

新型口服抗凝药和左心耳封堵器在非瓣膜性心房颤动运用中的有效性及安全性的 Meta 分析*

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【摘要】 目的:运用 Meta 分析方法研究新型口服抗凝药(NOAC)和左心耳封堵器(LAAO)在非瓣膜性心房颤动(房颤)运用中的安全性及有效性。**方法:**计算机检索 Pubmed、Embase 及 Cochrane 数据库有关新型口服抗凝药和左心耳封堵器的文章,包括随机对照实验(RCT)、病例登记及观察性研究。主要结局指标为缺血性卒中和大出血,次要结局指标包括出血性休克、总的卒中和心血管死亡。**结果:**共纳入 29 篇文章,总例数为 81 597 例。汇总分析表明,LAAO 的大出血发生率较 NOAC 更低(1.1/PY : 2.7/PY),LAAO 缺血性卒中的发生率较 NOAC 稍高(1.8/PY : 1.2/PY)。**结论:**NOAC 较 LAAO 发生大出血风险更高,但缺血性卒中风险发生可能较低。

【关键词】 心房颤动;左心耳封堵器;新型口服抗凝药;Meta 分析

doi:10.13201/j.issn.1001-1439.2019.07.015

【中图分类号】 R541.7 **【文献标志码】** A

Efficacy and safety of new oral anticoagulants and left atrial appendage occlusion devices in non-valvular atrial fibrillation :a Meta-analysis

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Abstract Objective: Meta-analysis was used to research the effectiveness and safety of left atrial appendage occlusion devices (LAAO) and new oral anticoagulants (NOAC) in non-valvular atrial fibrillation. **Method:** Pubmed, Embase and Cochrane were searched for articles about NOAC and LAAO, including randomized controlled trials (RCT), case registration and observational studies. The main outcome indicators were ischemic stroke and major bleeding. The secondary outcome indicators included hemorrhagic shock, total stroke and cardiovascular death. **Result:** A total of 29 articles with 81 597 cases were included. The summary analysis showed that the incidence of major bleeding in LAAO group was lower than that in NOAC group (1.1/PY vs. 2.7/PY), while the incidence ischemic stroke in LAAO group was slightly higher than that in NOAC group (1.8/PY vs. 1.2/PY). **Conclusion:** The risk of major bleeding is higher in NOAC, however, the rate of ischemic stroke may be lower.

Key words atrial fibrillation; left atrial appendage occluder; new oral anticoagulant; Meta analysis

心律失常中非瓣膜性心房颤动(房颤)最常见,约占 60 岁以上老年人的 25%。随着年龄的增长,房颤发生率进一步增加,且房颤所致缺血性卒中是其最主要危害^[1]。控制房颤的主要目的是预防缺血性脑卒中发生。目前预防房颤所致卒中的主要方式有 4 种:一是香豆素类抗凝剂,代表药物为华法林,临床运用时间悠久,其抗凝效果及预防缺血性卒中效果显著,且价格便宜、容易购买,发生不良反应后有相应拮抗药物,目前仍为房颤抗凝一线用药;但华法林的很多缺点限制了其在临床上的运用,口服华法林需定期规律监测 INR 值,其治疗窗口窄等特点使其容易治疗效果不达标或者出血,且治疗过程受到多种食物或药物影响。二是新型口

服抗凝药(NOAC),目前主要包括达比加群、利伐沙班、阿哌沙班和依度沙班,其中几个大型随机对照实验(RCT)ARISTOLTE、ENGAGE AF-TIMI 48、RE-LY、ROCKET-AF 表明,NOAC 预防房颤所致缺血性卒中效果不劣于甚至优于华法林,且不良反应较华法林少,且治疗期间不需要监测 INR 值;但是其也存在不足之处:NOAC 价格相对昂贵,肾功能要求较高,且据报道消化道出血风险较高,一旦发生大出血无很好拮抗药物及治疗方法。三是左心耳封堵器(LAAO)治疗,这是一种比较新型的治疗手段,LAAO 主要包括 WATCHMAN 和 Amplatzer cardiac plug (ACP);已有相关 WATCHMAN 的 RCT (PROTECT AF、PREVEIL)研究显示,其与华法林相比较有更低的卒中风险、心血管死亡风险及出血风险^[2-3];但左心耳封堵术也有其缺点:手术相关并发症(心包积液、心包填塞、操作相关死亡、休克、器械栓塞、出血、器械周

* 基金项目:国家自然科学基金(No:81370404)

