·临床研究·

远程磁导航指导下加强肺静脉前庭消融策略治疗心房纤颤有效性研究

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【摘 要】 **目的** 探讨在远程磁导航系统（RMN）辅助下应用加强消融策略行心房纤颤（AF）射频消融治疗对AF远期成功率的影响。**方法** 连续选取2013年1月至2015年6月在解放军总医院住院行导管射频消融治疗且自愿参加该临床研究的患者49例非瓣膜性AF患者随机分成两组，传统消融组（CAG，$n=24$）和加强消融组（EAG，$n=25$）。CAG组对左右肺静脉行单环线性消融，EAG组在CAG消融基础上，靠近原有消融径线，在心房侧再次行线性消融，形成双环线性消融。术中应用磁导航消融导管，RMN系统、CARTO 3系统和Lasso环状标测电极，术后常规使用24 h动态心电图随访。**结果** 所有患者均消融成功，EAG组较CAG组消融时间明显延长[（45.66±6.59）*vs*（40.10±3.48）min，$P<0.01$]，而在曝光时间、手术时间和静脉血测定脑利钠肽前体上差异无统计学意义（$P>0.05$）。术后随访（19.3±5.6）个月，应用动态心电图随访发现EAG组复发率较CAG组明显降低（33.33% *vs* 8.00%，$P<0.05$）。二次手术时发现复发患者均存在电传导恢复情况，8例再次手术均成功。**结论** 加强消融策略能有效改善AF患者的远期成功率，降低复发率。

【关键词】 心房颤动；导管消融术；射频电流；远程磁导航
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Efficacy of enhanced ablation on pulmonary vein antrum isolation under remote magnetic navigation in patients with atrial fibrillation

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【**Abstract**】 **Objective** To assess the long-term efficacy of enhanced ablation in pulmonary vein antrum (PVA) guided by remote magnetic navigation (RMN) in the patients with atrial fibrillation (AF). **Methods** From January 2013 to June 2015, 49 consecutive patients with refractory non-valvular AF who undergoing radiofrequency catheter ablation and voluntarily taking part in this study in our hospital were recruited in this study. They were randomized into a conventional ablation group (CAG, $n=24$) and an enhanced ablation group (EAG, $n=25$). PVA isolation was achieved by creating a single ablation circle in the patients of CAG group, and was double ablation circles at PVA in those of EAG group. An irrigated magnetic ablation catheter, CARTO 3 mapping system and Niobe magnetic navigation were used in both groups. A Lasso® mapping catheter was used to confirm PVA isolation. Regular Holter monitoring was used to follow up all patients. **Results** PVA isolation succeeded in all the patients. Ablation energy delivery time was obviously longer in EAG group than in CAG group [(45.66±6.59) *vs* (40.10±3.48) min, $P<0.01$]. There were no significant differences in fluoroscopic time, procedure time and venous NT-proBNP level between the 2 groups ($P>0.05$). During the follow-up of (19.3±5.6) months, Holter monitoring showed that the AF recurrence rate was remarkably lower in EAG group than in CAG group (8.00% *vs* 33.33%, $P<0.05$). Reconnection between left atrium and PV was confirmed in 8 relapsed patients during re-ablation, and reoperation was successful in all of them. **Conclusion** Enhanced PVA ablation effectively improves the long-term outcomes of AF and reduces the recurrence rate.

【**Key words**】 atrial fibrillation; catheter ablation; radiofrequency current; remote magnetic navigation
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对于有症状或不能耐受抗心律失常药物治疗的阵发性心房纤颤(atrial fibrillation, AF)患者和持续性AF患者,目前推荐使用导管射频消融治疗(radiofrequency catheter ablation, RFCA)恢复其窦性节律[1]。但就目前RFCA策略看,手术即时成功率、长期成功率分别在90%和36%~56%[2,3]。究其原因,可能与AF发生及维持机制、消融终点的判断、电重构及机械重构、RFCA过程中存在残留传导间歇等密切相关。为进一步提高AF手术的即时成功率、降低远期复发率,我中心认为加强肺静脉前庭(pulmonary vein antrum, PVA)消融有3点优势:(1)可有效消除消融过程中残留传导间歇;(2)可有效防止因RFCA后心肌重构所造成的电传导恢复;(3)加强了心房神经节的消融。本研究旨在评价在远程磁导航系统(remote magnetic navigation, RMN)指导下行PVA加强消融后,RFCA手术即时成功率及长期成功率。

