

心房颤动合并脑栓塞患者的抗凝治疗现状和出血转化分析

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【摘要】

目的 通过充血性心力衰竭、高血压、年龄 ≥ 75 岁(双倍)、糖尿病、卒中(双倍)、血管病变、年龄65~74岁、女性(Congestive heart failure, Hypertension, Age ≥ 75 (doubled), Diabetes Mellitus, Stroke (doubled), vascular disease, age 65~74 and sex category (female), CHA₂DS₂-VASc)评分观察心房颤动合并脑栓塞患者的抗栓治疗现状,分析高血压、异常的肝肾功能、卒中、出血、国际标准化比值(international normalized ratio, INR)不稳定、年龄、药物治疗或者饮酒(Hypertension, Abnormal renal and liver function, Stroke, Bleeding, Labile international normalized ratio, Elderly, Drugs and alcohol intake, HAS-BLED)评分及其他相关临床危险因素与心房颤动合并脑栓塞出血转化的关系。

方法 回顾性分析2012年5月至2014年12月在北京博爱医院神经康复科住院的心房颤动合并脑栓塞患者的临床资料。根据CHA₂DS₂-VASc评分观察低危组(0分)、中危组(1分)、高危组(≥ 2 分)的抗栓治疗情况。根据HAS-BLED评分,分析心房颤动脑栓塞出血转化(hemorrhagic transformation, HT)率在出血转化低危组(0~2分)和出血转化高危组(≥ 3 分)之间的差异,同时对多个临床变量进行多因素分析,寻找与HT相关的临床危险因素。

结果 研究共入组101例患者,患者在发生脑栓塞之前,根据CHA₂DS₂-VASc评分,低危组抗凝率66.7%(2/3),无抗血小板治疗;中危组抗凝、抗血小板率均为16.7%(2/12);高危组抗凝率19.8%(17/86),抗血小板率14.0%(12/86)。脑栓塞前1个月内停用抗凝治疗而发病的占所有抗凝患者42.8%(9/21)。发生脑栓塞之后,所有患者均为高危组,抗凝治疗率68.3%(69/101),抗血小板治疗率25.7%(26/101)。根据HAS-BLED评分,心房颤动合并脑栓塞后,出血转化高危组HT 58.5%(31/53),与低危组HT 37.5%(18/48)比较,差异有显著性($\chi^2=4.443, P=0.035$)。对HT组与非HT组的多个临床变量分析发现,两组美国国立卫生研究院(National Institutes of Health Stroke Scale, NIHSS)评分差异有显著性(14.860 ± 4.486 vs $11.940 \pm 5.648, P=0.006$);HAS-BLED评分差异有显著性(2.76 ± 0.80 vs $2.21 \pm 0.96, P=0.003$);病灶范围大的梗死灶HT为57.9%(44/76),小的梗死灶为HT 20%(5/25),两组有显著差异($P=0.001$)。多因素Logistic回归分析发现NIHSS ($OR 1.106, 95\%CI 1.106 \sim 1.216, P=0.036$)、病灶范围大小 ($OR 5.083, 95\%CI 1.826 \sim 14.148, P=0.002$)和HAS-BLED评分 ($OR 2.353, 95\%CI 1.326 \sim 4.175, P=0.003$)均是心房颤动患者脑栓塞后HT的危险因素。

结论 心房颤动合并脑栓塞的患者抗栓治疗率不理想, HAS-BLED评分能很好地预测心房颤动合并脑栓塞后的HT风险,另外,神经功能缺损较重、病灶范围大也是心房颤动合并脑栓塞患者发生HT的危险因素。

【关键词】 脑栓塞;心房颤动;出血转化;危险因素

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Observation of the Status of Anticoagulation and Analysis of Hemorrhagic Transformation of Cerebral Embolism Patients with Atrial Fibrillation

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【Abstract】

Objective To observe the status of anticoagulation of patients with cerebral embolism and atrial fibrillation through congestive heart failure, hypertension, age ≥ 75 years old (doubled), diabetes mellitus, stroke (doubled), vascular disease, aged between 65~74 years old and sex category (female)

(CHA₂DS₂-VASc) score; to analyse the correlation of hypertension, abnormal renal and liver function, stroke, bleeding, labile international normalized ratio (INR), age, drugs and alcohol intake (HAS-BLED) score and other clinical risk factors with hemorrhagic transformation in patients with cerebral embolism and atrial fibrillation.

