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专家介绍: 李树仁, 河北省人民医院心内一科, 医学博士, 主任医师, 教授, 硕士研究生导师。河北省有突出贡献的中青年专家, 河北省第八批省管优秀专家。中国中药协会微循环用药专业委员会常委、中国微循环学会瘀淤专业委员会委员、中华医学会心血管病学分会精准心血管病学学组委员、中国医师协会心血管分会委员、河北省药学会第八届理事会常务理事、河北省药学会微循环用药多学科协作专业委员会主任委员、河北省医学会心血管分会候任副主任委员、河北省医学会心电生理和起搏学分会副主任委员、河北省高血压防治协会常委、河北省介入质控专家、河北省预防医学会心血管病防治专业委员会副主任委员、河北省医师协会心律学医师分会常务委员、河北省突发事件卫生应急专家咨询委员会委员、河北省康复学会心血管康复学会常委。近年来, 主持了 20 余项省级科研课题, 发表科技论文 200 余篇, 主编著作 3 部, 参编著作 4 部, 获河北省科技进步奖 5 项。

心房颤动患者早期节律控制的证据与策略

马军枝^{1, 2}, 李天骄³, 安东^{2, 4}, 高琳^{2, 4}, 李树仁²



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【摘要】 心房颤动是临床常见的持续性心律失常类型, 其与血栓栓塞并发症、心力衰竭和其他心血管事件发生风险增加相关。因此, 早期阻止心房颤动进展对改善患者预后具有重要意义。根据治疗目标, 心房颤动的心律管理模式可以分为“心率控制”和“节律控制”, 其中节律控制指恢复并维持窦性心律, 是改善心房颤动患者症状的主要治疗措施之一, 也是心房颤动治疗的一个重要目标。近年来随着循证证据的积累, 临床更加重视通过节律控制(包括抗心律失常药和/或消融技术)来减少心房颤动患者不良心血管结局。基于此, 本文主要总结了支持心房颤动患者采取早期节律控制的证据, 并从药物治疗(Ic类和III类抗心律失常药)和非药物治疗(射频导管消融术、冷冻球囊消融术、热球囊消融术及脉冲电场消融术等消融方法)角度分析了心房颤动的早期节律控制策略, 以期改善心房颤动患者预后提供参考。

【关键词】 心房颤动; 节律控制; 抗心律失常药; 消融技术; 综述

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Evidence and Strategies for Early Rhythm Control in Patients with Atrial Fibrillation MA Junzhi^{1, 2}, LI Tianjiao³, AN Dong^{2, 4}, GAO Lin^{2, 4}, LI Shuren²

1. Graduate School of Hebei Medical University, Shijiazhuang 050017, China

2. Department of Cardiovascular Internal Medicine, Hebei General Hospital, Shijiazhuang 050000, China

3. Physical Examination Center, Hebei General Hospital, Shijiazhuang 050000, China

4. Graduate School of Hebei North University, Zhangjiakou 075000, China

Corresponding author: LI Shuren, E-mail: lsr64@126.com

【Abstract】 Atrial fibrillation is a common type of persistent arrhythmia in clinical practice, which is associated with increased risk of thromboembolism complications, heart failure and other cardiovascular events. Therefore, early prevention of atrial fibrillation progression is of great significance for improving the prognosis of patients. According to the treatment objectives, the rhythm management mode of atrial fibrillation can be divided into "heart rate control" and "rhythm control". Rhythm control refers to the recovery and maintenance of sinus rhythm. It is one of the main treatment measures to improve the symptoms of patients with atrial fibrillation and an important goal of atrial fibrillation treatment. In recent years, with the accumulation of

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作者单位: 1.050017河北省石家庄市, 河北医科大学研究生学院 2.050000河北省石家庄市, 河北省人民医院心内一科 3.050000河北省石家庄市, 河北省人民医院体检中心 4.075000河北省张家口市, 河北北方学院研究生学院

通信作者: 李树仁, E-mail: lsr64@126.com

evidence-based evidence, clinical attention has been paid to reduce adverse cardiovascular outcomes in patients with atrial fibrillation through rhythm control (including antiarrhythmic drugs and/or atrial fibrillation ablation). Based on this, this paper mainly summarizes the evidence supporting early rhythm control in patients with atrial fibrillation, and summarizes the early rhythm control strategies of atrial fibrillation from the perspective of drug therapy (class I c and class III antiarrhythmic drugs) and non-drug therapy (radio frequency ablation, cryoballoon ablation, hyperthermia balloon ablation and pulsed field ablation), in order to provide reference for improving the prognosis of patients with atrial fibrillation.