1 对象与方法

1.1 研究对象

连续选取2013年1月至2015年6月在解放军总医院住院行RFCA且自愿参加该临床研究的患者共49例。该项研究已通过解放军总医院伦理委员会论证并批准。纳入标准:(1)年龄≥18周岁;(2)有或无症状,但心电图或动态心电图证实为AF;(3)拒绝使用或不能耐受抗心律失常药物治疗;(4)术中使用RMN系统及CARTO 3系统。排除标准:(1)瓣膜性心脏病所致AF;(2)拒绝参加该临床研究的病例;(3)术中发生意外,终止手术的病例。

1.2 实验分组

连续募集病例,随机分为两组。传统消融组(conventional ablation group, CAG, $n=24$):常规对左右肺静脉行单环线性消融,左上肺静脉(left superior pulmonary vein, LSPV)和左下肺静脉(left inferior pulmonary vein, LIPV)合称左肺静脉(left pulmonary vein, LPV),右上肺静脉(right superior pulmonary vein, RSPV)和右下肺静脉(right inferior pulmonary vein, RIPV)合称右肺静脉(right pulmonary vein, RPV),消融包含LSPV、LIPV的左肺静脉前庭(left pulmonary vein antrum, LPVA)和包括RSPV、RIPV的右肺静脉前庭(right pulmonary vein antrum, RPVA)。加强消融组(enhanced ablation group, EAG, $n=25$),在CAG消融基础上,靠近原有消融径线,在心房侧再次行线性消融,形成双环线性消融。

1.3 手术过程

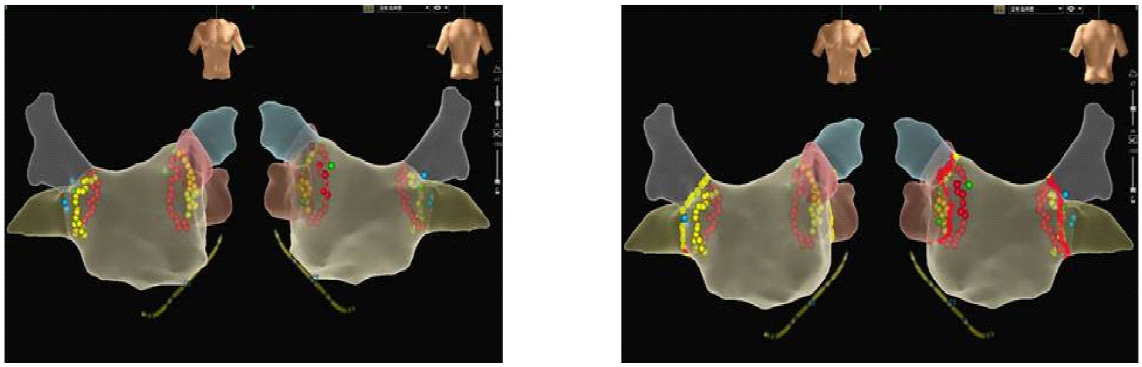
常规经静脉途径植入10极冠状窦电极至冠状窦远端,4极右室起搏电极至右心室心尖部,4极标测电极送希氏束。右侧股静脉穿刺植入8F鞘管,经该鞘管交换长导丝,置入8.5-F Swartz L1鞘管,经鞘管送入房间隔穿刺针,反复多角度定位成功后穿刺房间隔。沿鞘管送入磁导航专用冷盐水灌注消融导管。在CARTO 3辅助下标测LPV、RPV和左心房,用消融导管分别行LPVA消融和RPVA消融。CAG行双侧单环线性消融,EBG行双侧双环线性消融(图1)。再次使用上述方法行房间隔穿刺,沿鞘管送入环状标测导管(A Lasso® Biosense-Webster, Diamond Bar, California),确认LPV和RPV无电位,证明双侧肺静脉隔离消融成功。如存在局部肺静脉电位或自律性早搏,应在Lasso指导下行补点消融。消融终点需同时实现:(1)完成所有预设的左心房消融径线;(2)全部肺静脉均达电隔离(分别在窦性心律和冠状窦远端起搏下确认心房与肺静脉之间激动不能相互传导)。消融时温度控制在43℃,功率控制在25~30 W,每点最多放电30 s。消融完毕后再次行选择性肺静脉造影,明确是否存在肺静脉狭窄。房间隔穿刺成功后经鞘管给予肝素3000 IU,术中每小时静脉追加肝素1000 IU。如消融过程中患者述胸痛,可静脉泵入芬太尼(fentanyl)止痛。

