

# 经导管主动脉瓣置换术中的脑保护

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**【摘要】** 经导管主动脉瓣置换术经过 20 余年的发展,手术相关并发症已明显减少,唯术后脑卒中发生率无明显降低。近年多种脑保护装置应用于临床,但因缺乏高质量循证医学证据支持,其有效性尚存较大争议。本文综述经导管主动脉瓣置换术相关脑卒中危险因素以及术中脑保护装置的应用,为病例选择和脑保护策略制定提供参考。

**【关键词】** 经导管主动脉瓣置换; 栓塞保护装置; 手术后并发症; 卒中; 综述

## Cerebral embolic protection during transcatheter aortic valve replacement

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**【Abstract】** After more than 20 years of development, the complications of transcatheter aortic valve replacement (TAVR) have been significantly reduced, but the incidence of stroke has not been significantly reduced. In recent years, a variety of cerebral embolic protection device (CEPD) have been applied in clinical practice, but their effectiveness is still controversial due to the lack of high-quality clinical evidence. This article reviews progress on the risk factors for stroke and the characteristics of intraoperative CEPD in TAVR, so as to provide reference for the selection of TAVR cases and the formulation of cerebral embolic protection strategies.

**【Key words】** Transcatheter aortic valve replacement; Embolic protection devices; Postoperative complications; Stroke; Review

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2002 年,法国 Cribier 教授完成世界首例经导管主动脉瓣置换术(TAVR),该术式一经面世即掀起一场技术革命,成为近年来心血管外科领域最受瞩目的焦点<sup>[1-2]</sup>。随着手术技术的逐渐成熟,经导管主动脉瓣置换术相关并发症例如新发高度房室传导阻滞、外周动脉路径损伤、冠状动脉闭塞、循环崩溃等发生率明显降低,唯有脑卒中发生率未见明显变化<sup>[3-5]</sup>。经导管主动脉瓣置换术后脑卒中发生率为

2%~4%<sup>[4,6-7]</sup>,导致部分患者失去日常生活活动能力<sup>[8]</sup>。脑保护装置(CEPD)作为经导管主动脉瓣置换术中唯一可能有效的脑保护手段,其真实有效性备受争议<sup>[6,8-9]</sup>。自首个脑保护装置(Santa Rosa 系统,美国 Claret Medical 公司)临床研究发表以来<sup>[10]</sup>,脑保护装置应用率呈逐年升高趋势,至 2021 年,美国经导管主动脉瓣置换术中脑保护装置应用率达 13%<sup>[5]</sup>。2023 年 4 月,SENTINEL™抗栓塞脑保护装置(美国 Boston Scientific 公司)率先进入中国市场,先后在北京、上海市、浙江省、四川省等应用于临床,标志着我国正式步入经导管主动脉瓣置换术中脑保护装置应用与研究的新领域,然而目前尚未开展相关临床研究。本文拟综述经导管主动脉瓣置换术相关脑卒中危险因素以及术中脑保护装置的应用,以为临床选择经导管主动脉瓣置换术病例和

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制定脑保护策略提供参考。

### 一、常用经导管主动脉瓣置换术中脑保护装置

脑保护装置是一种置于主动脉弓或弓上分支内,通过导流或捕获方式阻碍血管内碎片进入脑血管,以预防术后缺血性卒中的装置。目前已实现体内植入的装置主要包括 Sentinel 系统、TriGuard 系统、Embrella 系统、Emblok 系统(图 1)<sup>[8,11-14]</sup>等,不同装置的设计原理、操作入路、保护范围等存在较大差异(表 1)<sup>[8,11-15]</sup>。Sentinel 系统是唯—同时获得美国食品与药品管理局(FDA)和欧洲共同体(CE)认证以及唯—进入中国市场的产品。该系统的栓子捕获率高达 99%<sup>[16]</sup>,但对左锁骨下动脉缺乏保护。TriGuard 系列产品(包括 TriGuard HDH 系统和 TriGuard 3 系统)采取经股动脉路径,可覆盖主动脉弓所有分支。但 REFLECT I (Randomized Evaluation of TriGuard HDH Cerebral Embolic Protection after Transcatheter Aortic Valve Implantation)试验显示, TriGuard HDH 系统主动脉弓上分支完全覆盖率为 57.3%,器械成功率(植入和撤出)为 93.4%<sup>[11]</sup>; REFLECT II 试验采用新一代升级产品 TriGuard 3 系统,其主动脉弓上分支完全覆盖率为 59.7%,器械成功率达 100%<sup>[12]</sup>;但 TriGuard 系列产品在主动脉弓的固定性较差,无法达到设计初衷,且较大的分流伞和股动脉路径占据经导管主动脉瓣置换术入路并影响其输送系统通过主动脉弓。Embrella 系统较早即获得欧洲共同体认证,但其封堵伞的贴附性较差,封闭不全,且缺乏大样本临床研究的支持。Emblok 系统于 2020 年被首次报道,其安全性已得到证实:器械成功率达 100%,术后 30 天随访未发生心血管不良事件<sup>[14]</sup>,但该系统完全封闭升主动脉,可能影响其输送系统的同轴性。结合上述脑保护装置的优缺点,笔者认为,理想的脑保护装置应具备以下特点:易于植入、栓子阻碍作用完全且稳定、对经导管主动脉瓣置换术影响小,且装置本身植入过程引起的脑卒中风险最小化<sup>[17]</sup>。

