栓塞,而近端阻断结合动静脉分流可以作为预防栓塞的可靠手段。该项研究开启了负压下应用尖端球囊导引导管进行颈动脉介入手术的探索。

2002 年,另一近端保护装置——Mo.Ma 系统(美国 Medtronic 公司)率先在欧洲应用于临床。Mo.Ma 系统的设计理念来源于颈动脉内膜切除术(CEA)的脑血流完全阻断方式,通过 2 个球囊同时阻断颈总动脉和颈外动脉。相较于 PAEC 导管,Mo.Ma 系统的脑血流阻断效果更确切,适用于重度狭窄(狭窄率 > 90%)、新鲜血栓病变、软性溃疡斑块、颈内动脉长节段病变、不稳定和易碎斑块等。PRIAMUS (Proximal flow blockage cerebral protection during carotid stenting: Results from a Multicenter Italian registry) 研究报道颈动脉支架成形术中应用 Mo.Ma 系统进行近端栓塞保护的 412 例颈动脉狭窄患者,技术成功率为 99.03% (408/412),术后脑卒中发生率为 4.61% (19/412),与 SAPHIRE [Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy, 4.40% (7/159)]、ARCHER (6.63%, 34/153) 等应用远端栓塞保护装置的前瞻性、多中心、随机试验结果相似^[10]。

随着取栓技术的普及与发展,球囊导引导管技术广泛应用于机械取栓术。从第一代以 Merci(美国 Stryker 公司)为代表的球囊导引导管,到 FlowGate(美国 Stryker 公司)、FULLBLOCK(上海心玮医疗科技股份有限公司)、Fluxcap[加奇生物科技(上海)有限公司]等新一代球囊导引导管,出现众多球囊导引导管相关取栓技术,同时涌现出越来越多的相关循证医学证据。

二、球囊导引导管的设计和结构

球囊导引导管由内杆、外鞘、球囊和尾部四部分组成。以 Merci 球囊导引导管为例,内杆由不锈钢材料编制,可提供远端的柔韧性及近端的支撑性平衡;内杆最远端与标记带之间存在距离,8F Merci

球囊导引导管 3 mm、9F Merci 球囊导引导管 4 mm,因此术中标记带应与岩骨段保持一定距离。内杆与外鞘同轴管腔的设计便于在血管迂曲处快速充盈和排空;外鞘通过尾部 Y 阀连接注射器以快速充盈或抽瘪球囊;球囊为具有气体扩散功能的顺应性球囊皮材质,最大充盈量为 0.60 ml,最大充盈时球囊直径为 10 mm,充分顺应血管壁形态,发挥近端血流控制功能;尾部为双管腔结构,包括导引导管管腔和球囊充盈管腔。

三、球囊导引导管的应用现状

2019 年的一项国外研究结果显示,仅 1/4 的术者在急诊机械取栓术中常规应用球囊导引导管^[11],而在低容量医疗中心的应用率更低^[12]。拒绝应用球囊导引导管的术者主要考虑以下因素^[7,13]:柔韧性差,迂曲血管中到位困难;与其他导引导管相比,需要更大的股动脉鞘,增加穿刺点并发症如假性动脉瘤、动静脉瘘等发生风险;可能导致血管痉挛、动脉夹层;球囊阻断血流过程中可能导致新发脑梗死;与大口径抽吸导管不兼容;对于大脑中动脉(MCA) M1 段及以远闭塞,中间导管负压抽吸即可达到血流逆转、防止血栓逃逸的效果,且 Willis 环正向血流削弱球囊导引导管血流控制效果;价格昂贵。材料学和工程学的发展促进球囊导引导管的不断革新,经过改良者相继上市,新一代球囊导引导管采用节段式管体加强层设计,在兼顾近端支撑性的前提下,增强远端柔韧性,到位更容易;同样 8F 外径下,内径更大,可适配 8F 股动脉鞘和 6F 中间导管;其头端不显影节段更短,可更准确判断头端位置,降低血管痉挛、动脉夹层风险。随着球囊导引导管的不断迭代更新,其在血管内治疗中防止血栓逃逸、提高首次再通率、缩短手术时间的优势愈发受到关注。

