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在线全文

·临床研究·

房颤射频消融患者的聚类分析及消融成功率评价*

黄凤誉[1]，钟 玥[1]，张 然[1]，白文娟[1]，李娅姣[1]，龚深圳[1]，
陈 石[1]，朱亭西[2]，陈一龙[2]，饶 莉[1△]

1. 四川大学华西医院 心内科（成都 610041）；2. 四川大学华西医院 生物医学大数据中心（成都 610041）

【摘要】 目的 房颤是一组异质性较高的疾病，本研究拟通过聚类分析探讨房颤患者的不同亚型，并进一步评估不同的射频消融术式在不同房颤亚型中的成功率。**方法** 本研究回顾性纳入1 102例接受房颤射频消融的患者，基于59项基线变量进行层次聚类分析，并在聚类分析产生的房颤亚型间比较射频消融术后窦性心律转复的成功率。**结果** 基于层次聚类分析产生了5类房颤患者亚型：①较年轻房颤患者组（*n*=404）；②较年长且合并慢病组（*n*=438）；③窦房结功能障碍发生率较高组（*n*=160）；④合并心衰组（*n*=80）；⑤缺血性心肌病组（*n*=20）。在术后6个月随访时，亚型1（较年轻组）的消融成功率最高（81.2%），但亚型5（缺血性心肌病组）的消融成功率最低（65.0%）（*P*<0.05）。就早期消融成功率而言，与肺静脉隔离（pulmonary veins isolation, PVI）基础上复合异位病灶消融的广泛消融策略相比，仅在亚型2（较年长且合并慢病组）的患者中，单纯PVI与较高的消融成功率相关〔79.6% vs. 66.5%；比值比（odds ratio, OR）=1.97，95%置信区间（confidence interval, CI）：1.28～3.03〕。**结论** 通过聚类分析产生的房颤亚型之间存在接受射频消融治疗效果的差异，聚类分析产生的亚组分型可为患者的个体化治疗提供一定的参考依据。

【关键词】 导管消融术 心房颤动 聚类分析

Cluster Analysis and Ablation Success Rate in Atrial Fibrillation Patients Undergoing Catheter Ablation

HUANG Fengyu[1], *ZHONG Yue*[1], *ZHANG Ran*[1], *BAI Wenjuan*[1], *LI Yajiao*[1], *GONG Shenzhen*[1], *CHEN Shi*[1], *ZHU Tingxi*[2], *CHEN Yilong*[2], *RAO Li*[1△]. 1. *Department of Cardiology, West China Hospital, Sichuan University*, Chengdu 610041, China; 2. *West China Biomedical Big Data Center, West China Hospital, Sichuan University*, Chengdu 610041, China

△ Corresponding author, E-mail: lrlz1989@163.com

【Abstract】 Objective Atrial fibrillation (AF) is a disease of high heterogeneity, and the association between AF phenotypes and the outcome of different catheter ablation strategies remains unclear. Conventional classification of AF (e.g. according to duration, atrial size, and thromboembolism risk) fails to provide reference for the optimal stratification of the prognostic risks or to guide individualized treatment plan. In recent years, research on machine learning has found that cluster analysis, an unsupervised data-driven approach, can uncover the intrinsic structure of data and identify clusters of patients with pathophysiological similarity. It has been demonstrated that cluster analysis helps improve the characterization of AF phenotypes and provide valuable prognostic information. In our cohort of AF inpatients undergoing radiofrequency catheter ablation, we used unsupervised cluster analysis to identify patient subgroups, to compare them with previous studies, and to evaluate their association with different suitable ablation patterns and outcomes. **Methods** The participants were AF patients undergoing radiofrequency catheter ablation at West China Hospital between October 2015 and December 2017. All participants were aged 18 years or older. They underwent radiofrequency catheter ablation during their hospitalization. They completed the follow-up process under explicit informed consent. Patients with AF of a reversible cause, severe mitral stenosis or prosthetic heart valve, congenital heart disease, new-onset acute coronary syndrome within three months prior to the surgery, or a life expectancy less than 12 months were excluded according to the exclusion criteria. The cohort consisted of 1 102 participants with paroxysmal or persistent/long-standing persistent AF. Data on 59 variables representing demographics, AF type, comorbidities, therapeutic history, vital signs, electrocardiographic and echocardiographic findings, and laboratory findings were collected. Overall, data for the variables were rarely missing (<5%), and multiple imputation was used for correction of missing data. Follow-up surveys were conducted through outpatient clinic visits or by telephone. Patients were scheduled for follow-up with 12-lead resting electrocardiography and 24-hours Holter monitoring at 3 months and 6 months after the ablation procedure. Early ablation success was defined as the absence of documented AF, atrial flutter, or atrial tachycardia >30 seconds at 6-month follow-up. Hierarchical clustering was performed on the 59 baseline variables. All