### 二、经导管主动脉瓣置换术中脑保护装置相关临床研究

现有的经导管主动脉瓣置换术中脑保护装置相关临床研究之间存在诸多矛盾之处,各项研究对终点结局指标、不良事件等缺乏统一定义,甚至导致研究结果截然相反<sup>[5,7,18]</sup>;加之采取经导管主动脉瓣置换术的患者病情较为复杂,难以准确识别术后

脑卒中,因此,经导管主动脉瓣置换术中脑保护装置的有效性研究面临诸多困难<sup>[5,17,19]</sup>。首先,脑保护装置仅可预防部分脑卒中。根据脑保护装置筛孔型的设计原理,该装置仅可阻止经导管主动脉瓣置换术中钙化或粥样硬化斑块脱落形成的大碎片进入脑血管,而对于术中非碎片相关脑卒中如重度脑血管病变、脑卒中病史、房颤、颈动脉疾病、非计划开胸手术、其他左心相关操作、循环不稳、心肺复苏、钙化瓣膜延迟脱落等导致的脑卒中,脑保护装置是无效的。其次,经导管主动脉瓣置换术后脑卒中的识别较为困难,其诊断时间窗存在争议。Lansky 等<sup>[17]</sup>形象地将经导管主动脉瓣置换术后脑卒中比作“在煤窑里寻找一只黑猫”,尽管其具有明确的诊断标准<sup>[20-21]</sup>,但临床实践中却存在较大差异。研究显示,与不具备脑卒中中心的医疗机构相比,具备脑卒中中心的医疗机构经导管主动脉瓣置换术后脑卒中识别率升高 > 1 倍<sup>[22]</sup>;仅 32% 的脑卒中发生于经导管主动脉瓣置换术后当日,48.9% ~ 68.4% 发生于术后 24 ~ 72 h<sup>[5,19]</sup>,推测是由于术后早期镇静药和麻醉药的应用限制对脑卒中的识别。实际上,应用脑保护装置的经导管主动脉瓣置换术 3 天后发生的脑卒中并非完全因术中保护无效所致,可能与低血压、脑灌注控制欠佳等有关,因此尚无法否定脑保护装置的保护作用。此外,脑保护装置费用昂贵(> 9000 美元)<sup>[3]</sup>,亦限制其临床研究的开展。

一项 Meta 分析共纳入 4 项临床研究计 606 例行经导管主动脉瓣置换术患者,发现与未应用脑保护装置组相比,应用 Sentinel 系统脑保护装置组术后 30 天症状性脑卒中发生率明显降低 [3.54% (21/593) 对 6.13% (29/473);  $RR = 0.510$ , 95%CI: 0.290 ~ 0.900,  $P = 0.020$ ,  $I^2 = 0.000\%$ ]<sup>[23]</sup>。另一项 Meta 分析却得出截然不同的结果,纳入 5 项随机对照试验计 625 例行经导管主动脉瓣置换术患者,发现脑保护装置并未显著降低术后发生脑卒中或死亡风险 ( $RR = 0.610$ , 95%CI: 0.350 ~ 1.070,  $P = 0.080$ ,  $I^2 = 0.000\%$ )<sup>[24]</sup>。大多数获得阴性结果的研究中是否接受影像学检查主要以卒中临床症状作为首要识别要素,一定程度上受到患者和医师主观因素的影响<sup>[20]</sup>。一项来自美国胸外科医师学会/美国心脏病学会经导管瓣膜治疗(STS/ACC-TVT)注册<sup>[5]</sup>的观察性研究纳入 599 个医疗中心计 123 186 例行经导管主动脉瓣置换术患者,同样获得阴性结果;不同之

