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· 论著 ·

“大拇指”心电监测仪对消融术后心房颤动复发的监测研究

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[摘要] 目的 探讨“大拇指”心电监测仪对消融术后心房颤动复发的监测效果, 以及人工智能算法在心房颤动诊断中的优势。方法 前瞻性选择2019年3月至2019年8月我院收治的符合条件的185例行介入消融治疗的非瓣膜性心房颤动患者, 利用随机数表法随机分为两组: 大拇指组(94例)和传统随访组(91例)。随访并比较两组患者的无心房颤动生存率, 比较人工智能算法与传统心电算法诊断心房颤动的灵敏度和特异度。

结果 至随访截止日大拇指组和传统随访组分别随访98~263(157.0 ± 38.4)d和91~268(158.8 ± 54.7)d, log-rank检验显示两组无心房颤动生存率分别为79.8% (75/94)和92.3% (84/91) ($P<0.05$)。术后3个月后大拇指组改变治疗策略的患者比例高于传统随访组 ($P<0.05$)。大拇指组94例患者共记录了18 981份心电图, 1 520份(8.0%)由心电图医师诊断为心房颤动, 人工智能算法诊断心房颤动的灵敏度和特异度分别为96.5% (1 467/1 520)和99.6% (17 391/17 461), 均高于传统心电算法的灵敏度和特异度[分别为89.7% (1 363/1 520)和97.2% (16 972/17 461)], 差异均有统计学意义(P 均 <0.05)。结论 “大拇指”心电监测仪在消融术后能更早地检出心房颤动复发, 利于及时改变治疗策略。人工智能算法能提高心房颤动诊断的准确性, 利用人工智能算法的“大拇指”心电监测仪用于心房颤动消融术后的随访结果可靠。

[关键词] 便携式设备; 人工智能; 便携式心电描记术; 导管消融术; 心房颤动

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Follow-up of atrial fibrillation recurrence after ablation with a BigThumb® electrocardiogram monitor

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[Abstract] **Objective** To investigate the monitoring efficacy of the BigThumb® electrocardiogram (ECG) monitor for the recurrence of atrial fibrillation (AF) after ablation and the advantages of artificial intelligence algorithm in the diagnosis of AF. **Methods** A total of 185 eligible patients with nonvalvular AF who underwent interventional ablation in our hospital from Mar. 2019 to Aug. 2019 were prospectively selected and randomly divided into two groups: BigThumb® group (BT group, $n=94$) and traditional follow-up group (TF group, $n=91$). The AF-free survival rates of the two groups were followed up and compared, and the sensitivity and specificity of artificial intelligence algorithm and traditional ECG algorithm in the diagnosis of AF were also analyzed. **Results** The patients in BT group and TF group were followed up for 98~263 (157.0 ± 38.4) d and 91~268 (158.8 ± 54.7) d, respectively. Log-rank test results showed that the AF-free survival rates were 79.8% (75/94) and 92.3% (84/91), respectively ($P<0.05$). Three months after ablation the proportion of patients who changed treatment strategy in BT group was higher than that in TF group ($P<0.05$). A total of 18 981 ECGs were recorded in BT group, of which 1 520 (8.0%) were diagnosed as AF by electrocardiographers. The sensitivity and specificity of the artificial intelligence algorithm were 96.5% (1 467/1 520) and 99.6% (17 391/17 461), respectively, which were significantly higher than those of the traditional ECG algorithm (89.7% [1 363/1 520] and 97.2% [16 972/17 461]), respectively (both $P<0.05$). **Conclusion** The BigThumb® ECG monitor improves the detection of AF recurrence after ablation, which is helpful to change the treatment strategy in time. Artificial intelligence algorithm can improve the accuracy of AF diagnosis and the BigThumb® ECG monitor based on this algorithm is reliable in the follow-up for AF after ablation.

