心房颤动高功率短时程量化消融的研究进展*

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［提要］ 肺静脉隔离是心房颤动消融治疗的基石。既往消融方式复杂耗时且远期复发率较高。消融指数和损伤指数为综合了消融功率、时间和压力的量化参数,其指导下的高功率短时程射频消融能显著缩短手术、消融时长,损伤效果更为持久。本综述旨在简述心房颤动射频消融治疗现况及主要挑战,并评估量化参数指导下高功率短时程消融策略的临床疗效和安全性。

［关键词］ 心房颤动;高功率短时程;肺静脉隔离;量化消融
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Advances in high-power short-duration quantitative radiofrequency ablation of atrial fibrillation

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Summary Pulmonary vein isolation is the cornerstone of atrial fibrillation ablation therapy. However, conventional ablation therapy is complicated and time-consuming, with disappointing long-term recurrence clinical outcomes. There are two surrogate endpoints in which contain complex mathematical formulas. Ablation index and lesion size index are the quantitative parameters corporating ablation power, contact force, and duration of ablation delivery. Both can effectively guide the clinician to achieve transmural lesions with high-power short-duration radiofrequency ablation, significantly shortening the duration of surgery and ablation. The purpose of this review is to summarize the current status and main challenges of radiofrequency ablation for atrial fibrillation and to evaluate the clinical efficacy and safety of the high-power short-duration ablation strategy under the guidance of quantitative parameters.

Key words atrial fibrillation; high-power short-duration; pulmonary vein isolation; quantitative ablation

心房颤动(房颤)是最常见的快速性心律失常。随着人口老龄化和心血管等疾病负担加重,房颤发病率呈逐年上升趋势,社会经济负担日益加重[1-2]。Haíssaguerre 等[3]在房颤机制及消融方面的先驱性工作,奠定了以肺静脉隔离(pulmonary vein isolation,PVI)为基石的导管消融术在房颤节律控制中的重要地位。环肺静脉隔离术已成为目前房颤射频消融的基础术式[4-5]。既往低功率长时程(low-power long-duration,LPLD)射频消融(功率20～40 W、时间30～60 s)急性期、术后3个月肺静脉电传导恢复率高达22%、15%[6-7];而阵发性房颤消融后1年的总成功率估计为59%～89%[8]。左房-肺静脉电传导恢复与房颤复发密切相关,其根本原因是未形成透壁性及连续性损伤[9]。研究发现高功率短时程(high-power short-duration,HPSD)导管射频消融(radiofrequency catheter ablation,RFCA)可显著提高手术效率,且疗效和安全性不劣于常规消融[10]。但目前尚无指南或专家共识就HPSD消融给予明确的定义,大多数研究中心采用的是输出功率45～90 W,单点消融时间<20 s[11-13]。

1 HPSD-RFCA 的生物学改变

射频能量是PVI的最常见能源,能将电磁能转化为热能,加热破坏靶组织。RFCA损伤过程由电阻性和传导式加热两个阶段构成:前者损伤发生在电极与组织交界面(1～2 mm)数秒内完成;而传导式加热具有时间和温度依赖性,热潜伏期长,射频停止后约2 min才达到热平衡,能损伤更深层组织[11,14]。LPLD-RFCA时,电阻性加热阶段因血液流动和液体灌注的冷却作用产生“心内膜保留效应”,即靠近心内膜区域损伤内径缩小;传导式加热

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阶段的"热潜伏效应"导致更深层组织损伤,最终形成"泪滴形"损伤灶[15-16]。而 HPSD-RFCA 电阻性加热比重更大,能降低"心内膜保留和热潜伏效应"作用,形成宽而略浅的椭圆形病灶[50 W/13 s 和 30 W/30 s;直径(8.9±0.4) mm vs(7.5±0.6) mm,$P<0.01$;深度(5.7±0.6) mm vs(4.7±0.6) mm,$P<0.01$],病灶体积与 LPLD-RFCA 相近[(271 ± 46) mm^3 vs (274 ± 34) mm^3, $P>0.05$][15]。这不但有利于减少"gap"点,增加 PVI 持久性,而且能提高手术效率,减少对深层结构损伤,更适合心房等薄壁组织消融[11,16]。靶组织接受的总能量是损伤形成的最重要因素。事实上,仅有 9%的射频能量用于形成损伤,其余由周围组织及血液吸收[14]。当温度≥50℃,损伤呈不可逆性;反之,则损伤可逆[16]。