1.4 随访

术前及术后2、6和12h分别4次抽取患者静脉血测定N端脑利钠肽前体(N terminal-pro brain natriuretic peptide, NT-proBNP)。术后随访,本研究采取门诊、住院、电话随访相结合的方法。患者在术前均行经胸肺静脉CT或冠状动脉CT造影,除肺静脉狭窄。术后3个月随访时,再次行经胸肺静脉CT或经食道超声,明确有无肺静脉狭窄。如出现异常情况,术后6个月和术后12个月随访时复查肺静脉CT。所有患者术后不服用抗心律失常药物,术后6个月和12个月复查动态心电图明确是否有AF复发,是否术后有心电图证实的AF复发。

1.5 统计学处理

采用SPSS 17.0(SPSS Inc., IL, USA)对数据进行统计分析。计量资料进行正态性检验和方差齐性检验,符合正态分布的数据用均数±标准差($\bar{x}\pm s$)表示,组间比较采用t检验,非正态分布则采用t'检验或秩和检验;计数资料用百分率或频率表示,并采用卡方检验或Fisher确切概率法分析。以Log-rank法比较两组患者的AF复发率,所有统计分析均进



A B

图 1 PVA 的标测与消融

Figure 1 Pulmonary vein antrum mapping and ablation

PVA: pulmonary vein antrum; CAG: conventional ablation group; EAG: enhanced ablation group. A: in CAG, two ablation circles were designed circumferentially at the junctions between atrium and pulmonary veins. Left superior and inferior pulmonary vein ostia were surrounded by left ablation circle. Right superior and inferior pulmonary vein ostia were encircled by right ablation circle. B: in EAG, except above ablation circle, another ablation circle was created at the left atrial side of the first PVA ablation circle and closely beneath it

行双侧检验。以 $P<0.05$ 为差异具有统计学意义。

2 结 果

2.1 两组患者基线资料比较

共入选 49 例患者，CAG 组 24 例，EAG 组 25 例。两组患者的基线资料之间差异无统计学意义（$P>0.05$；表 1）。

表 1 两组患者基本临床资料比较

Table 1 Comparison of baseline clinical characteristics between CAG group and EAG group

Item	CAG group ($n=24$)	EAG group ($n=25$)
Type of AF[n(%)]		
Paroxysmal	19(79.17)	19(76.00)
Persistent	5(20.83)	6(24.00)
Male[n(%)]	19(79.17)	17(68.00)
Age(years, $\bar{x}\pm s$)	56.67±11.04	57.20±10.93
Body mass index(kg/m^2, $\bar{x}\pm s$)	25.61±3.04	27.22±4.47
History[n(%)]		
Coronary heart disease	6(25.00)	4(16.00)
Hypertension	8(33.33)	12(48.00)
Diabetes mellitus	2(8.33)	3(12.00)
Hyperlipidemia	12(50.00)	7(28.00)
Disease duration(years, $\bar{x}\pm s$)	5.07±3.56	5.38±4.61
Echocardiogram(left atrium)		
Anterior and posterior (mm, $\bar{x}\pm s$)	38.21±4.88	37.22±4.40
Upper and lower(mm, $\bar{x}\pm s$)	58.75±7.15	58.96±5.94
Left and right(mm, $\bar{x}\pm s$)	37.50±4.63	37.36±3.61
LVEF(%, $\bar{x}\pm s$)	59.75±6.71	62.60±5.24

CAG: conventional ablation group; EAG: enhanced ablation group; AF: atrial fibrillation; LVEF: left ventricular ejection fraction

2.2 两组患者消融时间、曝光时间和手术时间比较

两组患者消融时间比较，EAG 较 CAG 耗时长（$P<0.01$）；但总的曝光时间和手术时间，两组患者间差异无统计学意义（$P>0.05$；表 2）。

表 2 两组患者消融时间、曝光时间和手术时间的比较

Table 2 Comparison of ablation time, fluoroscopy time and procedure time between CAG group and EAG group

