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· 综述与讲座 ·

经导管主动脉瓣植入术患者合并冠心病的研究进展

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[摘要]　经导管主动脉瓣植入术(TAVI)使老年人严重主动脉瓣狭窄(AS)的治疗模式发生了转变,并作为外科主动脉瓣置换术的替代方案,正在扩展至更年轻、风险更低的严重 AS 患者。高达 2/3 的 AS 患者合并冠状动脉疾病(CAD)。鉴于两种疾病同时存在时的挑战,这些患者需在诊断和治疗上采取有针对性的方法。本文回顾了计划进行 TAVI 患者并存 CAD 的研究进展。

[关键词]　经导管主动脉瓣植入术;　经皮冠状动脉介入治疗;　血运重建;　血流储备分数
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主动脉瓣狭窄(AS)和冠状动脉疾病(CAD)具有相似的病因和病理生理机制[1],临床中均伴有劳力性呼吸困难和心绞痛,且都会影响冠状动脉血流动力学状态。AS 患者的冠状动脉血流动力学变化是心肌与血液供应不匹配所致的结果。AS 增加了左心室的后负荷,进而增加了左心室室壁应力。心肌为克服后负荷并正常化室壁应力,使细胞进行性肥大,从而增加了左心室质量。这些变化影响了心肌的氧气需求和供应。由于毛细血管萎缩和血管周围或间质纤维化,左心室后负荷增加,舒张期灌注时间和冠状动脉血流储备(CFR)减少,供应受到限制[2]。

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一、AS 合并 CAD 的流行病学及挑战

AS 是老年人群中最常见的瓣膜病，常合并 CAD。重度 AS 患者的 CAD 患病率为 15% ~80%[3]。在接受经导管主动脉瓣植入术（TAVI）的严重 AS 患者中，AS 合并 CAD 患病率为 24.0% ~74.9%；一些观察性研究评估了 CAD 对接受 TAVI 治疗患者的影响，结果存在争议[4-5]。这可能与研究中 CAD 定义的异质性、血运重建的完整性及使用功能学检查对 CAD 严重程度的生理评估有关[5-7]。接受 TAVI 治疗的 AS 合并 CAD 患者约一半为多支血管病变，累及左主干和前降支的概率分别为 11% 和 50%[7]。

CAD 在 TAVI 治疗患者中的影响仍然存在争议，目前也尚无确切的最合适的血运重建策略，及血运重建的时机。一项使用 SYNTAX 评分评估 CAD 的注册研究表明，与无或轻至中度 CAD 患者相比，接受 TAVI 合并严重和解剖复杂的 CAD 患者的心血管死亡率增加[8]。同样，另一项回顾性队列研究数据显示，近 10% 的 TAVI 治疗患者在 25 个月（中位术后时间）后因急性冠状动脉综合征再次入院，这与 CAD 的存在明显相关[9]。而在一项针对 TAVI 患者 CAD 影响的 Meta 分析中，纳入 15 项非随机研究进行分析（9 项为回顾性研究，6 项为前瞻性研究），总计超过 5 000 例患者[6]。主要研究结果如下：（1）存在与不存在 CAD 患者 30 天的全因死亡率相似，但存在 CAD 的患者 1 年死亡率明显较高；（2）心肌梗死、心血管死亡、卒中、出血和血管并发症等并发症组间比较没有差异。然而，由于 CAD 定义的异质性，且缺乏对 CAD 严重程度的生理评估或使用 SYNTAX 评分，一些研究中基于 CAD 状态的终点报告不完整，此外这些研究排除了对 CAD 和结果之间因果关系的评估，因此这些结果应谨慎解释。随着选择 TAVI 治疗的患者越来越年轻化，预期寿命越来越长，CAD 的临床重要性也可能发生变化。

ACTIVATION 随机试验比较了接受 TAVI 治疗的患者术前行经皮冠状动脉介入术（PCI）与未行 PCI 的情况，这两类患者冠状动脉造影结果均提示明显 CAD，但缺乏心绞痛的症状[10]。1 年后，在 TAVI 术前接受 PCI 治疗的患者未能改善其预后，其中 41.5% 发生了死亡/再住院的主要终点事件，而在 TAVI 术前未接受 PCI 治疗的患者中，44% 发生了死亡/再住院的主要终点事件（$P=0.067$）。对于无明显心绞痛症状的拟接受 TAVI 患者，不建议术前常规植入冠状动脉支架。目前的指南建议在接受外科主动脉瓣置换术（SAVR）或 TAVI 的患者中同期进行血运重建，其干预的冠状动脉狭窄程度为 >50% 或 70%（证据级别：C）[11]。