2 HPSD-RFCA 临床前研究

Bhaskaran 等[17]在心肌假体和绵羊模型中比较 LPLD-RFCA(40 W/30 s)和 HPSD-RFCA(40～80 W/5 s)损伤灶的差异性。他们在体外模型中发现:40 W/5 s 消融未达到透壁性,其余 HPSD-RFCA 组(50～70 W/5 s)损伤深度>2 mm,均达到透壁要求。而后在绵羊右心房内评估有效性和安全性:平均 CF 为 10 g,HPSD-RFCA 组(60 W/5 s 和 80 W/5 s)损伤直径与 LPLD-RFCA 组[(7.7±1.2) mm vs (8.3±1.4) mm vs (9.1±1.9) mm,$P>0.05$]相当,各组间深度未见明显差异[40 W/30 s vs 50～80 W/5 s;(2.2 ± 0.5) mm vs (2.3 ± 0.5) mm vs (2.1 ± 0.4) mm vs (2.0 ± 0.3) mm vs (2.3 ± 0.7) mm,$P>0.05$]。仅在最高功率和最长时间组(80 W/5 s 和 40 W/30 s)观察到 8%和 11%的"steam pops"。作者认为,相同 CF(10 g),HPSD-RFCA 组 50～60 W/5 s 可形成与 LPLD-RFCA 组类似的透壁性损伤,且加热较少,有利于减少"gap"点,降低"steam pops"等并发症。该研究初步证实了 HPSD-RFCA 的可行性和安全性。

Bourier 等[15]在硅胶模型观察功率、时间、压力三者对消融指数(ablation index, AI)的影响。当 CF 由 1 g 变为 10 g 时,AI 增加 73%;而 10 g 到 20 g,AI 仅增加 10.1%;>30 g 对 AI 影响极小。CF (15～20 g)相同时,HPSD-RFCA 组(50 W/13 s、60 W/10 s、70 W/7 s、80 W/6 s)的 AI 值相似于 LPLD-RFCA 组(30 W/30 s)(502±13 vs 508±13 vs 490±13 vs 501±13 vs 503±13,$P>0.05$)。随后的肌肉模型体外试验进一步证实:相比 LPLD-RFCA,HPSD-RFCA 损伤灶浅[(5.7±0.6) mm vs(4.7±0.6) mm vs(4.3±0.5) mm vs(3.9±0.5) mm,$P<0.01$],而直径增大[(7.5±0.6) mm vs (8.9 ± 0.4) mm vs (9.4 ± 0.5) mm vs (10.3±0.6) mm,$P<0.01$];断面由泪滴形变为半椭圆形,说明 HPSD-RFCA 能减弱"心内膜保留效应",形成宽而略浅的病灶;这有利于形成连续而透壁性病灶,减轻深层组织损伤。消融前 10 s 对损伤灶影响最大,20 s 后逐渐减小。因此,当时间、CF 对 AI 影响有限时,调节功率可影响消融损伤灶体积。另有动物研究发现,CF 保持不变,消融体积随着功率增大而成比例增加,且消融时间可减少一半[18]。PVI 后房颤复发最常见原因是左房-肺静脉电传导恢复。这与急性组织水肿导致可逆性损伤形成的"gap"点破坏了消融线完整性密切相关。