Methods The clinical data were analyzed retrospectively in patients with cerebral embolism and atrial fibrillation admitted in Department of Neurology in Beijing Boai Hospital from May 2012 to December 2014. The status of anticoagulation were observed in all patients who were divided into three groups with CHA₂DS₂-VASc score: low risk group (score=0), moderate risk group (score=1) and high risk group (score≥2). HAS-BLED score was used to analyse the difference in hemorrhagic transformation (HT) rate between low-moderate group (score=0~2) and high risk group (score≥3) and multivariate logistic regression analysis of several clinical variates was used to find clinical risk factors related to HT.

Results A total of 101 patients were recruited. Before the onset of cerebral embolism of patients with atrial fibrillation, according to CHA₂DS₂-VASc score, the rate of anticoagulation was 66.7% (2/3) and no patient received antiplatelet agent in low-risk group. The rate of anticoagulation and antiplatelet agent was also 16.7% (2/12) in moderate-risk group. The rate of anticoagulation was 19.8% (17/86) and antiplatelet agent was 14.0% (12/86) in high-risk group. The percentage of patients who stopped anticoagulation treatment within 1 month before the onset of cerebral embolism was 42.8% (9/21). The rate of anticoagulation was 68.3% (69/101) and antiplatelet agent was 25.7% (26/101) in all patients with atrial fibrillation after the onset of cerebral embolism. After cerebral embolism in patients with atrial fibrillation, according to HAS-BLED score, the rate of HT was 37.5% (18/48) in low-risk group, while 58.5% (31/53) in high-risk group, there was statistic signification in two groups ($\chi^2=4.443$, $P=0.035$). The analysis of several clinical variates found that there was statistic signification in NIHSS score (14.86±4.486 vs 11.94±5.648, $P=0.006$) and HAS-BLED score (2.76±0.80 vs 2.21±0.96, $P=0.003$) between HT group and non HT group. The HT in the group with bigger volume of the infarction was 57.9% (44/76) and HT in the group of smaller volume of the infarction was 20% (5/25), which had significant difference ($P=0.001$). NIHSS score (OR 1.106, 95%CI 1.106~1.216, $P=0.036$), HAS-BLED score (OR 2.353, 95%CI 1.326~4.175, $P=0.003$) and the volumes of the infarction (OR 5.083, 95%CI 1.826~14.148, $P=0.002$) were risk factors for HT in patients with cerebral embolism and atrial fibrillation.

Conclusion The rate of anticoagulant therapy is not satisfactory in patients with cerebral embolism and atrial fibrillation. HT risk could be well forecasted with HAS-BLED score in patients with cerebral embolism and atrial fibrillation. Severe neurofunction defect and bigger infarction volumes are risk factors for HT in patients with cerebral embolism and atrial fibrillation.

[Key Words] Cerebral embolism; Atrial fibrillation; Hemorrhagic transformation; Risk factor

心房颤动是脑梗死的独立危险因素^[1], 非瓣膜性心房颤动患者的卒中风险是正常人的5~6倍^[2], 年卒中发生率约为5%^[3], 对心房颤动患者来说预防卒中尤为重要。目前预防心源性脑栓塞最有效的方法是口服抗凝药, 可使心房颤动患者脑栓塞的相对危险降低60%~70%^[4-5], 优于单用或双联抗血小板治疗。然而, 抗凝治疗在减少卒中风险的同时伴随着出血风险。因此权衡卒中及抗凝出血风险是个体化抗凝决策的前提。