【Key words】 Atrial fibrillation; Rhythm control; Anti-arrhythmia agents; Ablation techniques; Review

心房颤动是临床常见的持续性心律失常类型之一，其早期主要是一种孤立的心电障碍，但间歇性心房颤动发作的影响可以累积，长期会导致心房的电性、收缩性和结构重塑，这种变化更容易发生持续性心律失常，促使能自行终止的阵发性心房颤动发展为需要干预的持续性心房颤动^[1-2]。研究表明，阵发性心房颤动进展为持续性心房颤动与心肌梗死、血栓栓塞和心力衰竭发生率增加有关^[3]。若未得到及时治疗，则多达75%的心房颤动患者在首次发病后的1年内会再次发病^[1, 4-5]。根据治疗目标，心房颤动的心律管理模式可以分为“心率控制”和“节律控制”，且近年来越来越多的循证医学证据支持在心房颤动早期阶段采取节律控制^[6-7]。相关指南推荐，抗心律失常药是维持心房颤动患者窦性心律的初始治疗^[8-10]，但其在维持窦性心律方面的效果一般，且存在短期和长期不良反应^[11]。一项大型随机对照试验结果表明，射频导管消融术（radio frequency ablation, RFA）治疗心房颤动的临床疗效优于抗心律失常药，且并发症发生率较低^[12]。本文主要总结了支持心房颤动患者采取早期节律控制的证据，并从药物治疗和非药物治疗角度分析了心房颤动的早期节律控制策略，以期改善心房颤动患者预后提供参考。

1 支持心房颤动患者采取早期节律控制的证据

近年来由于人口老龄化进程加剧和筛查方法改进，心房颤动发病率逐年上升，且部分心房颤动患者接受最佳治疗方案后仍会发生不良心血管事件，包括猝死、卒中和心力衰竭恶化^[13]。早期研究表明，与心率控制相比，节律控制对心房颤动患者的心血管结局无明显影响^[14]，且考虑抗心律失常药的安全问题，大多数新诊断的心房颤动患者最初没有接受节律控制治疗^[15]。但近年来观察性研究表明，在新发心房颤动和心血管疾病患者中，早期节律控制的临床疗效优于心率控制^[16-17]。

1.1 有效性 研究表明，系统启动早期节律控制策略可使心房颤动患者心血管死亡、卒中、因心力衰竭或急性冠脉综合征恶化而住院的复合结局事件发生风险降低21%^[16]。此外，早期节律控制可使伴有心力衰竭的心房颤动患者^[18]、伴有或未伴有临床症状的心房颤动患者^[19]和不同模式的心房颤动患者^[20]获益。EAST-

AFNET 4试验^[21]结果显示，与常规治疗相比，早期节律控制12个月后心房颤动患者窦性心律与复合结局事件（心血管死亡、卒中、因心力衰竭或急性冠脉综合征恶化而住院）发生风险降低相关（ $HR=0.81$ ）。CORLEY等^[22]对AFFIRM研究数据进行分析发现，成功维持窦性心律与心房颤动患者生存率升高有关。美国一项研究针对109 739例新发心房颤动患者进行分析发现，约3/4的新发心房颤动患者进行了早期节律控制^[6]。一项前瞻性队列研究结果显示，其招募的502 493例英国中年人中35 526例为新发心房颤动患者，新发心房颤动发生率为7.1%，且约80%的新发心房颤动患者进行了早期节律控制^[7]，该结果与美国研究^[6]结果相似。

1.2 安全性 美国一项研究表明，早期节律控制与新发心房颤动患者卒中发生风险降低有关〔 $HR=0.66$ ， $95\%CI(0.47, 0.93)$ ， $P=0.02$ 〕^[6]。一项前瞻性队列研究表明，早期节律控制组卒中、死亡或与早期节律控制相关的严重不良事件发生率为5.2%，常规护理组为6.0%，差异有统计学意义〔 $HR=0.85$ ， $95\%CI(0.74, 0.98)$ ， $P=0.024$ 〕^[7]。上述研究表明，采用早期节律控制治疗新发心房颤动的安全性较高，这使早期节律控制的治疗目的从症状驱动治疗转变为降低卒中等不良事件发生风险，其可以作为伴有卒中危险因素的新发心房颤动患者的默认疗法，以恢复并维持患者的窦性心律^[23-24]。