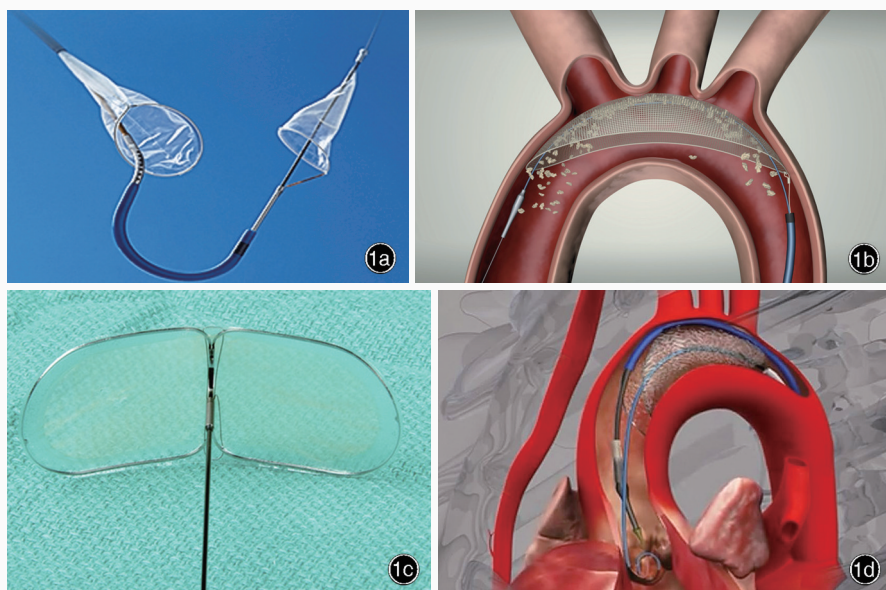


图1 经导管主动脉瓣置换术中实现体内植入的脑保护装置  
 1a Sentinel 系统<sup>[8]</sup>  
 1b TriGuard 系统<sup>[11-12]</sup>  
 1c Embrella 系统<sup>[13]</sup>  
 1d Emblok 系统<sup>[14]</sup>  
**Figure 1** CEPD in TAVR  
 Sentinel system<sup>[8]</sup> (Panel 1a).  
 TriGuard system<sup>[11-12]</sup> (Panel 1b).  
 Embrella system<sup>[13]</sup> (Panel 1c).  
 Emblok system<sup>[14]</sup> (Panel 1d).

表1 经导管主动脉瓣置换术中脑保护装置

Table 1. CEPD in TAVR

项目	Sentinel系统	TriGuard系统	Embrella系统	Emblok系统
生产公司	美国 Boston Scientific 公司	以色列 Keystone Heart 公司	美国 Edwards Lifesciences 公司	美国 Innovative Cardiovascular Solutions 公司
输送系统管径	6 F	8~9 F	6 F	11 F
动脉路径	桡动脉或肱动脉	股动脉	桡动脉或肱动脉	股动脉
滤网筛孔	140 μm	130 μm	100 μm	125 μm
原理	无名动脉和左颈总动脉内过滤或捕获栓子	将栓子分流,阻碍其进入无名动脉、左颈总动脉和左锁骨下动脉	将栓子分流,阻碍其进入主动脉弓上分支	完全封闭升主动脉,对主动脉弓上分支和降主动脉均有保护作用
缺点	左锁骨下动脉无保护	侵占股动脉路径,影响输送系统通过主动脉弓	贴附性较差,封闭不全,无法捕获栓子	压迫输送系统,无法保护冠状动脉
高质量临床试验	SENTINEL 试验 <sup>[8]</sup> , PROTECTED-TAVR 试验 <sup>[15]</sup>	REFLECT I 试验 <sup>[11]</sup> , REFLECT II 试验 <sup>[12]</sup>	PROTAVI-C 试验 <sup>[13]</sup>	European Study Evaluating the Emblok Embolic Protection System During TAVR <sup>[14]</sup>