(min, $\bar{x}\pm s$)

Item	CAG group ($n=24$)	EAG group ($n=25$)
Ablation time	40.10±3.48	45.66±6.59**
Fluoroscopy time	13.75±2.61	14.28±2.07
Procedure time	183.75±27.16	192.40±30.86

CAG: conventional ablation group; EAG: enhanced ablation group. Compared with CAG group, ** $P<0.01$

2.3 两组患者分阶段肺静脉隔离成功率的比较

所有手术，术者均使用 Niobe 磁导航系统完成。CAG 组，第一阶段根据肺静脉电位分别对 LPV 和 RPV 行单环线性消融（Step 1）；第二阶段消融完成后使用 Lasso 标测电极标测肺静脉电位，对于存在的传导间歇行补点消融（Step 2）。EAG 组，第一阶段对 PVA 行双环线性消融（Step 1）；完成上述步骤后使用 Lasso 标测电极标测肺静脉电位，对于加强消融后存在的传导间歇行补点消融，此为第二阶段（Step 2）。比较两组第一阶段的消融成功率，EAG 组较 CAG 组明显增高（$P<0.05$；表 3）。

2.4 两组患者血浆 NT-proBNP 水平比较

术前和术后 2、6 及 12 h 抽取患者静脉血 4 次，测定患者血浆 NT-proBNP 水平。比较 CAG 组与 EAG 组在 4 个时间点血浆 NT-proBNP 水平，差异均无统计学意义（$P>0.05$）；但术后 2 h 血浆 NT-proBNP 水平与术前基础水平比较，发现术后 2 h 血浆 NT-proBNP 水平明显上升（$P<0.05$；表 4）。

表3 两组患者各阶段肺静脉隔离成功率的比较

Table 3 Comparison of success rate of PV isolation between procedure steps in two groups [n(%)]

PV	CAG group			EAG group		
	n	Step 1	Step 2	n	Step 1	Step 2
LPV	24	13(54.17)	11(45.83)	25	21(84.00)*	4(16.00)
RPV	24	12(50.00)	12(50.00)	25	24(96.00)**	1(4.00)
Total	48	25(52.08)	23(47.92)	50	45(90.00)**	5(10.00)

PV: pulmonary vein; CAG: conventional ablation group; EAG: enhanced ablation group; LPV: left pulmonary vein; RPV: right pulmonary vein. One-way analysis of variance between step1 in CAG group and EAG group. Compared with step 1 in CAG group, *$P<0.05$, **$P<0.01$

表4 两组患者血浆NT-proBNP水平比较

Table 4 Comparison of NT-proBNP level between CAG and EAG groups (ng/L, $\bar{x}\pm s$)

Group	n	Before ablation	After ablation		
			2 h	6 h	12 h
CAG	24	9.81±5.73	25.76±9.28*	12.28±3.35	10.28±5.34
EAG	25	9.54±4.65	25.45±6.47*	12.83±3.45	10.89±5.18

NT-proBNP: N terminal-pro brain natriuretic peptide; CAG: conventional ablation group; EAG: enhanced ablation group. Compared with before ablation, *$P<0.05$

2.5 随访

两组患者随访(19.3±5.6)个月,随访期间无患者发生有临床意义的肺静脉狭窄,10例证实AF复发,有效率为79.59%(39/49),其中CAG组为8例,EAG组为2例,两组患者AF复发率差异具有统计学意义(33.33% *vs* 8.00%, $P<0.05$)。CAG组8例复发患者复发时间(1.50±1.51)个月,其中6例再次行RFCA治疗,术中Lasso标测提示4例为LSPV与左心房电传导恢复;2例为RSPV与左心房电传导恢复。再次行RFCA治疗,消融成功。EAG组2例患者复发,其中1例在术后1周内复发,另1例为术后3个月随访时动态心电图证实为AF复发。2例患者均在术后6个月再次行RFCA治疗,消融成功。术中证实其中1例为LSPV与左心房之间电传导恢复,另1例为RSPV与左心房之间电传导恢复。