本文对北京博爱医院神经康复科住院治疗的心房颤动合并脑栓塞患者的临床资料进

行了回顾性分析, 结合充血性心力衰竭、高血压、年龄≥75岁(双倍)、糖尿病、卒中(双倍)、血管病变、年龄65~74岁、女性[Congestive heart failure, Hypertension, Age≥75 (doubled), Diabetes Mellitus, Stroke (doubled), vascular disease, age 65~74 and sex category (female), CHA₂DS₂-VASc]评分和高血压、异常的肝肾功能、卒中、出血、国际标准化比值(international normalized ratio, INR)不稳定、年龄、药物治疗或者饮酒(Hypertension, Abnormal renal and liver function, Stroke, Bleeding, Labile

international normalized ratio, Elderly, Drugs and alcohol intake, HAS-BLED) 评分观察心房颤动合并脑栓塞患者的抗凝治疗现状及评估出血风险; 对于脑栓塞出血转化 (hemorrhagic transformation, HT) 的患者, 寻找HAS-BLED评分及其他相关临床危险因素与出血风险的关系, 指导临床治疗。

1 对象与方法

1.1 研究对象 连续选取2012年5月至2014年12月在北京博爱医院神经康复科住院的101例心房颤动合并脑栓塞患者。

1.2 入组标准 符合2010年欧洲心脏病学会心房颤动治疗指南建议的诊断标准^[6]; 合并脑栓塞, 符合中华医学会第四届全国脑血管学术会议通过的《各类脑血管疾病诊断要点》关于心源性脑栓塞诊断标准^[7]; 患者发生脑栓塞后首次头颅磁共振成像 (magnetic resonance imaging, MRI) 或计算机断层扫描 (computed tomography, CT) 检查未见颅内出血; 住院期间完成脑栓塞后CT或MRI复查; 头颅MRI或者CT检查提示病变累及颈内动脉系统; 年龄 ≥ 18 岁。

1.3 排除标准 其他原因如瓣膜病、心肌病或者先天性心脏病等所导致的心源性脑栓塞; 动脉粥样硬化性脑梗死患者; 其他原因或者原因不明的脑梗死患者。

1.4 研究方法 收集患者的年龄、性别等人口学资料及临床资料。按患者的病例资料对脑栓塞发病前后进行CHA₂DS₂-VASc评分; 按照脑栓塞发生后的情况对患者进行HAS-BLED评分。CHA₂DS₂-VASc评分^[8]用于卒中风险评估, 0分为低度卒中风险组, 1分为中度卒中风险组, ≥ 2 分为高度卒中风险组, 分析3组患者脑栓塞发生前后抗凝或抗血小板治疗情况。HAS-BLED评分^[9]用于评估心房颤动患者抗凝治疗的出血风险, 0~2分为低出血风险患者, 为低危组, ≥ 3

分提示出血风险增高, 为高危组, 分析2组患者的HT发生情况。按照患者是否发生HT分为HT组和非HT组, 对2组的年龄、性别、脑栓塞前后抗栓治疗、溶栓、病灶范围大小、糖尿病、冠状动脉粥样硬化性心脏病、高脂血症、住院时美国国立卫生研究院卒中量表 (National Institutes of Health Stroke Scale, NIHSS) 及HAS-BLED评分进行单因素和多因素Logistic回归分析, 研究心房颤动所致脑栓塞患者HT的危险因素。

HT诊断标准: 按照患者脑栓塞后住院期间复查的头部CT或MRI结果进行判断, 影像学上显示存在新发的出血则定义为HT^[10]。病灶范围大小分型^[11]: 根据CT分型, 大脑梗死分为: ①大梗死: 超过一个脑叶, 5 cm以上; ②中梗死: 小于一个脑叶, 3.1~5.0 cm; ③小梗死: 1.6~3 cm。本文将大中梗死合并与小梗死比较。