处在于,该项研究通过数据倾向匹配消除部分混杂因素后发现,应用脑保护装置的患者住院期间卒中发生率降低[1.27% (158/12 409)对 1.55% (1716/110 777)];  $OR = 0.820$ , 95%CI: 0.690 ~ 0.970,  $P = 0.018$ ],提示此类研究混杂因素较多,可能存在较大偏倚,为今后的随机对照试验设计提供了新的思路。PROTECTED TAVR (Routine Cerebral Embolic Protection in Transcatheter Aortic Valve Implantation)研究是目前公认的纳入病例数最多、设计最合理的随机对照试验,将3000例行经导管主动脉瓣置换术患者随机分为未应用脑保护装置组和应用 Sentinel 系统脑保护装置组,随访2年发现,两组术后卒中发生率无明显差异[2.27% (34/1501)对 2.87% (43/1499),  $P = 0.300$ ]<sup>[16]</sup>。但应注意的是,该项研究终点为术后72小时或出院前,术后72小时内顺利出院的患者默认为未发生卒中,事

实上这部分患者仍处于脑卒中高发期,因此该项研究不足以完全否定脑保护装置在经导管主动脉瓣置换术中的脑保护作用<sup>[16]</sup>。亦有MRI研究显示,应用脑保护装置的患者经导管主动脉瓣置换术后卒中发生率虽无明显降低,但其梗死灶体积和远期认知功能恢复均优于未应用脑保护装置的患者<sup>[25]</sup>。由此可见,脑保护装置的有效性达成共识并实现大规模临床应用,仍依赖更科学、合理的高质量随机对照试验的验证,现阶段脑卒中危险因素的认识和适应证患者的选择,有望减少经导管主动脉瓣置换术相关卒中风险<sup>[26]</sup>。

### 三、经导管主动脉瓣置换术相关卒中危险因素及病例选择

经导管主动脉瓣置换术相关卒中主要为钙化或粥样硬化斑块脱落导致的缺血性卒中<sup>[27]</sup>。经导管主动脉瓣置换术中经颅多普勒超声(TCD)可见



与钙化瓣膜相似的颅内短暂性高信号,且大多发生于瓣膜植入过程中<sup>[28]</sup>。左心室流出道钙化、严重瓣膜钙化、非股动脉路径<sup>[29]</sup>、球囊扩张、瓣膜移位、导管植入至撤出时间延长均可增加经导管主动脉瓣置换术中碎片脱落风险<sup>[9,26,30]</sup>,这也是球囊扩张式瓣膜置换术后脑卒中发生率高于自膨式瓣膜置换术的原因。浙江大学医学院附属第二医院王建安教授团队的MRI研究发现,与三叶瓣膜相比,经导管二叶主动脉瓣置换术后脑缺血面积更大<sup>[31]</sup>,表明二叶主动脉瓣狭窄患者更高的钙化积分和球囊扩张频率可以增加术后脑卒中风险。Almarzooq等<sup>[4]</sup>纳入2012-2017年共129 628例行经导管主动脉瓣置换术患者,术后缺血性卒中发生率为4.28%(5549/129 628),且此类患者女性、缺血性心脏病、充血性心力衰竭、周围血管病变、高血压、肾功能衰竭等的比例明显增加(均 $P < 0.001$ )。亦有研究显示,经导管主动脉瓣置换术后出血(穿刺部位、主动脉瓣根部)、术中输血、机械循环支持[体外膜肺氧合(ECMO)、Impella、左心室辅助装置(LVAD)等]的应用均与术后脑卒中密切相关<sup>[6]</sup>。尽管存在上述诸多危险因素,但目前尚无经导管主动脉瓣置换术后脑卒中风险预测模型,针对上述危险因素进行严格病例选择,可能提高脑保护装置的有效性<sup>[32]</sup>,但临床实践中预测何种患者能够真正从脑保护装置中获益尚存争议<sup>[3,33]</sup>,如严重瓣膜钙化、合并严重周围血管病变的高危人群常因动脉路径无法应用脑保护装置,如果强行置入,同样面临很高的脑卒中风险。

综上所述,经导管主动脉瓣置换术后脑卒中的识别较为困难,拥有脑卒中中心的医疗机构对术后脑卒中的识别和管理水平明显提高<sup>[22]</sup>,提示神经内科医师在此过程中承担重要角色。因此,未来心脏中心和脑卒中中心应紧密合作,对术前高危患者的筛查、术后脑卒中的早期识别和治疗以及远期生活质量的改善具有重要意义<sup>[9,18]</sup>。脑保护装置因其有限的预防作用和高昂的费用,尚未在国内推广应用,多数医疗机构尚处于观望或学习阶段<sup>[34]</sup>。然而,作为目前经导管主动脉瓣置换术中唯一可能有效的脑保护措施,脑保护装置仍被寄予厚望,相信随着临床经验的积累,未来国内将有更多的医疗机构参与到相关研究中来。

利益冲突 无

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