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△ 通信作者，E-mail: lrlz1989@163.com

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characteristic variables were standardized to have a mean of zero and a standard deviation of one. Initially, each patient was regarded as a separate cluster, and the distance between these clusters was calculated. Then, the Ward minimum variance method of clustering was used to merge the pair of clusters with the minimum total variance. This process continued until all patients formed one whole cluster. The "NbClust" package in R software, capable of calculating various statistical indices, including pseudo t^2 index, cubic clustering criterion, silhouette index etc, was applied to determine the optimal number of clusters. The most frequently chosen number of clusters by these indices was selected. A heatmap was generated to illustrate the clinical features of clusters, while a tree diagram was used to depict the clustering process and the heterogeneity among clusters. Ablation strategies were compared within each cluster regarding ablation efficacy. **Results** Five statistically driven clusters were identified: 1) the younger age cluster (*n*=404), characterized by the lowest prevalence of cardiovascular and cerebrovascular comorbidities but the highest prevalence of obstructive sleep apnea syndrome (14.4%); 2) a cluster of elderly adults with chronic diseases (*n*=438), the largest cluster, showing relatively higher rates of hypertension, diabetes, stroke, and chronic obstructive pulmonary disease; 3) a cluster with high prevalence of sinus node dysfunction (*n*=160), with patients showing the highest prevalence of sick sinus syndrome and pacemaker implantation; 4) the heart failure cluster (*n*=80), with the highest prevalence of heart failure (58.8%) and persistent/long-standing persistent AF (73.7%); 5) prior coronary artery revascularization cluster (*n*=20), with patients of the most advanced age (median: 69.0 years old) and predominantly male patients, all of whom had prior myocardial infarction and coronary artery revascularization. Patients in cluster 2 achieved higher early ablation success with pulmonary veins isolation alone compared to extensive ablation strategies (79.6% vs. 66.5%; odds ratio [OR]=1.97, 95% confidence interval [CI]: 1.28-3.03). Although extensive ablation strategies had a slightly higher success rate in the heart failure group, the difference was not statistically significant. **Conclusions** This study provided a unique classification of AF patients undergoing catheter ablation by cluster analysis. Age, chronic disease, sinus node dysfunction, heart failure and history of coronary artery revascularization contributed to the formation of the five clinically relevant subtypes. These subtypes showed differences in ablation success rates, highlighting the potential of cluster analysis in guiding individualized risk stratification and treatment decisions for AF patients.