二、AS 合并 CAD 患者冠状动脉的评估

目前关于 AS 合并 CAD 冠状动脉非侵入性评估数据均来自一些小型研究。因潜在低血压和心律失常风险，阻碍了该领域在运动及药物负荷试验中的研究，因此《2021 ESC/EACTs 心脏瓣膜疾病管理指南》中未推荐负荷试验。负荷心肌核素显像（SPECT）、正电子发射计算机断层显像（PET）和 MRI 在小规模的人群中进行了测试（$n=23$ ~50），结果显示与冠状动脉造影相比，其诊断 CAD 的敏感度为 91% ~100%、特异度为 80% ~91%[12]。心肌灌注不足和诱发功能异常的原因可能是 AS 引起的生理供需不匹配（细胞肥大、毛细血管稀疏、冠状动脉血流动力学状态的改变）、心外膜冠状动脉狭窄，或二者结合所致。区分这两种病因有一定难度[13]。这使得灌注试验在 AS 患者中的临床作用产生了质疑。

2019 年欧洲心脏病学会（ESC）发布的《慢性冠脉综合征的诊断和管理指南》中，冠状动脉断层扫描血管造影（CTA）成为诊断冠心病的一线检查手段。而在一些最新的瓣膜疾病管理指南中，多排计算机断层扫描（MSCT）也得到了推荐，通过三维重建，其可多切面观察瓣膜形态，评估瓣膜厚度、钙化程度及其在主动脉根部所占体积、在瓣环平面测量瓣环的周长和面积，继而计算瓣环内径，为瓣膜类型的选择提供依据，并可评估术后瓣周漏的风险；MSCT 还可用于评估冠状动脉开口高度，以预估冠状动脉阻塞风险，评估冠状动脉病变[11]。CTA 预测血管造影狭窄程度 >50% 或 70% CAD 的敏感度为 85% ~100%，特异度为 71% ~91%，在拟行 TAVI 治疗的患者中，TAVI 术前行 CTA 检查结果发现 93.3% 患者存在显著的 CAD（CAD 的定义是管腔狭窄 ≥50%）[14]。DEPICT CTA 数据库同样证明了在接受 TAVI 治疗的患者中排除左主干（LM）和近端冠状动脉狭窄的 CTA 诊断准确性较高[15]。另一项研究报告称，CTA 检测显著性 CAD 的阴性预测值为 96%[16]。这些数据均证实，CTA 在识别 CAD 的解剖学特征方面几乎与冠状动脉造影一样显著。虽然 CTA 本身不足以准确评估 CAD 的缺血程度，但在冠状动脉中重度狭窄时，其确实具有很高的阴性预测价值[17]。由于 TAVI 正朝着年轻患者发展，而其 CAD 的发病率较低，CTA 可能有助于提高成本效益。通过使用计算流体动力学的后处理从而可无创得出血流储备分数（FFR）/基于冠状动脉 CT 血管成像的无创血流储备分数（FFRCT）可提高 CTA 的准确性这一结论。CAST-FFR 研究对严重 AS 患者的 FFRCT 与有创 FFR 进行了评估[18]，并报告了比单独使用 CTA 更好的准