综上，早期节律控制应作为大多数新发心房颤动患者的常规治疗策略。

2 心房颤动患者早期节律控制的药物治疗

目前，临床上常用的节律控制药物有I c类（氟卡尼和普罗帕酮）和III类（胺碘酮和维那卡兰）抗心律失常药。研究表明，48%的新发心房颤动会自行转复为窦性心律，故心房颤动发作后24 h内应密切观察病情变化^[8]，若24 h内不能自行转复为窦性心律，则需要考虑采取药物治疗。目前，接受普罗帕酮治疗的心房颤动患者窦性心律转复成功率为59%~78%，接受氟卡尼治疗的心房颤动患者窦性心律转复成功率为43%~89%^[25]。胺碘酮仅适用于合并心力衰竭的心房颤动患者。研究表明，与胺碘酮或氟卡尼比较，维那卡兰治疗心房颤动更有效且安全^[26-30]。随机双盲试验结

果证实, 维那卡兰治疗新发心房颤动患者是有效的, 在心房颤动持续时间 <7 d的患者中, 维那卡兰组51%的患者转复为窦性心律, 而安慰剂组(接受0.9%氯化钠溶液)仅4%的患者转复为窦性心律; 此外, 在心房颤动持续时间 <3 d的心脏手术后患者中, 维那卡兰组47%的患者转复为窦性心律, 而安慰剂组(接受0.9%氯化钠溶液)仅14%的患者转复为窦性心律^[31]。PRIORI等^[32]研究结果显示, 维那卡兰组患者窦性心律转复成功率为51.7%, 而胺碘酮组仅为44.0%。但维那卡兰风险较高的不良反应是低血压、心动过缓和心房扑动。一项临床试验结果显示, 维那卡兰所致低血压发生率为3.9%, 心动过缓发生率为3.1%, 心房扑动发生率为1.6%^[28]。

3 心房颤动患者早期节律控制的非药物治疗

自HAÏSSAGUERRE等^[33]证明肺静脉异位冲动可诱发心房颤动后, 电生理学家一直在寻找更有效、安全的消融方法。消融的基础是完全隔离肺静脉, 这可以通过逐点或单次消融实现, 消融的缺点是肺静脉重复连接比率较高及存在副损伤。目前, 在临床实践中常用的消融方法有RFA^[34]和冷冻球囊消融术(cryoballoon ablation, CBA), 此外还有热球囊消融术(hyperthermia balloon ablation, HBA)和脉冲电场消融术(pulsed field ablation, PFA)。

3.1 RFA

3.1.1 多电极射频球囊消融导管 球囊消融导管有助于隔离肺静脉, 但受到单一消融元件的限制, 目前的技术可能导致薄组织过度消融、厚组织消融不足及手术时间延长。近年来随着电解剖可视化, 一种具有10个可冲洗的柔性电极的射频球囊消融导管应运而生, 其可独立、定向、定制输送能量, 以高效且安全地实现肺静脉隔离。研究表明, 多电极射频球囊消融导管具有以下优势: (1) 其能够均匀地实现肺静脉隔离, 而无需再行局灶导管消融; (2) 短期内, 在有限的射频消融方案中, 其可以简单、有效地完成肺静脉隔离; (3) 尽管多位操作者第1次使用多电极射频球囊消融导管, 但均能完成肺静脉隔离, 且安全性良好^[35]。此外, 基于多电极射频球囊消融导管的肺静脉隔离手术安全性较高, 无一例患者发生心脏穿孔、心脏压塞^[35], 分析其原因可能与多电极射频球囊消融导管通过有线方式进到每个肺静脉及球囊可以分散消融部位的射频能量有关。

3.1.2 视觉引导的多电极射频球囊消融导管 为了将不同消融工具的优势整合到单一消融技术中, 临床设计了一种带有集成摄像系统的视觉引导的多电极射频球囊消融导管, 用于单次肺静脉隔离^[36]。视觉引导的多电极射频球囊消融导管具有以下优势: (1) 球囊设计, 无论导管是否垂直于肺静脉长轴, 均可以在不进入静脉的情况下提供稳定的平台, 进而提供射频能量; (2) 其