【Key words】 Catheter ablation Atrial fibrillation Hierarchical clustering

对房颤患者实施导管射频消融术已逐渐发展成为房颤患者心脏节律控制的有效治疗选择[1]，而消融的基础是持久有效的肺静脉隔离(pulmonary veins isolation, PVI)[1-2]。然而，除了PVI外，其他消融术式(如左房顶部线性消融、复杂碎裂电位消融、异位病灶消融等)是否对预后有益尚待证实。尽管多种术式的复合消融增加了术中房颤终止的概率[3]，但近期的随机对照研究及Meta分析发现，在单纯PVI的基础上，复合线性消融或复杂碎裂电位消融并未改善持续性房颤患者的无心律失常生存期[4-6]。由于房颤是一组异质性较大的疾病，我们推测房颤患者间的个体差异可能造成了不同的消融术式在不同房颤亚型间的成功率不同，进一步探讨房颤患者的亚型可能有利于分析不同消融术式适合的患者类型，从而有利于个体化治疗方案的制定。

既往对房颤患者的分类(如通过房颤持续时间、心房大小和血栓栓塞风险等划分患者类型)可能无法对预后风险进行最佳分层，也无法指导制定个体化的治疗计划[7]。近年来关于机器学习的研究发现，聚类分析作为机器学习中一种无监督式的数据驱动分析方法，可以发掘数据的内在结构，从而在某一疾病大类中形成具有病理生理相似性的患者亚群[8]。聚类分析已经被用于进行房颤患者的表型划分，并且其结果可对临床提供有价值的预后信息[9-12]。然而，不同的房颤亚型是否有其所适合的消融术式目前尚无定论，且现有研究并没有涉及不同的射频消融术式在房颤不同亚型间消融成功率的差异。本研究基于接受射频导管消融术的房颤患者队列，使用无监督式的聚类分析以发掘并探讨具有相似表型的房颤患者亚型，并将此聚类分析形成的亚组集群与现有研究的结果进行比较，评估不同亚组集群是否与不同的消融术式成功率相关。现报道如下。

1 资料与方法

1.1 研究对象

本研究为回顾性研究，纳入自2015年10月–2017年12月在四川大学华西医院接受射频导管消融术的房颤患者，共连续入组1 414例房颤患者。纳入标准包括：年龄≥18岁，在住院期间接受了射频导管消融术，并在知情同意的情况下能够坚持随访。排除标准为：患有可逆原因的房颤、严重二尖瓣狭窄或人工心脏瓣膜术后、先天性心脏病或入组前3个月内新发急性冠状动脉综合征的患者，或预期寿命低于1年的患者。最终，本研究共纳入1 102例阵发性房颤或持续性/长期持续性房颤的患者。本研究

经四川大学华西医院生物医学伦理委员会审批(2019年审1007号),所有研究参与者均签署书面知情同意书。

1.2 消融术式

所有患者均接受了经心内膜途径的射频导管消融术。在三维标测系统(CARTO, Biosense Webster)的指导下,对所有患者均进行标准PVI消融程序。通过环向标测导管评估肺静脉与左心房之间的电隔离,从而确定手术是否达到终点。若患者存在三尖瓣峡部依赖性心房扑动,则考虑右侧峡部消融。为了在手术中终止房颤,在PVI的基础上,如有必要,术者可依据其判断增加异位病灶的局灶性消融、线性消融和碎裂电位消融。如果在消融过程中未实现房颤终止,则进行外部电复律。消融术后至少使用3个月的抗心律失常药物。

1.3 资料收集

通过59类不同的变量特征评估每例研究参与者,以此刻画患者的关键特征,变量的具体范围包括:人口统计学特征包括年龄,性别,吸烟饮酒情况,房颤持续时间,合并症如高血压、糖尿病、冠心病、既往有无心梗发作、慢性心衰情况、病态窦房结综合征、左束支传导阻滞、脑卒中/短暂性脑缺血发作、外周动脉疾病、癌症、阻塞性睡眠呼吸暂停综合征、慢性阻塞性肺病、胃肠道出血史、骨质疏松症,既往疾病治疗情况包括透析、既往起搏器植入、植入式心律转复除颤器、既往冠状动脉搭桥手术/经皮冠状动脉介入治疗情况,生命体征包括心率、收缩压、舒张压、体重指数、心电图检查结果、超声心动图检查各项指标,实验室检查指标包括血常规、血脂、肝肾功能、酶学。通过使用多重插补法处理缺失数据。以上特征变量的数据缺失情况均< 5%。