确性。不幸的是,FFRCT 的临床实施因其依赖于源数据的质量而受到限制[19]。

侵入性冠状动脉造影(CAG)作为确定 CAD 存在和严重程度的金标准,仍然被《慢性冠脉综合征的诊断与管理指南》所推荐。然而,一旦 CAG 和功能评估之间存在差异,使用 FFR 或瞬时无波形比率(iFR)对拟行 TAVI 患者的冠状动脉病变进行血流动力学功能评估,可能在存在冠状动脉病变但无证据表明相应心肌区域存在缺血的情况下有用[20]。虽然,FFR 从未在严重 AS 患者中得到验证,但注册数据结果表明 FFR 可能适用于 AS 患者[21]。TAVI 治疗前后高血流微血管阻力的变化及 FFR 的变化存在不确定性,研究结果不尽相同。一些研究表明,与 TAVI 术前 FFR 值相比,TAVI 术后 FFR 降低[22-24],而在另一些研究中,TAVI 术后 FFR 增加[25],还有一些研究则是轻微到无意义的变化[26-28]。NOTION-3 是一项多中心随机试验,旨在评估 452 例严重 AS 接受 TAVI 治疗患者常规 FFR 引导下完全血运重建与 CAD 保守治疗的效果,该试验于 2017 年开始,已于 2022 年结束,并将于本年报告研究结果[29]。在严重 AS 患者中,评估心肌灌注不足的标准 FFR 阈值≤0.80 并未证实。同样,在这个患者群体中,以 FFR >0.80 的病变推迟行 PCI 的阈值是否安全也未知。正在进行的 FAITAVI 试验旨在解决其中的一些问题,其计划将 320 例转诊以接受 TAVI 治疗的患者随机分配至冠状动脉造影或 FFR 指导下的血运重建[28]。NOTION-3 及 FAITAVI 的试验结果将会为 FFR 在 TAVI 合并 CAD 的诊治中提供更加有力的证据。定量血流分数(QFR)作为一种基于冠状动脉造影的分析技术,不使用压力导丝及腺苷/ATP 的实时分析工具,同样对冠状动脉的狭窄程度具有诊断能力。一项针对严重 AS 患者的研究表明,与 FFR 相比,QFR 具有识别冠状动脉狭窄所致缺血的良好诊断能力,准确率为 81%,受试者工作特征(*ROC*)曲线下面积为 0.88(95% *CI* 0.82 ~ 0.93)[30]。多项研究证实 QFR 可有效评估行 TAVI 且合并严重 AS 的冠心病患者的冠状动脉狭窄程度[28,31]。

三、TAVI 合并 CAD 的血运重建

在接受 TAVI 治疗之前 CAD 的血运重建有很多不确定性,如 TAVI 患者合并 CAD 是否应接受 PCI、PCI 和 TAVI 的最佳顺序、更复杂的 CAD(复杂的 PCI + TAVI 或 CABG + SAVR)患者的治疗选择。血运重建可缓解心绞痛症状并预防如急性冠状动脉综合征等未来不良事件,这一问题在未合并 AS 的稳定 CAD 患者和急性 ST 段抬高心肌梗死(STEMI)患者治疗中已得到证实[32-33]。关于 AS 患者行 PCI 的另一个担忧是支架血栓形成和靶血管介入治疗失败,但这些情况在 TAVI 术前接受 PCI 治疗中极为罕见[34]。由于缺乏来自 AS 和 CAD 患者的对照数据,目前仅能依靠来自 CAD 的单一数据[20]。

1. TAVI 围术期的 PCI:对于 SAVR 治疗患者,考虑到再次开胸手术的风险,SAVR 同时行 CABG 显然更合理。CABG 已证明其在三血管和严重 CAD 患者(SYNTAX 评分 >32 分)中的预后优势,这也使得严重 AS 患者从经皮治疗策略转向外科手术治疗策略[35-36]。一项比较 SAVR + CABG 与 TAVI + PCI 的 Meta 分析结果发现,在 425 篇筛选的参考文献中,仅 3 项研究符合条件[37],其中仅 1 项研究是随机试验[38]。Meta 分析结果发现 SAVRR + CABG 与 TAVI + PCI 在 30 天安全结果(心肌梗死、卒中)和 2 年死亡率方面差异无统计学意义。这一证据表明 TAVI + PCI 与 SAVR + CABG 效果相当,但关于接受 TAVI 治疗患者的 PCI 最佳时机的建议仍有待确定。目前还没有随机数据证明同期进行 TAVI 和 PCI 优于分阶段进行,反之亦然。《2021 ESC/EACTs 心脏瓣膜疾病管理指南》指出:根据临床情况、CAD 类型和心肌受损程度,PCI 和 TAVI 可联合或分阶段进行[11]。另一方面,《2020 ACC/AHA 心脏瓣膜病患者的管理指南》则建议对于有明显的 LM 或近端 CAD 的患者,在进行 TAVI 之前应先行 PCI 手术[39]。在 SURTAVI 试验中,128 例患者接受 TAVI 和 PCI,其中 76 例(56.4%)分阶段治疗,而 52 例(40.6%)同时行 TAVI 和 PCI。与同期进行的手术相比,分阶段方法与明显较高的造影剂负荷及急性肾脏损伤有关,但两种治疗策略其他 30 天主要临床终点事件结果相似。[38]。在 TAVI 术前行 PCI 冠状动脉通路不受阻碍,可能也支持 TAVI 术前行 PCI 的分阶段策略。一项纳入 1 197 例中高风险患者在 TAVI 围术期行 PCI,其结果显示即使是多血管疾病、LM 疾病和钙化病变,在 TAVI 术前行 PCI 可行且安全[34]。另一项纳入12 182例 TAVI 合并 CAD 患者的 Meta 分析结果显示,TAVI 术前行 PCI 治疗的血运重建策略与短期或中期的死亡结果改善无关,在完成 TAVI 术后 30 天内急性肾损害(AKI)的发生率较高[40]。但对于冠状动脉病变相对简单且无肾功能不全的患者,也可考虑同时行 TAVI 和 PCI[41]。