1.5 统计学分析 采用SPSS 17.0进行统计学分析, 计数资料用百分比表示, 应用完全随机设计的 χ^2 检验; 计量资料如符合正态分布采用 $(\bar{x} \pm s)$ 表示, 两组间比较用独立样本 t 检验。采用单因素和多因素Logistic回归分析, 调整相关的混杂因子, 用相对危险度的估计比值比 (odds ratio, OR) 及95%可信区间 (95% confidence interval, 95%CI) 表示该因素与HT发生相关的联系强度。所有检验均采用双侧检验, $P < 0.05$ 为差异有显著性。

2 结果

2.1 一般资料 共收集101例心房颤动合并脑栓塞的患者资料, 其中女性49 (48.5%) 例, 男性52 (51.5%) 例。年龄28~87岁, 平均年龄 (65.97 ± 11.55) 岁。根据患者复查头颅CT有无并发颅内出血分为HT组与非HT组, 其中HT组49 (48.5%) 例, 男27例 (55.1%), 女22例 (44.9%), 年龄46~87岁, 平均年龄 (67.71 ± 10.96) 岁; 非HT组52 (51.5%) 例, 男25

(48.1%)例,女27(51.9%)例,年龄28~86岁,平均年龄(64.33±11.96)岁。

2.2 心房颤动合并脑栓塞前后的抗凝率和抗血小板率根据CHA₂DS₂-VASc评分,心房颤动患者在并发脑栓塞之前,低危组3例,抗凝率66.7%(2/3),抗血小板为0;中危组12例,抗凝率、抗血小板率均为16.7%(2/12);高危组86例,抗凝率19.8%(17/86),抗血小板率14.0%(12/86),总体抗凝和抗血小板治疗率均不理想。所有抗凝的21例患者中,有9例患者发病前1个月之内停用抗凝治疗而发生卒中,占所有抗凝患者的42.8%。

合并脑栓塞发生后,所有患者CHA₂DS₂-VASc≥2分,均为高危卒中风险组,抗凝率68.3%(69/101),抗血小板率25.7%(26/101),显著高于脑栓塞发病前所有患者的抗凝率20.8%(14/101)($\chi^2=79.200, P<0.001$),也显著高于脑栓塞发病前高危卒中风险组的抗凝率($\chi^2=77.179, P<0.001$)。

2.3 HAS-BLED评分与心房颤动合并脑栓塞患者HT的关系 对入组患者进行HAS-BLED评分,其中出血转化低危组48例,HT发生率37.5%(18/48);出血转化高危组53例,HT发生率58.5%(31/53),2组HT发生率有显著差异($\chi^2=4.443, P=0.035$)。

2.4 心房颤动合并脑栓塞HT相关危险因素的Logistic回归分析 以有无HT为因变量,对年龄、性别、冠状动脉粥样硬化心脏病、高脂血症、糖尿病、脑栓塞前抗栓治疗、脑栓塞后抗栓治疗、溶栓、病灶范围大小、NIHSS评分、HAS-BLED评分进行单因素分析,筛选出影响HT的相关危险因素有NIHSS评分、病灶范围大小、HAS-BLED评分(表1),然后进行多因素Logistic回归分析,调整相关的混杂因素,结果发现NIHSS评分、病灶范围大小和HAS-BLED评分均是HT的独立危险因素(表2)。NIHSS评分每增加1分,HT的风险

增加10.6%(OR 1.106, 95%CI 1.106~1.216, $P=0.036$)。病灶范围大的脑梗死(病灶最大直径≥3 cm)的患者出现HT的风险,较小的脑梗死(病灶最大直径<3 cm)的风险增加4.08倍(OR 5.083, 95%CI 1.826~14.148, $P=0.002$)。HAS-BLED每增加1分,HT风险增加1.3倍(OR 2.353, 95%CI 1.326~4.175, $P=0.003$)。