1.4 随访及研究终点

随访调查通过电话预约时间后门诊进行,随访时记录患者的症状及当前用药情况。随访时间安排在消融术后3个月及术后6个月,所有纳入患者随访时均行12导联心电图和24 h动态心电图检查。研究终点为早期消融成功,定义为在6个月随访时患者为窦性心律,没有记录到超过30 s的房颤或心房扑动或房性心动过速。

1.5 统计学方法

本研究使用层次聚类的方法对患者特征进行分析,通过对给定数据对象的集合进行层次分解,以划定具有相似特征的患者集群。在分析的初始阶段使用数字化的形式标化所有纳入的特征变量,使用R软件的"hclust"包,将两类样本数据点间的相似性通过欧氏距离来表示,对所有数据点中最为相似的两个数据点进行组合,并反复迭代这一过程,使用Ward最小方差法对具有最小总方差的组合进一步合并[13],直到所有患者都成为一个整体。使用R软件的"NbClust"包计算以下的统计指数:伪t^2指数、立方集群准则、线条指数,用于投票选出最优聚类数量[14]。得票最多的最优聚类数量选定后,生成热图以说明聚类的临床特征,并使用树形图来展示聚类过程和聚类之间的异质性。

符合正态分布的连续性变量用$\bar{x} \pm s$表示,具有偏态分布的连续性变量用中位数(四分位数间距)表示。分类变量用频数和百分比表示。通过Kolmogorov-Smirnow检验评估连续性变量分布的正态性。连续性变量的组间比较通过方差分析或Kruskal-Wallis检验进行。χ^2检验用于分类变量组间的比较,使用比值比(odds ratio, OR)评估不同亚组与射频消融成功率之间关联的强度。检验水准$\alpha_{双侧}$= 0.05。数据分析软件使用R 4.0.5版。

2 结果

2.1 聚类分析所产生的房颤患者表型集群

通过分析投票显示本研究中房颤患者的最佳集群数量为5(图1),基线特征形成集群的情况如资源附件中附图1所示,在该热图中,浅色代表特征表型水平增加,而深色代表特征表型水平降低。通过层次聚类分析发现,5种数据驱动表型的关键特征如下:①较年轻、阻塞性睡眠呼吸暂停患病率较高的亚型(n= 404);②较年长且高血压、糖尿病和慢性阻塞性肺病患病率较高的亚型(n= 438);③窦房结功能障碍患病率较高的老年患者亚型(n= 160);④合并心力衰竭的患者亚型(n= 80);⑤缺血性心肌病组(n= 20)。5个亚型集群的基线人口统计学和临床特征如资源附件中附表1所示。

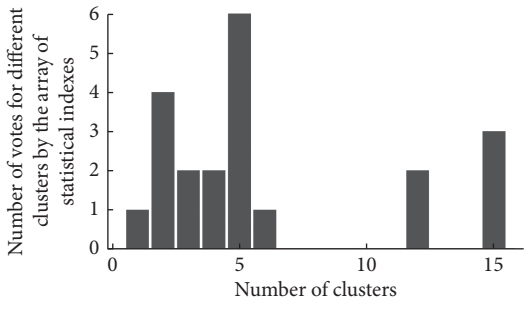

图 1 最佳聚类数目的投票划分

Fig 1 Analysis for the identification of the optimal number of clusters

亚型1为较年轻、阻塞性睡眠呼吸暂停患病率较高的集群,中位年龄为54.0岁,吸烟占比在5组中最高。虽然该集群患者心脑血管合并症的患病率最低,但阻塞性睡眠呼吸暂停综合征的患病率最高(14.4%)。该组患者主要为阵发性房颤,左房径线在5类集群中最小(中位值