Barkagan 等[19]在猪心脏模型对比 HPSD-RFCA(90 W/4 s)和 LPLD-RFCA(30 W/30 s)在 PVI 的安全性和消融线完整性。结果发现,急性期两组消融线均保持完整,但术后 1 个月 HPSD-RFCA 组消融线完整性优于 LPLD-RFCA 组(3/3 vs 1/3)。此外,效率和安全性方面,HPSD-RFCA 较 LPLD-RFCA 时间缩短 80%($P<0.01$),且避免 LPLD-RFCA 存在的肺损伤等并发症,表明 HPSD-RFCA 能安全高效地形成更持久的消融线。Leshem 等[11]也在猪模型研究中发现,HPSD-RFCA(90 W/4～6 s 或 70 W/8 s)较 LPLD-RFCA(25 W/20 s)阻抗下降程度更大[90 W/4 s vs 70 W/8 s,(19.6±12)Ω vs(14.3±6)Ω,$P<0.001$],能在心房等较薄组织形成透壁性损伤,消融线更持久。上述研究均说明 HPSD-RFCA 能改变电阻性和传导式加热比例,形成浅而宽的透壁性病灶,同时减少对周围组织损伤。

3 HPSD-RFCA 临床研究

3.1 HPSD-RFCA 临床有效性

早在 2003 年 Oral 等[20]就在分段性与环肺静脉消融的比较研究中发现高功率可能是影响 PVI 的重要因素。2006 年 Nilssion 等[21]发表了首项 HPSD-RFCA 与 LPLD-RFCA 对 PVI 影响的对照研究。两组短期内疗效及并发症并无差异[随访时间(15±7)个月,HPSD 组和 LPLD 组窦律维持率分别为 76%和 74%,$P>0.05$],但前者消融时间[(94±33) min vs(127±57) min,$P<0.02$]及透视时间[(55 ± 16) min vs (73 ± 23) min, $P<0.001$]均显著缩短,首次在临床证实 HPSD-RFCA 安全性及疗效不劣于 LPLD-RFCA。尽管既往众多模型和动物实验对 HPSD-RFCA 进行了充分的临床前验证,但鉴于安全问题,该消融策略临床应用相对较少。近年来,随着 LPLD-RFCA 疗效趋于瓶颈以及压力感应导管等新型器械出现,众多研究中心转向对 HPSD-RFCA 的尝试。Vassallo 等[22]在一项回顾性研究中发现:与 LPLD-RFCA(30 W/30 s,CF 10～30 g)相比,HPSD-RFCA(45～50 W/6 s,CF 10～20 g)能明显缩短手术、消融时间[(106

±23) min vs (148 ± 33.6) min, $P < 0.00001$; (1909±675) s vs(4338±1998) s, $P < 0.000001$];远期快速型心律失常复发率更低(随访 12 个月,17.07% vs 31.42%,$P = 0.14$),但未达到统计学差异。另一项前瞻性单中心研究[23]中 HPSD-RFCA(45～50 W/8～15 s)较 LPLD-RFCA(20～40 W/20～30 s)急性成功率更高(90.2% vs 83%,$P = 0.006$),消融时间更短[(17.2 ± 3.4) min vs (31.1±5.6) min,$P < 0.001$],慢性肺静脉电传导恢复率更低(16.6% vs 52.2%,$P = 0.03$),均有统计学差异。50%以上的慢性肺静脉传导恢复与导管移动范围>1 mm 相关;而 HPSD-RFCA 导管≥50%时间移动小于 1 mm(88.6% vs 72.8%,$P < 0.001$),能量传输更稳定,可减少“gap”点出现。LPLD-RFCA 传导式加热占比高而穿透力强,更适合在二尖瓣等较厚组织消融。