3 讨论

心房颤动患者的抗凝治疗选择应基于卒中危险分层,经典的CHADS₂^[12]评分系统是临床应用最为广泛的评估心房颤动患者危险因素的工具,但有研究认为CHADS₂方案可能低估了“年龄、外周动脉疾病及女性”在心房颤动卒中发生所起的作用^[13-14]。因此,在CHADS₂基础上制定了CHA₂DS₂-VASc^[8]心房颤动卒中风险分层方案,该方案已得到欧洲心脏病学会(European Society of Cardiology, ESC)心房颤动指南的推荐^[6]。与CHADS₂积分相比,CHA₂DS₂-VASc评分有利于界定真正的卒中低危患者;此外还扩大了高危人群的范围,有利于提高整体抗凝率。ESC的指南中推荐CHA₂DS₂-VASc评分≥2分者需服用口服抗凝药物;CHA₂DS₂-VASc评分为1分者,口服抗凝药或阿司匹林均可,但优先推荐口服抗凝药物;无危险因素,即CHA₂DS₂-VASc评分0分者,可服用阿司匹林或不进行抗栓治疗,不抗栓治疗优先^[6]。

本研究中心房颤动患者的抗凝抗栓治疗比例低下,所有101例患者抗凝率为20.8%,抗血小板率为13.7%。其中,高危组患者抗凝率仅19.8%,抗血小板率16.7%;但亦存在过度抗凝的情况,低危组3例患者中有2例接受抗凝治疗。在合并脑栓塞后,抗凝治疗比例有一定的提高,高危组抗凝率达到68.3%,抗血小板率25.7%。另外,研究中停用抗凝治疗的心房颤动患者其卒中的发生率大大增加,因此,临床上遇到特殊情况需要停用抗凝治疗如围术期,应选择肝

表1 心房颤动合并脑栓塞HT危险因素的单因素分析

变量	合计	HT组	非HT组	P值
N	101	49	52	
性别 (n, %)				0.480
男	52	27 (51.9%)	25 (48.1%)	
女	49	22 (44.9%)	27 (55.1%)	
年龄 (岁)	65.97±11.55	67.71±10.96	64.33±11.96	0.142
冠状动脉粥样硬化性心脏病 (n, %)				0.524
无	65	30 (46.2%)	35 (53.8%)	
有	36	19 (52.8%)	17 (47.2%)	
高脂血症 (n, %)				0.899
无	55	27 (49.1%)	28 (50.9%)	
有	46	22 (47.8%)	24 (52.2%)	
糖尿病 (n, %)				0.251
无	81	37 (45.7%)	44 (54.3%)	
有	20	12 (60%)	8 (40%)	
病前抗栓治疗 (n, %)				0.710
无	66	34 (51.5%)	32 (48.5%)	
抗凝	21	9 (42.9%)	12 (57.7%)	
抗血小板	14	6 (42.9%)	8 (57.1%)	
病后抗栓治疗 (n, %)				0.04
无	6	5 (83.3%)	1 (16.7%)	
抗凝	69	28 (40.6%)	41 (59.4%)	
抗血小板	26	16 (61.5%)	10 (38.5%)	
NIHSS (分)	13.36±5.38	14.86±4.48	11.94±5.65	0.006
溶栓 (n, %)				0.668
否	68	34 (50.0%)	34 (50.0%)	
是	33	15 (45.5%)	18 (54.5%)	
病变范围 (n, %)				0.001
<3 cm	25	5 (20%)	20 (80%)	
≥3 cm	76	44 (57.9%)	32 (42.1%)	
HAS-BLED (分)	2.48±0.92	2.76±0.80	2.21±0.96	0.003

注: HT: 出血转化; NIHSS: 美国国立卫生研究院卒中量表; HAS-BLED: 高血压、异常的肝肾功能、卒中、出血、国际标准化比值 (international normalized ratio, INR) 不稳定、年龄、药物治疗或者饮酒评分