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心房颤动是临幊上最常见的心律失常之一, 全球患病人数超过3 000万例^[1]。心房颤动可导致心力衰竭、认知障碍、缺血性脑卒中、猝死等并发症^[2], 严重威胁着人类健康。导管消融可改善心房颤动患者的症状, 已成为心房颤动的一线治疗策略^[3]。但是, 心房颤动消融术后部分患者仍存在无症状发作, 使其复发难于监测^[4]。“大拇指”心电监测仪是一种采用人工智能算法的新型便携式心电监测仪器, 有望提高消融术后的心房颤动检出率, 为临幊治疗策略的制定和改变提供依据。本研究拟探讨“大拇指”心电监测仪对消融术后心房颤动复发的监测作用, 以及人工智能算法在心房颤动诊断中的优势。

1 资料和方法

1.1 研究对象 前瞻性选择2019年3月至2019年8月我院收治的200例行介入消融治疗的非瓣膜性心房颤动患者。利用随机数表法将患者随机分为两组: 大拇指组和传统随访组, 各100例。大拇指组6例患者、传统随访组9例患者入组后因拒绝进一步随访予以剔除, 最终大拇指组纳入94例患者, 传统随访组纳入91例。本研究通过我院伦理委员会审批(CHE2018-102)。

1.2 研究方法 收集两组患者的人口统计学资料、术前检查资料、手术资料、术后随访资料。大拇指组患者出院前接受“大拇指”心电监测仪使用培训, 并嘱其每天常规采集心电图至少3次, 若有不适症状随时进行心电图采集。传统随访组患者接受传统随访, 嘱其术后1、3、6、12个月来院接受动态心电图检查, 若有不适随时至医院行心电图检查。心房颤动复发的定义: 消融治疗3个月后, 普通心电图或“大拇指”心电监测仪记录到心房颤动、心房扑动或房性心动过速发作, 或动态心电图上记录到持续超过30 s的房性心律失常。随访截止日期为2019年12月31日。

1.3 消融方法 消毒穿刺点皮肤, 穿刺左侧股静脉, 置入10极冠状窦电极和4极右心室电极。穿刺右侧股静脉, 行房间隔穿刺, 置入2根Swarts鞘管, 将冷盐水消融电极和环状电极置入左心房, 采用EnSite Velocity心脏三维标测系统构建左心房电

解剖图。设置功率为25~30 W, 温度为43 °C, 流速为17 mL/min, 使用冷盐水消融电极行双侧环肺静脉电隔离术, 环状电极置于肺静脉内确认双向电隔离。阵发性心房颤动消融终点为环肺静脉电极验证的肺静脉隔离; 持续性心房颤动患者行环肺静脉隔离后, 行同步直流电复律转为窦性心律, 再行左心房电压标测, 同时行电生理检查和心房扑动诱发。根据左心房基质和心房扑动机制, 行左心房顶部线、左心房前壁线或二尖瓣峡部线、三尖瓣峡部线消融, 消融终点为起搏标测验证的双向阻滞。

1.4 “大拇指”心电监测仪 该仪器由上海越光医疗科技有限公司研发和生产, 可用于记录单导联心电图。患者将双手大拇指置于“大拇指”心电监测仪的2个电极板上, 仪器自动采集30 s~5 min(采集时程可调节)心电信号, 并通过声波传送至智能手机, 心电图数据自动上传至云端数据库。“大拇指”心电监测仪获得的单导联心电图由传统算法和人工智能算法分别进行诊断, 之后提交至2位心内科副主任医师审核并做出最终诊断, 若诊断结果不一致则提交给1位主任医师进行审核诊断(以该诊断结果为金标准)。心电图数据和诊断自动发送至医师客户端和患者客户端, 以便数据调取和统计分析。“大拇指”心电监测仪的使用和软件界面如图1所示。

传统心电算法是对心电数据进行带通滤波去噪后, 根据心电图各主要波形(如QRS波、T波和P波)的频域能量范围再次进行滤波分解, 并提取对应的特征进行判断和诊断。特征提取原则基于临床医师识别心电图波形的原则, 再根据医师对心电异常或心律异常的临床判定条件设定特征变量之间的数学逻辑关系及其相关决策阈值。因此传统心电算法是一种相对静态、固定和经验性的方法。“大拇指”心电监测仪的传统算法在中国国家药品监督管理局与美国FDA和欧盟认证要求提供的标准数据库中进行了测试及优化, 在心律检测和对30 s及以上的心房颤动事件可分别达到99.8%和100%的准确率(未公开资料), 但在实际心电图诊断中的准确率还需进一步验证。

人工智能算法是一个人工构建的神经网络, 对输入的心电图信号首先提取信号特征和复杂时序信

息,然后采用最大池化和平均池化方法分别提取高频特征和低频特征,最后利用全连接层整合所有时

间步的特征并输出预测结果。该过程是一个经过不断学习、优化的动态诊断过程。



图1 “大拇指”心电监测仪系统示意图

Fig 1 Diagram of BigThumb® electrocardiogram (ECG) monitor system

A: BigThumb® system (the patient thumbs placed on two electrodes and the single lead ECG will be recorded); B: Mobile phone software interface (users will be asked whether there are symptoms and then the ECG will be recorded); C: BigThumb® recorded ECG of atrial fibrillation; D: The display of ECG diagnosis with BigThumb®. ○ represents the diagnosis of atrial fibrillation, and ◆ represents sinus rhythm.