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围漏),术后需口服抗凝药如华法林一段时间(一般 45 d 左右),如超声心动图提示器械周围漏 > 5 mm,则需抗凝 6 个月^[4]。四是外科手术结扎或切除左心耳,此方法目前数据较少,治疗效果不确切,且对患者一般情况要求高,同样也存在术后并发症问题。本文旨在比较目前临床主要的 NOAC 和热门 LAAO(WATCHMAN、ACP)预防房颤所致卒中的有效性和安全性,最终为不同患者提供合适治疗方式的证据。

1 资料与方法

1.1 文献纳入与排除标准

文献纳入标准:①为 RCT、观察性研究或病例登记;②随访时间大于半年;③比较 NOAC 和 LAAO(WATCHMAN、ACP)预防房颤所致卒中的安全性和有效性,使用华法林桥接比较;④英文文献。排除标准:①综述类文献、动物实验、Meta 分析;②数据不全的文献;③重复发表的文献。

1.2 资料检索

检索 Pubmed、Embase 和 Cochrane 数据库,关键词为:atrial fibrillation, atrial appendage occlusion, New Oral Anticoagulants, WATCHMAN, Amplatzer /Amulet, stroke, bleeding 等,截止日期为 2018 年 10 月 31 日。

1.3 文献筛选与数据提取

由 2 名研究员根据预先设定好的文献纳入与排除标准独立筛选文献,首先浏览文题和摘要,必要时查看全文,产生疑问时与第 3 位研究员讨论后作出结论。对于符合纳入标准的文献,由 2 名研究员按预先设计的表格提取数据。提取内容包括各事件(缺血性卒中、大出血、出血性休克、总的卒中、心血管事件)发生率,随访发生率按 100 人每年发生事件数计算(例/PY)进行比较。大出血定义为一次出血血红蛋白降低 20 g/L 或需要进行输血治疗。

1.4 文献质量评价

RCT 文献利用 Jadad 量表评分,满分为 5 分;非 RCT 利用 NOS 量表评分,满分为 9 分。

1.5 统计学处理

运用 Stata 14 的 Meta 分析模块对提取的数据进行统计分析。采用随机效应模型(异质性大于 50%)或固定效应模型(异质性小于 50%)进行 meta 分析。统计值以 OR(95%CI)表示。以 Begg 检验评估潜在的发表偏倚。

2 结果

2.1 文献筛选结果

初检出相关文献 4 261 篇。根据纳入与排除标准,最终纳入文献 29 篇,总例数 81 597 例^[2-30]。其中,LAAO 相关文献 25 篇,共计 9 894 例,含 2 篇 RCT(732 例);NOAC 相关文献 4 篇,共计 7 1703

例,均为 RCT。文献筛选流程见图 1,文献基本特征见表 1。

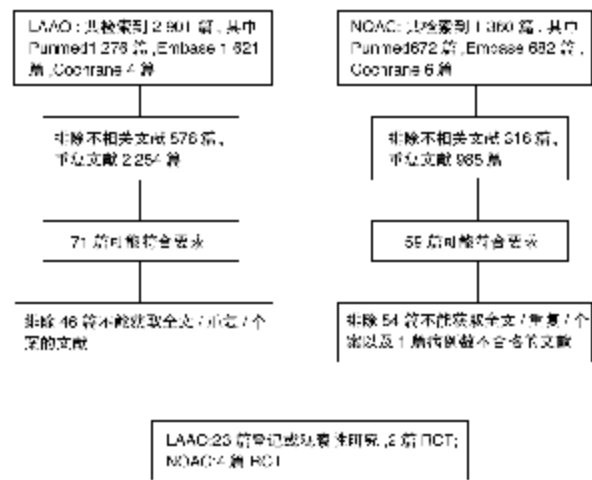


图1 文献筛选流程

Figure 1 The literature screening process

2.2 大出血发生率比较

共 13 篇文献报道了大出血发生率。各文献间存在较大统计学异质性($I^2 = 91.7\%$, $P < 0.05$),故运用随机效应模型。Meta 分析显示,LAAO 的大出血发生率较 NOAC 更低(1.1/PY : 2.7/PY)。见图 2。

2.3 缺血性卒中发生率比较

共 21 篇文献报道了缺血性卒中发生率,各文献间存在较大异质性($I^2 = 53\%$, $P < 0.05$),故运用随机效应模型。Meta 分析显示,LAAO 缺血性卒中的发生率较 NOAC 稍高(1.8/PY : 1.2/PY),但两者之间并无明显统计学差异。见图 3。