34.0 mm)。该类患者CHA2DS2-VASc评分的中位数最低,大多数患者(68%)的CHA2DS2-VASc得分为0～1分(图2)。亚型2人数最多,该类房颤患者较年长且慢性病患病率较高,高血压、糖尿病、中风和慢性阻塞性肺病的患病率相对增加。尽管有33.3%的此型房颤患者合并冠心病,但只有少数人患有心力衰竭或心肌梗死。该亚型的CHA2DS2-VASc得分的分布相对均匀。此亚型的形成可能反映了慢病患者在衰老过程中逐渐出现房颤的这一病理过程。亚型3为窦房结功能障碍患病率较高的老年患者,该集群女性占比最大(53.1%),病态窦房结综合征患病率(29.4%)和起搏器植入(10.0%)的比例最高。并且外周动脉疾病(6.9%)、癌症(16.3%)和骨质疏松症(19.4%)的患病率高于其他集群。值得注意的是,所有植入心律转复除颤器的患者均被专门归类于这一亚型。亚型4为房颤合并心衰的患者集群,其中心力衰竭的患病率为58.8%,且持续性/长期持续性房颤患病率为73.7%。该亚型患者中位年龄为63.0岁。该集群的主要特征为患者心室腔扩大、瓣膜反流严重程度较高,且酗酒者更多。同时,与其他聚类亚型相比,该亚型中的肝功能异常者较多。亚型5为缺血性心肌病组,此亚型患者的中位年龄最高(69.0岁),患者多为男性,该组中的所有房颤患者均有心肌梗死和冠状动脉血运重建的病史,此类亚型患者肾小球滤过率普遍偏低,空腹血糖水平普遍偏高。该集群中约60%的患者CHA2DS2-VASc评分≥4(图2)。

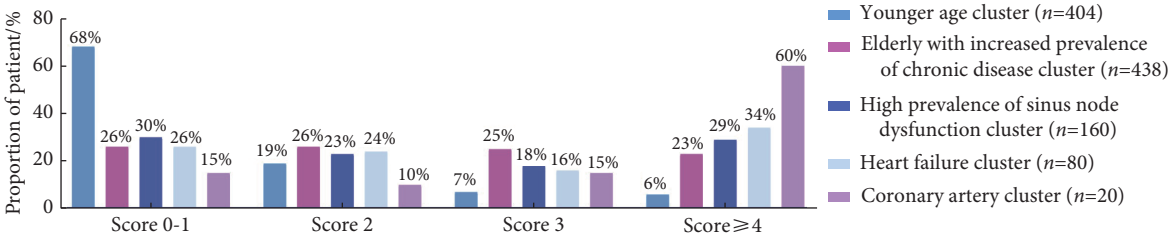

图 2 不同房颤亚型患者的CHA2DS2-VASc评分分布情况

Fig 2 Distribution of CHA2DS2-VASc scores among different atrial fibrillation clusters

2.2 房颤患者各亚型集群接受射频消融术式的成功率分析

各亚型集群组患者消融策略的差异如表1所示。亚型1(较年轻组)和亚型5(缺血性心肌病组)的患者主要接受单纯PVI术式,而较少选择额外的消融方式。亚型5(缺血性心肌病组)仅有20%的患者接受线性消融,无患者接受碎裂电位消融;亚型1(较年轻组)仅有6.4%的患者接受异位病灶消融;亚型2(较年长且合并慢病组)及亚型3(窦房结功能障碍发生率较高组)的患者在单纯PVI基础上接受线性消融的概率相似,而亚型4(合并心力衰竭组)的患者更有可能在PVI的基础上采用广泛的消融策略进行治疗,包括线性消融(55%)、异位病灶消融(13.8%)和碎裂电位消融(17.5%)。表2显示了各集群的消融结果。在术

表 1 不同房颤患者亚组肺静脉隔离以外消融策略的差异

Table 1 Differences in ablation strategies among different clusters of atrial fibrillation patients excluding pulmonary vein isolation