1.5 统计学处理 应用 SPSS 18.0 软件进行统计学分析。呈正态分布的计量资料以 $\bar{x} \pm s$ 表示,组间比较采用 t 检验。计数资料以例数和百分数表示,组间比较采用 χ^2 检验。灵敏度和特异度的计算以医师诊断结果为金标准,人工智能算法与传统心电算法诊断心房颤动的灵敏度和特异度比较采用 χ^2 检验。采用 Kaplan-Meier 曲线和 log-rank 检验进行两组患者的无心房颤动生存分析,采用 Cox 比例风险回归模型分析介入消融治疗后患者无心房颤动生存的危险因素。检验水准 (α) 为 0.05。

2 结 果

2.1 两组患者基线资料比较 大拇指组行介入消融治疗的非瓣膜性心房颤动患者 94 例,男 72 例、女 22 例,年龄 48~75 岁,平均 (60.9 ± 9.6) 岁;传统随访组患者 91 例,男 65 例、女 26 例,年龄 54~73 岁,平均 (61.5 ± 9.2) 岁。两组患者的性别、年龄、房颤类型、BMI、CHA₂DS₂-VASc 评分、HAS-BLED 评分、肝肾功能、左心房大小、左心室射血分数等资料差异均无统计学意义 (P 均 >0.05)。见表 1。

2.2 两组患者消融术式比较 两组患者术中所有肺静脉均成功隔离,左心房顶部线、三尖瓣峡部线均双向阻滞,左心房前壁线各消融 3 例,其中传统随访组 3 例均成功阻滞;大拇指组成功阻滞 2 例,1 例患者因无法耐受手术而终止手术。两组无患者行二尖瓣峡部线消融。见表 2。

2.3 两组患者主要终点比较 大拇指组和传统随访组分别随访 98~263 (157.0 ± 38.4) d 和 91~268 (158.8 ± 54.7) d。术后 3 个月后,大拇指组有 13.8% (13/94) 的患者重新启动抗凝治疗,重新抗凝治疗患者比例高于传统随访组 [4.4% (4/91)],两组比较差异有统计学意义 ($\chi^2=4.932$, $P=0.026$)。术后 3 个月后,大拇指组和传统随访组分别有 19 例 (20.2%, 19/94) 和 6 例 (6.6%, 6/91) 患者使用抗心律失常药物控制心房颤动,分别有 11 例 (11.7%, 11/94) 和 2 例 (2.2%, 2/91) 患者行第 2 次射频消融手术,两组比较差异均有统计学意义 ($\chi^2=7.338$, $P=0.007$; $\chi^2=6.393$, $P=0.012$)。两组患者的无心房颤动生存 Kaplan-Meier 曲线如图 2 所示,log-rank 检验提示大拇指

组患者介入消融治疗后无心房颤动生存率低于传统随访组 [79.8% (75/94) vs 92.3% (84/91), $\chi^2=6.001$, $P<0.05$]。Cox 比例风险回归模型分析提

示“大拇指”心电监测随访和左心房前后径是心房颤动患者介入消融治疗后心房颤动复发的预测因素 (表3)。

表1 大拇指组与传统随访组心房颤动患者的人口统计学资料比较

Tab 1 Comparison of demographic data of atrial fibrillation patients between BT group and TF group