2.4 心血管死亡率比较

共 20 篇文献报道了心血管死亡率,各文献间存在较大异质性($I^2 = 68.5\%$, $P < 0.05$),故采用随机效应模型。Meta 分析显示,LAAO 心血管死亡率较 NOAC 稍低(1.6/PY : 2.2/PY),但两者之间并无明显统计学差异。见图 4。

2.5 出血性休克发生率比较

共 20 篇文献报道了出血性休克发生率,各文献间存在异质性($I^2 = 48.8\%$, $P < 0.05$),故运用固定效应模型。Meta 分析显示,LAAO 与 NOAC 的出血性休克发生率均较低(0.5/PY : 0.2/PY)。见图 5。

2.6 总的卒中发生率比较

共 20 篇文献报道了,各文献间存在较大异质性($I^2 = 53.5\%$, $P < 0.05$),故运用随机效应模型。Meta 分析显示,LAAO 与 NOAC 之间总的卒中发生率并无明显统计学差异(2.2/PY : 1.5/PY)。如图 6。

表 1 纳入文献的基本特征
Table 1 Basic Characteristics of included literatures

作者	措施	例数	文献类型	年龄 /岁	男性 /%	CHA2DS2 -VASc 评分	HAS- BLED 评分	卒中史 /%	高血压 /%	心力 衰竭 /%	糖尿病 /%	冠心病 /%	出血史 /%	文献 评分
Boersma(2016) ^[28]	WATCHMAN	1 021	病例登记	73±9	59.90	4.5±1.6	2.3±1.2	30.40	81.70	34.20	29.60	N/A	31.20	5
Reddy(2013) ^[30]	WATCHMAN	150	病例登记	72.5±7.4	64	4.4±1.7	N/A	40.70	94.70	28.70	32.00	N/A	93	5
Landmesser(2017) ^[29]	ACP	1 088	病例登记	75±8	64.40	4.2±1.6	3.3±1.1	37.70	84.20	17.40	31.40	N/A	72.50	5
Reddy(2017) ^[7]	WATCHMAN	3 882	病例登记	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	5
Tzikas(2016) ^[5]	ACP	1 047	病例登记	75±8	62	4.5±1.6	3.1±1.2	39	87	26	29	36	47	6
Betts(2017) ^[6]	WATCHMAN/ACP	371	观察性研究	72.9±8.26	88.90	4.2±1.5	3.3±1.2	49.60	74.70	19.10	18.90	N/A	64.90	6
Saw(2017) ^[8]	WATCHMAN	106	病例登记	74.8±7.7	62.30	4.3±1.5	3.2±1.2	28.30	82.10	30.20	35.80	45.30	89.60	6
Berti(2017) ^[9]	ACP	613	病例登记	75.1±8.0	62.50	4.2±1.5	3.2±1.1	37	N/A	N/A	N/A	N/A	27.40	6
Huang(2017) ^[10]	WATCHMAN	106	病例登记	64.2±8.6	59.40	3.6±1.6	N/A	41	62.30	N/A	11.30	30.20	11.30	5
Figini(2017) ^[11]	WATCHMAN/ACP	165	观察性研究	72±8	57.30	3.8±1.6	3.4±1.3	19	N/A	N/A	N/A	22.70	21.20	6
Park(2011) ^[12]	ACP	143	病例登记	73.7±9.3	62	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	5
Buchbinder(2013) ^[4]	WATCHMAN	80	病例登记	76±8	55	4.1±1.5	3.1±1.1	15	N/A	N/A	N/A	N/A	N/A	5
Lopez-M?nguez (2013) ^[26]	ACP	35	病例登记	74.7±7.6	57.10	3.9±1.8	4.4±1.4	25.71	71.42	17.10	34.28	—	45.70	6
Nietlispach(2013) ^[13]	ACP	120	病例登记	74±10	68	3.7±1.6	2.6±1.2	33	82	N/A	28	N/A	N/A	6
Urena(2013) ^[14]	ACP	52	病例登记	74±8	57.70	5(4~6)	N/A	61.60	92.30	19.20	40.40	50	90.40	6
Wiebe(2014) ^[15]	ACP	60	病例登记	72.9±8.1	61.70	4.3±1.7	3.3±1.0	33.30	95.00	31.70	26.70	N/A	81.70	6
Santoro(2016) ^[27]	ACP	134	病例登记	76.6±7.6	59.70	3(2~3.75)	N/A	N/A	N/A	N/A	N/A	N/A	40	5
Jens Wiebe(2015) ^[19]	WATCHMAN	102	病例登记	71.6±8.8	62.70	4.3±1.7	2.9±1.2	40.10	N/A	36.30	27.50	N/A	N/A	6
Kim(2016) ^[21]	WATCHMAN/ACP	96	观察性研究	65.6±8.8	58.70	4.1±1.7	2.8±1.2	43.50	76.10	52.20	37	39.10	N/A	7
Danna(2013) ^[16]	ACP	37	病例登记	73.4±8.3	70.30	4.3±1.4	3.5±1.1	16.20	28	N/A	45.90	18.90	45.90	5
Sick(2007) ^[17]	WATCHMAN	75	病例登记	68.5	64	N/A	N/A	N/A	83.30	N/A	33.30	N/A	N/A	5
Glockler(2017) ^[18]	ACP	50	病例登记	76.1±8	60	5.2±1.8	3.5±0.9	34	100	16	44	70	N/A	5
Guérios(2017) ^[20]	ACP/WATCHMAN	92	观察性研究	73.1±10.1	59.30	4.5±1.5	3.6±1.0	49.50	85.70	30.80	36.30	N/A	61.50	6
Holmes(2009) ^[3]	WATCHMAN	269	RCT	74.0±7.4	67.70	3.8±1.2	N/A	27.50	88.50	23.40	33.80	N/A	N/A	4
Reddy(2014) ^[2]	WATCHMAN	463	RCT	71.7±8.7	70.40	N/A	N/A	17.70	89.60	26.80	24.40	N/A	N/A	4
Connolly(2009) ^[22]	NOAC	18 113	RCT	71.4±6	63.7	2.1±1.1	N/A	20.1	78.9	20.1	23.4	N/A	N/A	5
Granger(2011) ^[23]	NOAC	18 201	RCT	70±6	64.5	2.1±1.1	N/A	19.2	87.3	19.2	25	N/A	16.7	5
Patel(2011) ^[24]	NOAC	14 264	RCT	73±5	60.3	3.48±0.94	N/A	54.9	90.3	54.9	40.4	N/A	N/A	5
Giugliano(2013) ^[25]	NOAC	21 105	RCT	72±6	62.3	2.8±1.0	N/A	28.2	93.6	28.2	35.8	N/A	N/A	5