HPSD-RFCA 能在短时间内形成有效损伤,提高 PVI 手术效率。但其安全性与疗效窗口狭窄。因此,HPSD-RFCA 需要有可靠参数指标的指导,常见的有 AI 和损伤指数(lesion size index,LSI)量化消融参数。它们由综合了功率、时间和压力的加权公式计算得出。临床前研究已证明其在消融损伤中的重要作用。FAFA-AI 高功率研究[24]首次评估 AI 联合 HPSD-RFCA(50 W,AI 左房前壁 550/后壁 400)在 PVI 的疗效。该研究肺静脉单圈隔离率为 92%,6 个月后窦律维持率高达 96%。同样,Okamatsu 等[25]也在相同 AI 引导的低、中、高功率消融(30、40、50 W)研究中证实:HPSD-RFCA 组更多消融靶点达到目标 AI,显著提高单圈隔离率(高 vs 中 vs 低:85% vs 80% vs 55%,$P = 0.002$),降低左房-肺静脉传导恢复(高 vs 中 vs 低:0% vs 10% vs 8%,$P = 0.03$)。此后,随机对照研究进一步证实量化消融参数引导 HPSD-RFCA 在 PVI 的可行性及疗效。其中,Shin 等[26]随机纳入 150 例各类型房颤患者,AI 引导下比较不同消融功率(30 W/40 W/50 W)的临床疗效。研究中所有患者均实现即刻 PVI,HPSD-RFCA 组能显著缩短手术、消融时间[50 W vs 40 W vs 30 W:(108.7 ± 23.1) min vs (135.6 ± 29.5) min vs (161.9 ± 37.9) min,$P < 0.001$;(38.2 ± 14.8) s vs (52.3 ± 21.5) s vs (73.1 ± 30.5) s,$P < 0.001$]。随访 1 年,各组远期疗效并未见明显差异(50W vs 40W vs 30W:14% vs 16% vs 18%,$P = 0.862$)。Leo 等[27]在不同功率/LSI 消融策略(20 W/4 s、20 W/5 s、40 W/4 s 和 40 W/5 s)研究中也发现:LPLD-FRCA 更难达到目标 LSI[73.1(68.8～82.9)% vs 37.1(22.8～57.2)% vs 91.3(88.1～96.5)% vs 78.7(69.6～92.8)%,$P < 0.001$],首过肺静脉隔离率更低(73.8% vs 47.5% vs 73.8% vs 73.8%,$P < 0.001$),急性肺静脉电传导恢复率更高(6.3% vs 21.3% vs 12.5% vs 6.3%,$P < 0.008$)。平均随访 29 个月,HPSD-RFCA 组房颤复发率更低(22.5% vs 47.5%,$P = 0.034$),说明 LSI 对 HPSD-RFCA 预后的指导意义更大。

Kottmaier 等[12]首先报道了更高功率消融(70 W/前壁 7 s,后壁 5 s)在 PVI 的临床应用。纳入患者均为阵发性房颤,相较于 LPLD-RFCA(30～40 W/20～40 s),HPSD-RFCA 术后 1 年手术成功率明显更高(83.1% vs 65.1%,$P < 0.013$)。而此前,Reddy 等[13]已在 QDOT-FAST 多中心前瞻性临床试验中首次描述了极高功率(very high-power short-duration,vHPSD)消融(90 W/4 s)的临床经验。该研究所用的新型导管附带可实时温度监测的微电极和 6 个热电偶优化了温控式射频消融,CF 5-30 g,灌注速度 8 mL/min,截至温度 65～70℃,患者均实现即刻 PVI;3 个月后窦律维持率为 94.2%。综上所述,在可靠量化参数指导下 HPSD-RFCA 更能在更短时间形成有效损伤,且不需要额外射频能量强化消融点的透壁性和消融线的连续性。