Procedural strategies in addition to PVI	Overall (*n*=1 102)	Younger age cluster (*n*=404)	Elderly with increased prevalence of chronic disease cluster (*n*=438)	High prevalence of sinus node dysfunction cluster (*n*=160)	Heart failure cluster (*n*=80)	Coronary artery revascularization cluster (*n*=20)	*P*
Linear ablation	342 (31.0)	83 (20.5)	153 (34.9)	58 (36.3)	44 (55.0)	4 (20.0)	<0.001
Non-pulmonary vein triggers ablation	98 (8.9)	26 (6.4)	42 (9.6)	16 (10.0)	11 (13.8)	3 (15.0)	0.146
CFAEs ablation	119 (10.8)	19 (4.7)	68 (15.5)	18 (11.3)	14 (17.5)	0 (0.0)	<0.001

Variables are presented as case (%). CFAEs: complex fractionated atrial electrograms; PVI: pulmonary veins isolation.

表 2 不同房颤患者亚组消融策略与消融成功率的关系(术后6个月)

Table 2 Relationship between ablation strategies and success rates in different clusters of atrial fibrillation patients (6-month follow-up)

Different clusters	PVI (*n*=688)		Extensive ablation in addition to PVI (*n*=414) [reference]		Odds ratio (95% CI)
	Events/total	Ablation success rate (95% CI)	Events/total	Ablation success rate (95% CI)	
Younger age cluster	249/300	83.0% (78.2%-87.0%)	79/104	76.0% (66.4%-83.6%)	1.55 (0.90-2.66)
Elderly with high prevalence of chronic disease cluster	199/250	79.6% (74.0%-84.3%)	125/188	66.5% (59.2%-73.1%)	1.97 (1.28-3.03)
High prevalence of sinus node dysfunction cluster	71/94	75.5% (65.4%-83.6%)	43/66	65.1% (52.3%-76.2%)	1.65 (0.83-3.30)
Heart failure cluster	19/28	67.9% (47.6%-83.4%)	39/52	75.0% (60.8%-85.5%)	0.70 (0.26-1.94)
Coronary artery revascularization cluster	11/16	68.8% (41.5%-87.9%)	2/4	50.0% (9.2%-90.8%)	2.20 (0.24-20.40)

CI: confidence interval; PVI: pulmonary veins isolation.

后6个月随访时，亚型1（较年轻组）的消融成功率最高（81.2%），但亚型5（缺血性心肌病组）的消融成功率最低（65.0%）（P< 0.05）。就早期消融成功率而言，与PVI基础上复合异位病灶消融的广泛消融策略术式相比，仅在亚型2（较年长且合并慢病组）的患者中，单纯PVI与较高的消融成功率相关〔79.6% vs. 66.5%; OR= 1.97, 95%置信区间（confidence interval, CI）: 1.28 ~ 3.03〕。尽管亚型4（合并心力衰竭组）接受广泛消融策略的成功率略高，但未发现差异有统计学意义（67.9% vs. 75.0%; OR= 0.70, 95%CI: 0.26 ~ 1.94）。

3　讨论

在本研究中，聚类分析确定了5种临床特征显著不同的房颤患者亚型，不同亚型所适合的消融术策略不同。既往的队列研究通过对房颤患者的聚类分析发现了房颤的异质性[9, 11-12]，在一些房颤患者的门诊队列和社区队列中常观察到动脉粥样硬化合并房颤，而在本住院队列中也发现了类似的情况。经冠状动脉血运重建后的合并房颤的患者较窦性心律的冠心病患者死亡风险更高[15]，对于这种缺血性心肌病合并房颤的高风险表型，可能应该更积极进行抗凝及控制心律失常的治疗。心血管合并症较少的年轻房颤患者更有可能患有阻塞性睡眠呼吸暂停，该疾病也可能降低抗心律失常治疗的疗效[16]。同时，本研究结果提示年龄仍然是影响房颤患者分类的一个重要因素。通过整合详细的特征变量，聚类分析可充分发掘房颤患者的异质性和合并症对治疗效果的影响。