CHA2DS2-VASc:房颤卒中风险评分;HAS-BLED:抗凝出血危险评分。

2.7 偏倚分析

对报道了缺血性卒中的文献绘制漏斗图,结果显示,散点集中分布在无效线两侧,漏斗图基本对称,提示纳入的相关文献存在发表偏倚的可能性较小。见图 7。

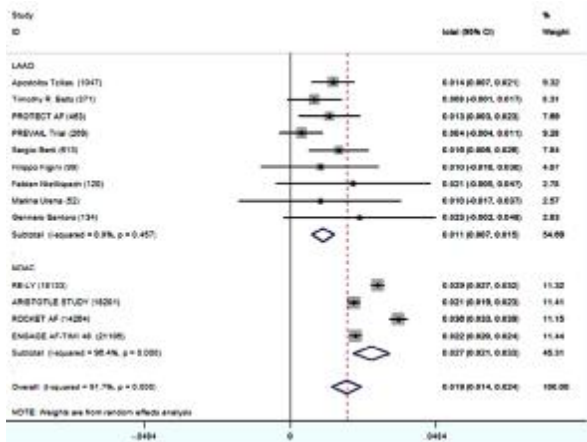


图 2 LAO 及 NOAC 随访期间大出血发生率的比较
Figure 2 The incidence of major bleeding during the follow-up period

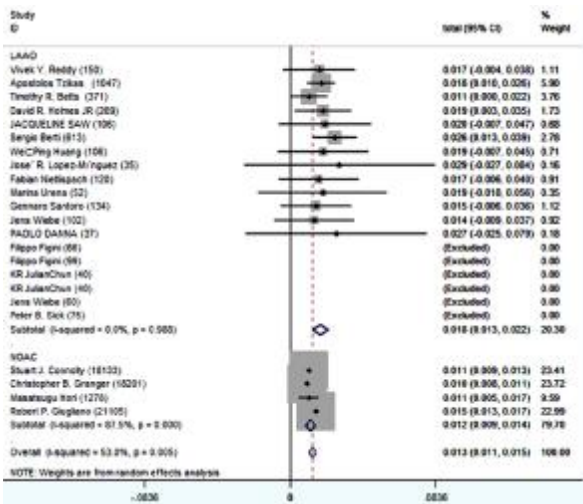


图 3 LAO 及 NOAC 随访期间缺血性卒中发生率的比较
Figure 3 The incidence of ischemic stroke during the follow-up period