具有18个盐水冲洗射频消融导管电极阵列, 以优化消融路径; (3) 集成摄像机使操作者能更直观地识别与组织接触的电极; (4) 所有电极可以同时提供烧蚀能量, 且每个电极具有独立的功率输出控制功能。一项首次采用视觉引导的多电极射频球囊消融导管进行消融的多中心临床试验结果显示, 阵发性心房颤动患者消融后1年心房颤动复发率为15.9%, 心房颤动/心房扑动/房性心动过速复发率为22.5%, 安全终点事件发生率为1.1%, 提示视觉引导的多电极射频球囊消融导管在实现肺静脉隔离方面是安全、有效的, 其可以在视觉引导下定向滴定烧蚀能量, 并在短时间内安全隔离肺静脉, 有望成为一种操作简单、高效的肺静脉隔离工具^[36]。

3.2 CBA 为了使肺静脉隔离操作更加安全、有效, 且减少对操作者经验的依赖, 研究者开发了北极锋低温球囊(美敦力CryoCath), 其专门用于实现单个消融病变的肺静脉隔离。与RFA相比, CBA有以下优势^[37]:

(1) 冷冻球囊导管在具有挑战性的区域(如左心房附件和肺静脉之间的脊部)具有很好的稳定性; (2) 与RFA导致的界限模糊的病变相比, CBA导致的界限清晰的病变更持久, 且心律失常发生率更低; (3) CBA导致的心内膜表面破坏范围较小, 这使得血栓发生风险更低; (4) CBA可以保留超微结构组织的完整性, 可降低心脏穿孔、食管损伤、肺动脉瓣狭窄等并发症的发生风险。从临床角度分析, CBA导致的病变可持久地隔离导致心律失常的肺静脉^[38]。尽管操作人员的技术水平不同, CBA均与手术成功率高($>98\%$ 的患者达到完全肺静脉隔离)、长期心房颤动未复发相关, 且其重复消融率较低^[39]。

近期有3项多中心随机试验比较了CBA与抗心律失常药治疗症状性初治阵发性心房颤动患者的节律控制效果, 结果显示, 治疗后CBA组患者房性心动过速复发率为17.8%~42.9%, 抗心律失常药组患者房性心动过速复发率为32.4%~67.8%^[40-42]。

“FIRE and ICE”多中心、随机、非劣性、平行对照、非盲性试验^[43]共纳入762例药物难治性阵发性心房颤动患者, 结果显示, CBA组和RFA组患者主要疗效终点事件(心房颤动复发、心房扑动或房性心动过速、使用抗心律失常药或重复消融)[$OR=0.96, 95\%CI(0.76, 1.22)$]、主要安全终点事件(死亡、脑血管事件或严重的治疗相关不良事件)[$OR=0.78, 95\%CI(0.52, 1.18)$]发生率比较, 差异无统计学意义($P>0.05$), 提示CBA治疗药物难治性阵发性心房颤动患者的疗效并不劣于RFA。一项Meta分析结果显示, RFA组与CBA组复发性房性快速心律失常发生率相似[$OR=1.04, 95\%CI(0.71, 1.51)$, $P=0.84$]; 与RFA组相比, CBA组心包积液[0.8%比

2.1%, $OR=0.44$, 95% CI (0.28, 0.69), $P<0.01$] 和心脏压塞 [0.4%比1.4%, $OR=0.31$, 95% CI (0.15, 0.64), $P<0.01$] 发生率降低, 但短暂性膈神经麻痹发生率升高 [$OR=7.40$, 95% CI (2.56, 21.34), $P<0.01$] [44]。

综上, CBA的发明是为了更有效地实现环肺静脉隔离, 以弥补RFA逐点消融的缺点, 其临床疗效和安全性与RFA相当 [45], 且可重复性更高 [39], 可能作为初始消融的首选术式。

3.3 HBA 既往研究发现, HBA导致的病变比CBA导致的病变小, 分析原因可能为: 热球囊的顺应性及热球囊大小的可调节性导致肺静脉窦腔远端部分闭塞, 故与球囊接触区对应的消融病灶可能在肺静脉深部; HBA通常需要在左上肺静脉前端进行补强射频, 而CBA通常需要在下肺静脉进行补强射频; HBA组消融后血清肌钙蛋白T、肌酸激酶和肌酸激酶同工酶水平高于CBA组; HBA组和CBA组消融后6个月 (3%比11%, $P=0.36$) 或12个月 (16%比16%, $P=1.00$) 时心房颤动复发率比较, 差异无统计学意义 [46]。但MIYAZAKI等 [47] 研究表明, 复发性心房颤动可能源自左心房, 其可以通过传统射频实现环肺静脉隔离, 但不能通过CBA实现环肺静脉隔离。因此, CBA在心房颤动患者中的应用效果仍有待进一步研究证实。