四、球囊导引导管在急性大血管闭塞临床应用中的理论基础

1. 近端血流控制,防止血栓逃逸 取栓过程中血栓受两端压力梯度、血栓与管壁摩擦力、取栓装置牵拉力的综合作用,无论是支架取栓、抽吸取栓还是二者结合,均可能发生血栓破碎,在无血流控制的情况下向远端逃逸^[14]。另外,大负荷量血栓被支架牵拉进中间导管过程中会发生血栓切割,也存在血栓逃逸风险^[14]。球囊导引导管通过球囊充盈,实现近端血流控制,配合负压抽吸实现血流逆转,最大程度减少血栓破碎、切割造成的逃逸。体外研

究发现,近端球囊导引导管阻断的取栓过程中,大脑中动脉大负荷量血栓被支架抓取牵拉过程中破碎,进入球囊导引导管时被切割,但并未向远端逃逸,而是残留在球囊导引导管头端^[15]。

2. 降低跨血栓压力梯度,提高首次再通率 血栓在血管中受跨血栓压力梯度以及血栓与管壁间黏附力、摩擦力的共同作用^[15]。正向血流冲击和侧支循环逆向血流构成跨血栓压力梯度,因此存在良好侧支循环的患者跨血栓压力梯度更小,血栓更易取出。球囊导引导管通过阻断正向血流,完全消除或减弱正向的血流冲击力,取栓支架或抽吸导管所需提供的拉力更小,首次再通率更高。

3. 以球囊导引导管为基础的血管再通技术

(1) BADDASS 技术(BALloon guide with large bore Distal access catheter with Dual Aspiration with Stent-retriever as Standard approach): 该项技术在球囊导引导管阻断近端血流的基础上,应用大管腔中间导管充分接触血栓,球囊导引导管和大管腔中间导管双抽吸,结合取栓支架实现血管再通,可以同时发挥大口径抽吸导管和取栓支架的作用^[16]。(2) 球囊接力技术(relay-balloon technique): 球囊接力技术通过交替充盈球囊导引导管和颈动脉扩张球囊实现血流阻断,充分体现球囊导引导管在取栓中的独特优势^[17]。STRATIS (Systematic Evaluation of Patients Treated with Neurothrombectomy Devices for Acute Ischemic Stroke) 研究表明,球囊导引导管组首次再通率(47.86%, 212/443) 高于常规导引导管组(25.81%, 16/62; $P = 0.001$) 和远端通路导管组(35.32%, 83/235; $P = 0.002$); 球囊导引导管组预后良好率(66.37%, 294/443) 高于传统导引导管组(41.94%, 26/62; $P < 0.001$) 和远端通路导管组(55.13%, 129/234; $P = 0.003$), 提示球囊接力技术可有效改善远端脑灌注^[18]。(3) TSAT 技术(Two-Stage Aspiration Technique): 该项技术为双导管抽吸技术,应用双抽吸导管 Penumbra 3MAX (美国 Penumbra 公司) 和 Penumbra 5MAX ACE (美国 Penumbra 公司), 并联合应用球囊导引导管近端阻断血流^[19]。(4) RETS (Reperfusion - Expanding - Thrombectomy - Stenting) 技术: 该项技术先在远端闭塞段置入支架恢复血流灌注,球囊扩张近端闭塞段后再于球囊导引导管保护下完成取栓及近端颈动脉支架成形术,充分发挥球囊导引导管的作用,提高首次再通率,同时减少远端栓塞事件。取栓支架

远端释放后,对于有 Willis 环代偿的患者,可第一时间恢复远端血供,减少缺血时间,改善临床预后。(5) TRAP (TRevo with Aspiration and Proximal flow control) 技术: 该项技术是以 Trevo 支架为基础,通过球囊导引导管和中间导管负压抽吸以实现近端血流控制。其核心包括以下三要素: 推拉技术释放 Trevo 支架; 远端通路导管进一步抽吸和锚定近端血栓; 球囊导引导管控制近端血流。