Characteristic	TF group N=91	BT group N=94	Statistic	P value
Male, n (%)	65 (71.4)	72 (76.6)	$\chi^2=0.643$	0.423
Age/year, $\bar{x}\pm s$	61.5±9.2	60.9±9.6	$t=0.434$	0.665
Paroxysmal atrial fibrillation, n (%)	61 (67.0)	56 (59.6)	$\chi^2=1.106$	0.293
BMI/(kg·m ⁻²), $\bar{x}\pm s$	24.3±2.7	24.6±2.5	$t=0.785$	0.434
CHA ₂ DS ₂ VASC score, $\bar{x}\pm s$	1.7±1.3	1.4±1.5	$t=1.452$	0.148
HAS-BLED score, $\bar{x}\pm s$	1.2±0.9	1.0±1.0	$t=1.428$	0.155
SCr/(μmol·L ⁻¹), $\bar{x}\pm s$	80.1±20.6	77.5±14.1	$t=1.005$	0.317
GFR/(mL·min ⁻¹), $\bar{x}\pm s$	89.2±18.4	90.5±14.7	$t=0.532$	0.596
ALT/(U·L ⁻¹), $\bar{x}\pm s$	28.7±28.0	27.9±19.0	$t=0.228$	0.820
AST/(U·L ⁻¹), $\bar{x}\pm s$	22.2±13.1	19.5±7.3	$t=1.739$	0.085
LAAPD/mm, $\bar{x}\pm s$	3.9±0.6	3.8±0.5	$t=1.233$	0.222
LVEF/%, $\bar{x}\pm s$	60.9±6.3	61.1±5.3	$t=0.234$	0.815
Follow-up duration/d, $\bar{x}\pm s$	154.9±48.7	157.0±38.4	$t=0.326$	0.745
Procedure duration/min, $\bar{x}\pm s$	159.5±68.8	143.4±46.6	$t=1.869$	0.062
Fluoroscopy time/min, $\bar{x}\pm s$	10.3±6.2	10.2±5.8	$t=0.113$	0.910
Radiation dose/mGy, $\bar{x}\pm s$	251.1±201.6	223.5±146.4	$t=1.068$	0.287

BT group: BigThumb® group; TF group: Traditional follow-up group; BMI: Body mass index; SCr: Serum creatinine; GFR: Glomerular filtration rate; ALT: Alanine transaminase; AST: Aspartate transaminase; LAAPD: Left atrial anteroposterior diameter; LVEF: Left ventricular ejection fraction.

表2 大拇指组与传统随访组心房颤动患者的消融术式比较

Tab 2 Comparison of ablation strategies of atrial fibrillation patients between BT group and TF group

Index	TF group N=91	BT group N=94	χ^2 value	n (%)
Pulmonary vein isolation	91 (100.0)	94 (100.0)	0.000	1.000
Linear ablation	15 (16.5)	18 (19.1)	0.224	0.636
Roof line ablation	8 (8.8)	9 (9.6)	0.034	0.854
Left atrial anterior wall ablation	3 (3.3)	3 (3.2)	0.002	0.968
Cavotricuspid isthmus ablation	4 (4.4)	6 (6.4)	0.357	0.550

BT group: BigThumb® group; TF group: Traditional follow-up group.

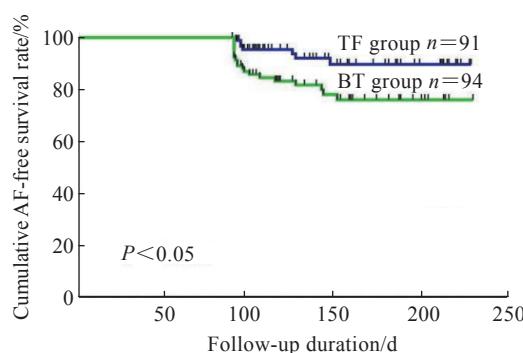


图2 心房颤动患者介入消融治疗后无心房颤动生存期 Kaplan-Meier 曲线

Fig 2 Kaplan-Meier curves of AF-free survival after interventional ablation in AF patients

AF: Atrial fibrillation; BT group: BigThumb® group; TF group: Traditional follow-up group.

2.4 “大拇指”心电监测仪诊断心房颤动的有效性 大拇指组94例患者共记录了18 981份心电图,1 520份(8.0%)由心电图医师诊断为心房颤动,其中1 208份(79.5%)被患者标记为有症状,312份(20.5%)无症状。人工智能算法诊断心房颤动的灵敏度和特异度分别为96.5% (1 467/1 520)和99.6% (17 391/17 461),传统心电算法诊断心房颤动的灵敏度和特异度分别为89.7% (1 363/1 520)和97.2% (16 972/17 461), χ^2 检验结果提示人工智能算法诊断心房颤动的灵敏度和特异度均高于传统心电算法 ($\chi^2=55.3$, $\chi^2=17.9$, P 均<0.05)。大拇指组患者术后3个月内的心电图监测频率高于术后3个月后[(1.8±1.3)份/d vs (0.6±1.1)份/d, $t=6.832$, $P=0.001$]。