3.4 PFA 心房导管消融是治疗有症状、药物难治性心房颤动的有效方法 [8, 48]。传统热消融可能并发食管损伤、膈神经损伤、肺静脉狭窄等不良事件 [49], 但PFA可以通过不可逆电穿孔机制在几毫秒内非热性地造成心脏组织损伤 [50-51], 其作用机制是在高电场梯度下, 心肌细胞膜的通透性增加, 进而导致细胞凋亡, 但无实质性的蛋白质变性或组织损伤 [52]。研究表明, PFA在无附带损伤的情况下可以实现肺静脉隔离, 且时间较短 [53]。除了良好的安全性外, 首次人体PFA试验结果还显示出良好的有效性, 如IMPULSE、PEFCAT、PEFCAT II 试验 [54] 结果显示, 121例阵发性心房颤动患者接受PFA后1年房性心律失常复发率为15.5%; 小样本量研究结果显示, 25例持续性心房颤动患者接受PFA后1年房性心律失常复发率仅为8% [55]。PULSED AF关键试验 [56] 结果显示, 66.2%的阵发性心房颤动患者和55.1%的持续性心房颤动患者接受PFA 1年内有效。inspire研究 [57] 结果显示, 采用PFA进行肺静脉隔离的阵发性心房颤动患者12个月内无症状性心房颤动/心房扑动/房性心动过速复发率和重复消融率分别为78.9%、92.3%。有2项大型研究结果显示, 接受PFA的心房颤动患者12个月的成功率分别为78%和82%, 无重复消融率为90%~94% [58-59]。阵发性心房颤动患者RFA后12个月内房性心律失常复发率仅为

13%~21% [35, 54, 60]。有研究者对MANIFEST-PF注册中的24个欧洲中心的1568例行PFA的心房颤动患者进行分析发现, 患者肺静脉隔离成功率达99.2%, 中位随访367 d, 其单次手术后1年房性心律失常 (心房颤动/心房扑动/房性心动过速) 复发率仅为21.9%; 且阵发性心房颤动患者房性心律失常复发率较持续性心房颤动患者更低 (18.4%比28.5%, $P=0.001$) [61]。

4 小结与展望

心房颤动是临床常见的持续性心律失常类型, 近年越来越多的研究表明, 对于非长期存在的心房颤动患者, 尤其是新发及有症状的心房颤动患者, 越来越多的证据支持其进行早期节律控制 [6-7]。早期节律控制可有效降低心房颤动患者不可逆的心房重构发生率, 预防高危患者发生心房颤动相关死亡、心力衰竭和卒中, 延缓疾病进展 [6-7]。近年来消融技术的发展使心房颤动患者不再依赖侵入性手术或治疗效果不佳的抗心律失常药; 而在抗心律失常药中, 维纳卡兰在窦性心律转复方面有效, 故消融技术和维纳卡兰均可能替代传统复律策略, 并有望减轻心房颤动和室性心动过速患者的疾病负担。

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本文无利益冲突。

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· 信息速递 ·

2023年国内外心房颤动指南、共识年中盘点

◆ 2023 EHRA意见书: 房颤的筛查

该文主要提供了大规模筛查参与者的预选方法, 建立最佳监测时间的基本原理, 并评估在不同临床情况下可用的心房颤动检测方法。

◆ 2023 AHA科学声明: 急性住院期间发生心房颤动

该文主要介绍了急性住院期间发生心房颤动的定义及管理内容。

◆ 心房颤动诊断和治疗中国指南2023

该文详尽阐述了心房颤动管理的各个环节, 重新评价了心房颤动筛查的临床应用, 根据亚洲心房颤动人群特点提出了CHA₂DS₂VASc-60评分, 强调了早期节律控制的意义和导管消融在节律控制中的核心地位。

◆ 2023心房颤动节律控制药物规范应用专家共识

该文主要内容为心房颤动节律控制的整体原则、抗心律失常药的特性及不同类型心房颤动患者的用药建议, 以供临床决策参考, 指导合理规范用药。

◆ 中国左心耳闭合预防心房颤动卒中外科专家共识

该文主要介绍了左心耳的解剖与生理, 左心耳的危害及闭合左心耳的意义、外科处理左心耳的方法与评价、外科闭合左心耳安全性和有效性的循证医学证据及外科干预左心耳的专家共识。

(本刊编辑部整理)