五、球囊导引导管在急诊机械取栓术中应用的循证医学证据

NASA (The North American Solitative Stent Retriever Acute Stroke) 和 TRACK (Trevo stent - Retriever Acute Stroke) 登记研究是两个最大的真实世界关于支架取栓的经验数据库^[20-21], 旨在评价美国食品与药品管理局(FDA) 批准的两种支架取栓装置在实际临床应用中的效果。NASA 登记研究在北美 24 所医疗中心纳入 354 例急性大血管闭塞患者, 338 例有球囊导引导管相关数据的患者中 149 例(44.08%) 应用球囊导引导管, 结果显示, 相较于传统导引导管组, 球囊导引导管组手术时间较短 $[(120 \pm 28.5)$ 分钟对 (161 ± 35.6) 分钟, $P = 0.020$], 补救性治疗更少 $[19.46\% (29/149)$ 对 $28.57\% (54/189)$, $P = 0.050$], 脑梗死溶栓血流分级(TICI) 3 级占比更高 $[53.69\% (80/149)$ 对 $32.80\% (62/189)$, $P < 0.001$]; 出院时美国国立卫生研究院卒中量表(NIHSS) 评分更低 $[(12 \pm 14.5)$ 分对 (17.5 ± 16) 分, $P = 0.002$], 术后 3 个月功能独立率更高 $[51.59\% (65/126)$ 对 $35.84\% (62/173)$, $P = 0.020$]; 而两组之间的远端栓塞和新发梗死发生率无明显差异; 进一步多因素 Logistic 回归分析表明, 应用球囊导引导管是临床结局良好的独立预测因素($OR = 2.500$, 95%CI: 1.200 ~ 4.900; $P < 0.01$)^[20]。TRCK 登记研究是迄今最大的由制造商发起的独立上市后登记研究, 评价 Trevo 支架在 23 所医疗中心共 634 例缺血性卒中患者中的实际临床经验, 在 TRACK 队列中球囊导引导管应用率达到 47.38% (298/629), 其与传统导引导管再灌注时间、首次再通率、取栓次数或补救性治疗方面无明显差异; 球囊导引导管组患者术后 90 天预后良好率更高 $[57.05\% (170/298)$ 对 $39.90\% (251/629)$, $P = 0.0004$], 病死率更低 $[13.09\% (39/298)$ 对 $23.05\% (145/629)$, $P = 0.008$]; 进一步行多因素 Logistic 回归分析显示, 应用球囊导引导管是临床结局良好的独立预测因素($OR = 1.790$, 95%CI:

1.290 ~ 2.490, $P < 0.05$)^[21]。STRATIS 研究是迄今最大的关于球囊导引导管的前瞻性、多中心、非随机、观察性登记研究,结果显示,应用球囊导引导管是首次再通和功能独立的独立预测因素,常规应用球囊导引导管可提高早期血管再通率和临床良好结局^[18]。一项纳入 5 项非随机对照试验共 2022 例急性大血管闭塞患者(球囊导引导管组 1083 例和非球囊导引导管组 939 例)的 Meta 分析显示,与非球囊导引导管组相比,球囊导引导管组功能独立率更高 [59.71% (572/958) 对 43.82% (369/842); $OR = 1.840$, 95%CI: 1.520 ~ 2.220, $P < 0.01$], 病死率更低 [13.69% (62/453) 对 24.84% (116/467); $OR = 0.520$, 95%CI: 0.370 ~ 0.730, $P < 0.01$], 首次再通率更高 [63.07% (497/788) 对 45.23% (280/619); $OR = 2.050$, 95%CI: 1.650 ~ 2.550, $P < 0.01$]; TICI 分级 3 级 [57.86% (114/197) 对 38.16% (87/228); $OR = 2.130$, 95%CI: 1.430 ~ 3.170, $P < 0.01$] 和 2b ~ 3 级 [78.94% (817/1035) 对 67% (603/900); $OR = 1.540$, 95%CI: 1.210 ~ 1.970, $P < 0.01$] 占比更高; 平均取栓次数更少 [1.7 次对 2 次; $WMD = -0.340$, 95%CI: -0.470 ~ -0.220, $P < 0.01$]^[22]。