3 讨论

目前预防房颤所致缺血性卒中的主要方式中, LAO及NOAC之间的效果及不良反应尚不明

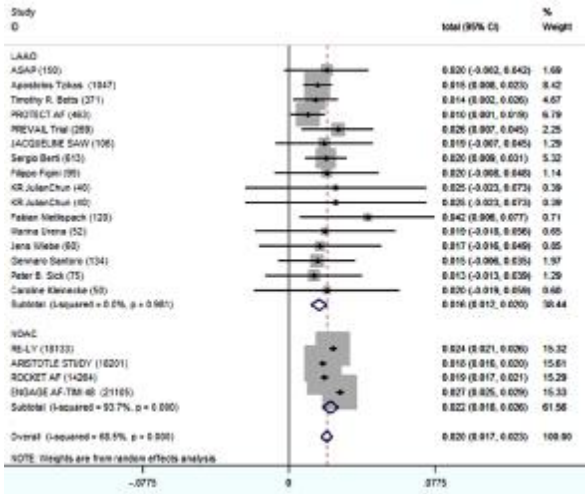


图 4 LAAO 及 NOAC 随访期间心血管死亡率的比较
Table 4 The incidence of cardiovascular death during the follow-up period

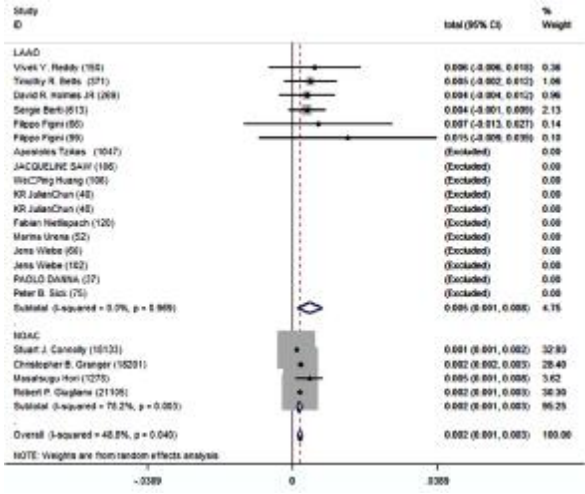


图 5 LAAO 及 NOAC 随访期间出血性休克发生率的比较
Figure 5 The incidence of hemorrhagic shock during the follow-up period

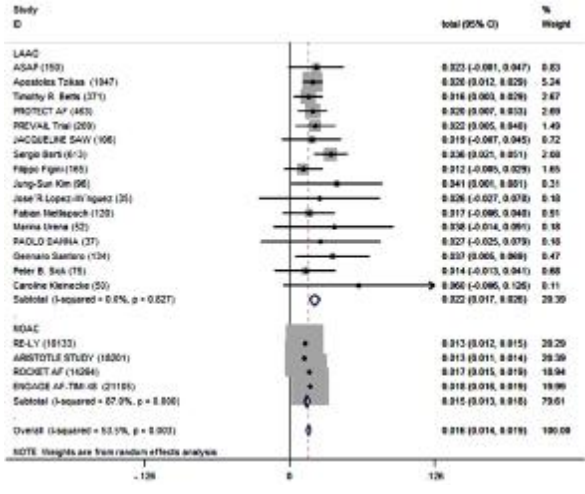


图 6 LAAO 及 NOAC 随访期间总的卒中发生率比较
Figure 6 The incidence of total stroke during the follow-up period

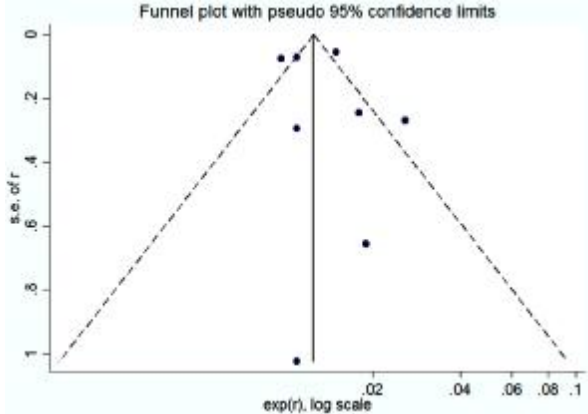


图 7 缺血性卒中相关文献的漏斗图
Figure 7 The funnel plot of literatures related to ischemic stroke