3 讨 论

PVA隔离是目前RFCA治疗的经典术式,然而通过长期随访发现其远期成功率较低,究其原因是存在肺静脉与左心房之间电传导的恢复[2-5]。本研究使用RMN系统辅助消融,在CAG组应用单环一步消融策略的成功率也只有66.67%。而在EAG组应用双环两步消融策略,其成功率明显上升至92.00%。说明加强消融可明显减少肺静脉与左心房之间电传导的恢复或减少由于单环消融所遗留的传导间歇,从而大大提高所有类型AF的远期成功率。虽然加强消融较传统消融在消融时间上略长,但在术后验证及补点消融中所耗费的时间明显较少,具有积极的临床意义。

目前,全世界各个AF治疗中心AF治愈率各不相同,有经验的中心AF治愈率可高达将近90%[6]。但由于AF形成及维持机制不完全明确、术者术式及治疗策略不一致、各中心的仪器设备不统一等多方面原因,各类型AF的首次射频后长期随访成功率仍较低,只有30%~40%[7]。虽然有一些研究证实左心房局灶电位、心房神经节、转子[8]在AF的形成和维持中均有作用,射频消融这些部位可有效减少AF的复发,但大多数研究证实积极有效彻底地消融肺静脉电位是提高AF治愈率的关键[9]。对复发AF的研究也证实了AF复发的关键是肺静脉与左心房之间的电传导恢复,再次消融的位点也主要针对其存在的传导间歇。传导间歇存在的原因,一是肺静脉隔离时存在漏点或点与点之间间歇太宽;二是消融组织电传导再恢复。

Kowalski等[9]对22例RFCA术后AF复发患者行电生理检查及组织病理学检查,发现其中21例(95%)存在内膜增厚,18例(82%)存在纤维疤痕。电生理检查电传导未恢复区域大多可见透壁疤痕,而在电生理检查中发现电传导恢复的区域多可见解剖性传导间歇和非透壁性区域,这些均提示RFCA过程中透壁消融的重要性。

众多研究已证实,导管-组织有效接触是提高其射频近远期效果的关键环节之一。本研究显示,无论是CAG组还是EAG组都不能保证100%的射频消融成功率,其主要原因可能有两点,其一为不规则的肺静脉解剖,另一原因可能是消融过程中导管-组织接触不良[10]。Kumar等[11,12]应用接触压力(contract force,CF)导管评价CF与射频消融成功

率之间的关系。他们发现导管 CF 大小与患者的呼吸之间明确相关,所以对于导管-组织接触不良部位应通过增加消融时间的方法提高其消融的远期成功率[13]。另外,他们还发现在消融双侧 PVA 时所需要的导管 CF 最小。本研究在行加强 RFCA 治疗时,选择在双侧 PVA 的近左心房侧进行加强消融以提高消融的远期成功率。远期 AF 复发主要是由肺静脉与左心房之间的电传导恢复所致。心房的可逆性损伤和传导组织从可逆性炎症反应中的功能恢复是其两大主要原因。Arujuna 等[14]应用磁共振成像技术研究 AF 复发患者的肺静脉和左心房结构,发现复发患者更多地表现为可逆性损伤,而治愈患者则多呈现不可逆性损伤表现。本研究 EAG 组较 CAG 组近远期成功率明显提高,说明加强双环消融策略能保证更多的传导组织形成不可逆损伤,从而可能有效提高消融远期成功率。

局灶电位和心房神经节在 AF 的发生与维持中可能也存在作用[15]。本研究 EAG 组行加强双环消融过程中,对于集中在 PVA 周围的局灶电位和心房神经节也进行了很好的消融,这对于提高 RFCA 远期成功率也起到了一定的作用。但双环消融有可能增加肺静脉狭窄的可能性,但本研究所有患者均无气短、咳嗽、咯血等症状,影像学检查也未发现有临床意义的肺静脉狭窄,可能与双环消融部位在 PVA 而非肺静脉内有关[16]。

本研究样本量仍较少,需要进一步增大样本量。原计划纳入 50 例样本,有 1 例患者因术后无法取得联系而排除。NT-proBNP 是反映左心房损伤的一个重要指标,EAG 组较 CAG 组消融位点多,消融面积大,NT-proBNP 应该增大,但两组患者之间无明显差异,可能与 NT-proBNP 与多种因素相关有关,以后可采用 A 型 BNP 等其他综合评价射频消融损伤。

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