另有一些小样本研究证实球囊导引导管在降低远端栓塞、提高首次再通率、改善预后等方面的优势。研究发现,应用球囊导引导管行近端血流阻断,结合抽吸取栓可以有效减少颈内动脉末端 L 型或 T 型大负荷量血栓,提高血管再通率^[23]。一项纳入 183 例前循环大血管闭塞患者的回顾性研究发现,应用球囊导引导管患者血管再通率和首次再通率更高,手术时间更短^[24]。Kammerer 等^[25]对 201 例急性大血管闭塞患者进行回顾性研究发现,球囊导引导管结合支架取栓首次再通率达 65%,血管再通率达 91%。球囊导引导管的应用可以显著减少远端栓塞事件,提高血管再通率^[26]。球囊导引导管在临床应用中受限的主要原因之一是可能引起穿刺点并发症。为匹配 8F 或 9F 球囊导引导管,通常选择 8F 或 9F 股动脉鞘。一项单中心研究对 472 例急性大血管闭塞患者(均应用 8F 或更大尺寸球囊导引导管行血管内治疗)进行回顾分析发现,具有临床意义的大口径鞘管相关腹股沟并发症发生率极低 (0.4% ~ 0.8%),对大口径鞘管相关腹股沟并发症的担忧不应成为拒绝应用球囊导引导管的原因^[27]。

海军军医大学附属第一医院(上海长海医院)刘建民和杨鹏飞教授团队发起的全国前瞻性、多中

心、随机对照 PROTECT-MT (Proximal Temporary Occlusion using Balloon Guide Catheter for Mechanical Thrombectomy) 研究共纳入 329 例急性大血管闭塞患者,结果显示,与球囊导引导管组相比,传统导引导管组血管再通时间更短(44 分钟对 53 分钟),病死率更低(16% 对 24%),临床预后更佳(mRS 评分 0 ~ 3 分比例 56% 对 41%)。尽管该项研究并未显示出球囊导引导管的疗效优于传统导引导管,但仍为球囊导引导管的临床应用增添了新的循证医学证据^[3]。

随着球囊导引导管在急诊机械取栓术中的循证医学证据越来越充分,2019 年新版美国心脏协会(AHA)/美国卒中协会(ASA)《急性缺血性卒中早期管理指南》^[28]推荐:应用球囊导引导管或大口径远端通路导管联合支架取栓,较传统导引导管更有可能获益(II a 类推荐, C 级证据)。2023 版欧洲卒中组织(ESO)-欧洲微创神经治疗学会(ESMINT)指南推荐,任何取栓技术均应在近端球囊导引导管保护下进行^[29]。我国《急性缺血性卒中血管内治疗中国指南 2023》^[30]也对球囊导引导管的应用给出了推荐(II a 类推荐, C 级证据)。

综上所述,球囊导引导管因其近端血流阻断作用,可降低跨血栓压力梯度,增加首次再通率,减少远端血栓逃逸风险,提高预后良好率。随着球囊导引导管材料和工艺的进步,不断更新迭代的球囊导引导管具有更好的支撑力和柔韧性,具有更大的内腔,相信在临床应用中也会更加普及。其临床应用效果尚需大样本前瞻性研究进一步证实。

利益冲突 无

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· 小词典 ·

中英文对照名词词汇(二)

克-雅病 Creutzfeldt-Jakob disease(CJD)

扩展脑梗死溶栓血流分级

extended Thrombolysis in Cerebral Infarction(eTICI)

立体定向脑电图 stereo-electroencephalography(SEEG)

颅内出血 intracranial hemorrhage(ICH)

颅内动脉粥样硬化性狭窄

intracranial atherosclerotic stenosis(ICAS)

颅内压 intracranial pressure(ICP)

裸导丝技术 bare wire thrombectomy(BWT)

美国卒中协会 American Stroke Association(ASA)

美国国立神经病学与卒中研究所

National Institute of Neurological Disorders and Stroke (NINDS)

美国国立卫生研究院卒中量表

National Institutes of Health Stroke Scale(NIHSS)

美国介入放射学学会

Society of Interventional Radiology(SIR)

美国介入和治疗性神经放射学学会

American Society of Interventional and Therapeutic Neuroradiology(ASITN)

美国食品与药品管理局

Food and Drug Administration(FDA)

美国心脏病学会 American College of Cardiology(ACC)