表3 介入消融治疗后心房颤动复发的Cox比例风险回归分析

Tab 3 Cox proportional hazards regression analysis of atrial fibrillation recurrence after interventional ablation

Variable	Univariable analysis		Multivariable analysis	
	OR (95% CI)	P value	OR (95% CI)	P value
Follow-up with BigThumb®	0.39 (0.18, 0.86)	0.019	0.53 (0.14, 0.93)	0.032
LAAPD	2.84 (1.91, 5.12)	0.007	2.11 (1.07, 3.88)	0.029

LAAPD: Left atrial anteroposterior diameter; OR: Odds ratio; CI: Confidence interval.

3 讨 论

本研究探讨了“大拇指”心电监测仪对心房颤动诊断的准确性和实用性,发现心房颤动消融术后“大拇指”心电监测仪能更早地发现心房颤动复发,从而指导临床及时改变治疗策略。人工智能算法提高了“大拇指”心电监测仪诊断心房颤动的准确性。

目前有多种仪器和设备用于心房颤动消融术后的心律监测与随访。心电图和动态心电图是既往研究中最常用的监测心房颤动复发的技术,然而低频率的心电短程记录并不能满足心房颤动患者随访的要求,尤其是容易遗漏阵发性心房颤动的记录^[5]。脉搏波监测仪也被用于心房颤动的监测,如电子血压计、苹果智能手表、华为智能手表、心率监测手环等^[6-7],但是其对心律失常诊断的精度不高,对心房颤动患者术后的随访并不适用。随着穿戴式和植入式心电监测设备的发展,长时程心电监测成为可能^[8]。多项临床试验结果表明,植入式心电监测装置可长时间记录患者的心律情况,有很高的诊断精度和统计能力,为心房颤动消融术后患者提供连续全程的心律监测,并能更好地界定心房颤动负荷^[9-11],有利于尽早发现心房颤动复发以指导治疗策略改变,尤其是再次消融或重新启动抗心律失常药物治疗^[12]。

AliveCor是一款新兴的便携式心电记录仪^[13],获取的心电信号通过蓝牙传递至iPod并发送至远程数据库^[14]。有学者开展了一项随机对照试验,用AliveCor心电记录仪进行心房颤动筛查发现,在60 440份心电图中只有1%(600份)的心电图被AliveCor的算法诊断为心房颤动,其中仅5%(30份)被证实为心房颤动,阳性预测值低^[15-16]。

“大拇指”心电监测仪在结构设计上与AliveCore心电记录仪相似,但其人工智能算法的灵敏度和特异度较高,本研究结果显示其诊断心房颤动的灵敏度和特异度分别为96.5%(1 467/1 520)和99.6%(17 391/17 461),表现出较准确的诊断,更适用

于心房颤动消融术后患者的随访。

心房颤动消融术后无症状复发较常见^[17-19]。本研究中心房颤动消融术后,20.5%(312/1 520)的复发属于无症状,传统的随访策略可能会遗漏一部分无症状心房颤动发作。本研究发现,使用“大拇指”心电监测仪可提前发现心房颤动复发,并可使患者参与制定健康决策,更早且灵活地改变治疗策略。

“大拇指”心电监测仪在心房颤动术后随访中具有明显的优势,但也存在不足:(1)“大拇指”心电监测仪的心电采集为随机性,其诊断准确性在很大程度上取决于患者测量的依从性。正如本研究所发现,“大拇指”心电监测仪在术后3个月内的测量频率高于术后3个月后。如果使用“大拇指”心电监测仪作为随访设备,需要根据患者测量依从性对患者进行测量提醒,以提高测量频率,增加诊断准确性。(2)“大拇指”心电监测仪的心电采集不能在夜间睡眠时实现,因此会遗漏睡眠中的心房颤动发作。(3)“大拇指”心电监测仪的反复测量可能会增加患者的焦虑情绪,还需要临床试验进一步探讨。

综上所述,“大拇指”心电监测仪在消融术后能更早地发现心房颤动复发,利于及时改变治疗策略。人工智能算法提高了诊断的准确性,使“大拇指”心电监测仪在心房颤动术后随访中保持较好的诊断准确性和实用性,具有广阔的应用前景。

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