导管消融术后房颤的复发可能与许多临床因素有关。既往的房颤分类缺乏对消融成功相关的特征的区分[17]。房颤的异质性可能在很大程度上影响消融治疗的效果[18]。据报道，合并心力衰竭患者通过单次消融完全治愈房颤较其他类型房颤更为困难[19-20]。本研究发现，除心力衰竭外，既往因心肌缺血存在冠状动脉血运重建史或窦房结功能障碍的房颤患者的消融成功率也相对较低，这可能与这些合并症潜在地改变了患者的心房基质有关[20-22]。尽管本研究发现，在合并心力衰竭患者亚型中，使用基质改良策略消融的概率略有增加，但在这种亚型中，没有发现手术成功与这种额外复合消融术式之间的显著关联。哪种消融策略最适合房颤合并心力衰竭人群仍然缺少确切的证据，未来研究需进一步加深对致心律失常的基质的理解，尽可能减少不必要的广泛消融[23]。

在本研究中，亚型2（较年长且合并慢病组）的患者通过单纯PVI术式实现早期房颤控制的机会较大。据报道，复合术式的广泛房颤消融策略不会增加围手术期的风险[24]，但老年患者更倾向于选择单纯PVI术式。在本研究中，亚型2的老年房颤患者对PVI反应良好。尽管该集群的慢性病患病率相对较高，但与其他老年集群相比，该亚组患者较少出现心脏的结构或功能变化，推测可能该类患者心房基质改变较少，单纯PVI消融的转复窦性成功率可能因此更高。在对房颤患者的预后风险研究中发现，控制欠佳的血压和血糖水平比高血压或糖尿病病史对预后的影响更大[25-26]，对于没有结构性心脏病，血压血糖控制良好的合并慢性病老龄房颤患者，单独的PVI消融可能风险收益比是最佳的。

本研究存在以下局限性，应谨慎解读研究结果。首先，机器学习辅助风险评估模型的开发受到外部验证的限制[8]。尽管本研究没有进行外部验证，但本研究所得出的房颤患者亚组与既往大规模房颤患者队列所呈现出的亚组具有相似性[11-12]，从侧面说明了聚类分析的稳健性，课题组将在未来的研究中重点关注外部验证。其次，聚类分析并不是为了建立房颤的标准分类，而是发掘传统分类可能忽略的临床相关表型。不同的聚类和链接方法可能会生成不同的亚组集群。合并房颤的缺血性心肌病集群可能因样本量太小而无法得出可靠的结果，但同时这一结果也提示着该类合并血运重建术房颤患者的特质明显。并且，有关患者电生理检查时的电标测结果和晚期复发的信息未包括在本次分析中，同时本研究缺少对混杂因素的有效控制。在未来的研究中需要包含尽可能全面的临床数据变量，校正混杂因素，从而对集群进行细化、提高分类的合理性。

本研究通过聚类分析对接受导管消融的房颤患者进行了特征分类。患者的年龄、合并慢性病情况、有无窦房结功能障碍、心力衰竭和缺血性心肌病史有助于形成5种房颤表型。这些表型与消融策略的成功率有一定关系。本研究所确定的房颤分类特征有助于房颤患者的个体化风险分层和治疗决策的选择。

*　　*　　*

作者贡献声明　黄凤誉负责论文构思、正式分析和初稿写作，钟玥负责正式分析、经费获取和初稿写作，张然、李娅姣和龚深圳负责调查研究，白文娟负责经费获取和审读与编辑写作，陈石负责研究方法，朱亭西和陈一龙负责数据审编和研究方法，饶莉负责论文构思、经费获取和审读与编辑写作。所有作者已经同意将文章提交给本刊，且对将要发表的版本进行最终定稿，并同意对工作的所有方面负责。

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