确,本文汇总分析显示:NOAC 较 LAAO 预防缺血性卒中效果可能更好,但发生大出血风险更高,两者在出血性休克、总卒中及心血管死亡方面无明显差异。Reddy 等^[31]报道,LAAO 近期花费较 NOAC 更高,但是远期花费更少且有效性更高。本文发现,NOAC 有更高的出血风险,缺血风险高、出血风险低患者选择 NOAC 可能更好,而出血风险高而缺血风险相对低患者可能更适合 LAAO。

本文纳入文献的异质性较高考虑以下可能原因:各中心患者基线资料存在差异;达比加群、依度沙班存在两种剂量,本文统计两种剂量综合资料;各文献病例数差距较大;考察标准不一致,封堵器技术熟练度不一致;率的 Meta 分析存在稳定性欠佳的不足。目前尚无直接比较 NOAC 和 LAAO 的随机对照试验,其真实情况是怎样的还不清楚,不过有相关研究正在进行^[32]。本文未对外科手术切除或结扎左心耳预防血栓的效果进行比较,主要原因是相关文章及病例数量缺乏,但近期有报道显示,左心耳切除+心外膜射频消融治疗房颤效果较好^[33]。今后外科联合内科预防房颤所致卒中能否成为主要治疗方向也值得探讨。

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冷冻球囊消融右下肺静脉的临床实践体会

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【摘要】 目的:在心房颤动(房颤)冷冻球囊消融(CBA)中,应用不同方法封堵右下肺静脉(RIPV),以评价其对肺静脉电隔离(PVI)成功率的影响及其临床价值。**方法:**回顾性分析 2017-12—2018-10 于我院心血管内科接受 CBA 治疗的阵发性房颤(PAF)43 例,其中以采取“倒 U”冷冻 RIPV 共 24 例作为试验组,非“倒 U”冷冻 RIPV 共 19 例作为对照组。比较两组的单次消融 RIPV 电隔离成功率、双侧 PVI 成功率、手术时间、X 线曝光时间、并发症等情况。**结果:**与非“倒 U”冷冻法相比,采取“倒 U”冷冻 RIPV 的单次消融电隔离率高,手术时间及 X 线曝光时间明显缩短,但两组的双侧 PVI 成功率、并发症基本一致。**结论:**CBA 治疗房颤时,采取“倒 U”冷冻 RIPV 提高单次消融电隔离成功率,缩短手术时间和 X 线曝光时间,具有良好的可操作性及安全性。

【关键词】 心房颤动;阵发性;冷冻球囊消融;肺静脉电隔离

doi:10.13201/j.issn.1001-1439.2019.07.016

【中图分类号】 R541.7 **【文献标志码】** A

Clinical experience of cryoballoon ablation of right inferior pulmonary vein

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Abstract Objective: To evaluate the effect and clinical value of cryoballoon ablation (CBA) in blocking the right inferior pulmonary vein (RIPV) with different ways in patients with atrial fibrillation, and to discuss the success rate of pulmonary vein electrical isolation (PVI). **Method:** A retrospective analysis was made in 43 cases with paroxysmal atrial fibrillation (PAF) treated with CBA from December 2017 to October 2018. Among them, 24 cases were treated with "inverted U" CBA (experimental group) and 19 cases were treated with non-"inverted U" CBA (control group). The success rates of RIPV isolation and bilateral PVI, operation time, X-ray exposure time, and complications were compared between the two groups. **Result:** Compared with non-"inverted U", the success rate of RIPV after a single ablation was higher, while the operation time and the X-ray exposure time were obviously shortened in patients treated with "inverted U". There was no significant statistical difference in the success rate of bilateral PVI and complications in the two groups. **Conclusion:** The "inverted U" freeze method can improve the success rate of RIPV after a single ablation and shorten the operation time and X-ray exposure time, which is safe and operable to operate in patients with atrial fibrillation.

Key words paroxysm atrial fibrillation; cryoballoon ablation; pulmonary vein isolation

心房颤动(房颤)为临床常见的心律失常之一,长期房颤容易导致心功能不全、左心房血栓、脑卒

中等严重并发症。导管消融可降低射血分数下降的心力衰竭(heart failure with reduced ejection fraction, HFrEF)合并房颤患者的死亡风险,亦是临床治疗药物难治性症状性房颤的 I A 类推荐^[1]。

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(收稿日期: 2019-02-19)