2. TAVI 术后的 PCI:AS 患者接受主动脉瓣植入术后,心绞痛和呼吸困难等症状大多能得到缓解。在这些症状尚不明确由 AS 和(或)CAD 引发的情况下,采取初始瓣膜植入术(至少在 TAVI 治疗情况下),术后症状持续存在,则 PCI 推迟到 TAVI 治疗后也可能合理。然而在 TAVI 术后行 PCI 在技术上存在难度,

因为通往冠状动脉通道可能会被原生瓣膜或人工瓣膜的裙边部分阻挡，特别是在使用自膨式人工瓣膜的情况下[42]。但最近研究报告显示，无论何种瓣膜假体类型，TAVI 术后 PCI 的成功率都很高（>95%）[43-45]。同时可借助 CTA 协助规划模拟 PCI 和 TAVI，以评估假体对冠状动脉血流动力学状态的影响及其与冠状动脉口的相对位置[43]。在接受 TAVI 治疗时，对某些瓣膜进行优化，使合缝柱正确对位以保持冠状动脉口通道可行，这对环上人工生物瓣膜尤其重要[46]。如存在冠状动脉阻塞风险，可采用经导管瓣膜撕裂（BASILICA）技术（撕裂人工生物瓣膜或原生主动脉瓣以防止医源性冠状动脉阻塞）对原生或人工生物瓣膜瓣叶进行电外科撕裂[47]。

四、TAVI 合并 CAD 的抗栓治疗

无症状 ACS 或稳定 CAD 患者接受抗血小板治疗必不可少，同样推荐用于 TAVI 合并 CAD 的人群[48]。ARTE 研究发现与单一抗血小板治疗（阿司匹林）相比，在 3 个月的随访中，阿司匹林联合氯吡格雷（DAPT）有增加死亡、心肌梗死、缺血性卒中/短暂性脑缺血发作及重大或危及生命的出血事件发生率复合终点事件的趋势[49]。Popular-TAVI 试验结果显示，在没有长期口服抗凝药物（OAC）指征的患者中，1 年的随访结果类似[50]。GALILEO 研究证实，在成功 TAVI 术后没有确定 OAC 指征的患者中，与基于抗血小板的策略相比，包括每日 10 mg 剂量的利伐沙班在内的治疗策略与更高的死亡或血栓栓塞并发症风险及出血风险相关[51]。在更多临床研究证明抗凝治疗的有效性及安全性前，对于无 OAC 指征的患者，目前仍考虑单用抗血小板治疗。此外，超过 1/3 的 TAVI 患者合并有心房颤动，有 OAC 治疗的指征[52]。在这种情况下，应单用 OAC[39,53]。对于有 OAC 和抗血小板治疗指征的患者，应避免使用三联疗法（DAPT + OAC），只建议血栓风险非常高的患者使用，且仅限于很短的时间内（通常在近期 PCI 后 1 个月），然后单用氯吡格雷 + OAC[54]。目前尚无对接受 TAVI 治疗患者的出血风险分层进行评估的工具，但 HAS-BLED 和 PRECISION-DAPT 等评分可帮助衡量出血风险[55]。

五、总结

TAVI 已彻底改变了严重 AS 的治疗，TAVI 的适应证正在向更年轻和更低风险的患者群体扩展，尚未解决的重要问题为是否、如何及何时治疗并存的 CAD。到目前为止，关于这些关键问题的数据仍然较少，但正在进行的临床试验将提供重要的证据，这是非常值得期待的。

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