表2 心房颤动合并脑栓塞HT危险因素的Logistic回归分析

变量	粗OR	95%CI	P值	调整OR	95%CI	P值
NIHSS	1.114	1.029~1.206	0.008	1.106	1.106~1.216	0.036
病灶范围						
<3 cm	1			1		
≥3 cm	6.126	2.201~17.052	0.001	5.083	1.826~14.148	0.002
HAS-BLED	2.007	1.246~3.235	0.004	2.353	1.326~4.175	0.003

注: 调整因素包括: 年龄、性别、脑栓塞前抗栓治疗、脑栓塞后抗栓治疗、溶栓、冠状动脉粥样硬化性心脏病、高脂血症和糖尿病; HT: 出血转化; NIHSS: 美国国立卫生研究院卒中量表; HAS-BLED: 高血压、异常的肝肾功能、卒中、出血、国际标准化比值 (international normalized ratio, INR) 不稳定、年龄、药物治疗或者饮酒评分; OR: 比值比; CI: 可信区间

素桥接治疗。

虽然多项研究已经表明,血栓栓塞风险高的心房颤动患者进行规范化抗凝治疗可以显著改善预后,但在临床诊疗过程中仍有大量心房颤动患者未接受抗凝治疗。造成这一现状的原因是多方面的,其中很重要的一个原因是患者担心抗凝治疗发生出血。关于心房颤动患者脑栓塞后HT发生率的报道存在较大差异,为3%~43.7%^[15]。本研究中患者的HT率为48.5%,造成这种较高的HT的原因考虑与患者在康复医院住院周期长,复查头颅CT或者MRI检查及时有关。

目前临床上最常用于评价抗凝治疗出血风险评估的是HAS-BLED出血风险评分。本研究中,心房颤动患者合并脑栓塞之后,根据HAS-BLED评分,高危组的HT为58.5%,显著高于低危组,可见,HAS-BLED评分能很好地预测心房颤动合并脑栓塞患者的HT风险,尤其是对于评分 ≥ 3 的高危出血风险患者,无论接受华法林还是阿司匹林治疗均应谨慎。

但是HAS-BLED评分的目的不是要让出血高危的患者不接受抗凝治疗。应用该评分的目的是使临床医师有客观的工具评估心房颤动患者的出血风险,及时纠正未被控制出血危险因素。ESC心房颤动指南^[6]推荐应用HAS-BLED评分视为高危患者,应规律复诊,严密观察以防止出血事件。另有研究显示^[16],对于高危卒中风险即CHA₂DS₂-VASc ≥ 2 分的患者,无论出血风险如何,使用抗凝均可获得净临床获益。因此,临床上对于高危出血风险的患者应注意筛查,及时纠正增加出血风险的可逆性因素,进一步加强监测。

除此之外,本研究还对多个临床变量进行单因素分析和多因素Logistic分析,调整相关的混杂因素,发现NIHSS评分、病灶范围大小也是HT的危险因素,NIHSS评分每增加1分,HT的风险增加10.6% (OR 1.106,

95%CI 1.106~1.216, $P=0.036$)。也就是说神经功能缺损越重,HT风险越高,这与Kablau等^[17]的报道是一致的。而病灶范围 ≥ 3 cm出现HT的风险较病灶范围 < 3 cm的HT风险增加4.08倍 (OR 5.083, 95%CI 1.826~14.148, $P=0.002$)。另外,本研究结果显示心房颤动患者在脑栓塞发生之前接受抗栓治疗不会显著增加脑栓塞后的HT风险;溶栓治疗亦不会显著增HT风险。

由于本研究为回顾性分析,且病例数较少,未进一步将HT分型进行亚组分析,可能会影响本研究的可信度。期望在未来的研究中能够扩大样本量、采用前瞻性等研究方法进一步探讨此问题。

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【点睛】

本研究通过多因素分析显示HAS-BLED评分、发病后神经功能缺损严重以及梗死面积大是心房颤动患者脑栓塞后出血转化的危险因素。

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