3.2 临床研究安全性及并发症

HPSD-RFCA 形成病灶宽而略浅,有望降低食管等邻近器官损伤。而 HPSD-RFCA 安全性与疗效窗口窄;存在损伤左心房后壁毗邻结构,造成食管瘘、心包填塞等风险。在延迟钆增强磁共振成像监测食管损伤的研究中[28],HPSD-RFCA(50 W/5 s)与 LPLD-RFCA(35 W/10～30 s)食管强化模式类似(HPSD vs LPLD;无强化 64.8% vs 57.5%,轻度强化 21.0% vs 28.3%,中度强化 11.5% vs 11.5%,重度强化 2.8% vs 2.7%;$P = 0.370$),无心房食管瘘等严重并发症。而 Kaneshiro 等[29]却发现 HPSD-RFCA 食管热损伤(esophageal thermal injury,ETI)发生率显著高于 LPLD-RFCA(37% vs 22%,$P = 0.011$),而食管病变率(7% vs 8%,$P = 0.827$)并无统计学差异。但前者 ETI 以胃动力低下为主,热损伤仅限于食管黏膜浅层,并未累及深层组织。多中心研究中纳入 10 284 例患者,严重并发症发生率极低:心包填塞 0.24%、卒中 0.043%、肺静脉狭窄 0.014%、死亡率 0.014%。HPSD-RFCA 组心房食管瘘更低(0.0087% vs 0.0788%,$P = 0.021$),3 例心房食管瘘中有 2 例未监测食管温度。2 例死亡系心房食管瘘和卒中相关[10]。上述研究中发现尽管 HPSD-RFCA(限制 50 W)死亡、心房食管瘘等严重并发症发生率极低,但不论以何种功率在后壁消融,都应在术中确定食道位置并实时监测食管温度,避免热量堆积。另外,在更高功率(后壁 70 W/5 s)研究中仅观察到 2 例心包积液,无严重并发症[12]。QDOT-FAST

极高功率(90 W/4 s)临床试验[13]虽无死亡、心房食管瘘等严重并发症,但术后出现 1 例食管溃疡性出血;2 例假性动脉瘤和无症状性栓塞;5 例无症状脑部病变。总之,尽管新型导管对尖端温度的监测可能有助于减少风险,但目前尚无充足的临床证据证明 vHPSD-RFCA 的安全性。

房颤机制复杂,除最常见的肺静脉触发灶外,还存在诸如左心耳、上腔静脉、marshall 韧带等肺外触发灶。尤其对于持续性房颤,常规 PVI 联合其他辅助消融的个体化消融策略可能会改善预后;例如,BELIEF 研究[30]中 PVI 附加左心耳隔离显著提高持续性房颤成功率(76% vs 56%, $P=0.003$)。同样,术者熟练程度也会影响消融疗效。Sairaku 等[31]在多中心研究发现,熟练术者能减少主要并发症(1.4% vs 7.8%; $P=0.001$),缩短手术时间[(139.9 ± 25.3) min vs(149.3 ± 27.1) min; $P=0.03$];最重要的是,能降低房颤复发率(76.4% vs 62.8%; $P=0.001$),是避免房颤复发的独立预测因素(HR:1.73,95%CI:1.23~2.48; $P=0.002$)。对于患者而言,年龄是房颤发生及消融后复发的不可干预性因素,与房颤类型、持续时间共同反映心房电重构和结构重构;而左房容积更是心房重构的客观指标,均会影响消融疗效[32-33]。体质指数是房颤消融后复发的独立预测因素,每增加一个单位,复发风险增加 3%[32]。有效控制体重能减轻其负荷,防止阵发性房颤向持续性房颤进展,甚至逆转房颤类型[34]。对于房颤合并睡眠呼吸暂停低通气综合征者,持续正压通气亦能降低房颤复发(24.88% vs 42.47%, $P<0.001$)[35]。房颤消融疗效一方面与术者经验、所采取消融策略密切关联,另一方面也依赖于患者自身对肥胖、睡眠呼吸暂停低通气综合征等可控性危险因素的干预。

4 展望

目前,越来越多的临床研究证实 HPSD-RFCA 在 PVI 安全性和有效性良好。但缺少多中心、前瞻性、随机对照研究评估 HPSD-RFCA 的临床结果。小规模临床试验在评价肺静脉狭窄、心房食管瘘等罕见且严重的并发症时,很难检验 HPSD-RFCA 的安全性。而 vHPSD-RFCA 方面的临床试验更有限,暂无实质性数据支持其安全性。此外,HPSD-RFCA 的最佳参数设置仍然存在争议,特别是在左房后壁靠近食管区域参数选择差异性巨大,如何在最大疗效跟最小并发症之间取得平衡,也值得进一步探索。

综上,AI 和 LSI 等量化消融参数在 HPSD-RFCA 行 PVI 时扮演着非常重要的角色,有利于提高手术疗效,减轻对周围组织器官过度损伤,是一种值得期待的消融策略。

利益冲突 所有作者均声明不存在利益冲突

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