论著·临床医学

非瓣膜性房颤在DSA/TEE引导下行“一站式”介入治疗的安全性及有效性研究

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[**摘要**] **目的** 非瓣膜性房颤(non-valvular atrial fibrillation, NVAF)“一站式”介入治疗传统依赖经食道超声(transesophageal echocardiography,TEE)引导,存在麻醉及食道损伤等局限;而数字减影血管造影(digital subtraction angiography,DSA)联合经胸超声心动图(transthoracic echocardiography,TTE)引导能否兼顾疗效与流程简化尚不明确。为此,对不同影像学引导下NVAF“一站式”治疗的安全性与有效性进行对比分析。**方法** 采用队列研究设计,严格依据既定纳入与排除标准,选择2014年8月1日至2024年07月31日在陆军军医大学第一附属医院心内科住院并行“一站式”介入治疗的NVAF患者为研究对象,根据术中引导方式不同分为DSA联合TTE组(简称DSA组,n=77)与DSA联合TEE组(简称TEE组,n=209)。从医院大数据智能平台病历系统收集患者的相关资料包括:性别、年龄、合并基础疾病、TTE和TEE检查结果等,随访患者术后心房颤动复发、卒中、出血、器械相关血栓(device-related thrombosis,DRT)、心包填塞、心衰住院、心源性死亡等情况,应用统计学方法比较2组患者行“一站式”介入治疗的安全性和有效性。**结果** 共计286例患者入组本研究,其中男性170例,女性116例,DSA组77例,TEE组209例。所有患者均完成6个月以上随访,平均随访时间(36.49±14.26)个月。2组患者的基线资料比较无统计学差异。DSA组平均手术时间更短[(202.4±39.3)min *vs* (214.1±33.4)min,P=0.013]。DSA组DRT的发生比例高于TEE组(3.9% *vs.* 1.4%),但两者比较无统计学差异。DSA组心房颤动复发为10例(13%),TEE组为19例(9.1%),两者相比无统计学差异。在终末事件比较上:2组患者在卒中、大出血、心包填塞、心衰再住院及心源性死亡等方面均无统计学差异。Kaplan-Meier生存曲线分析结果显示,2组患者复合终点[复合心脑血管事件(major adverse cardiovascular and cerebrovascular Events,MACE)、疗效复合终点(房颤复发、心衰再住院、卒中、TIA)]方面无统计学差异。**结论** NVAF患者行“一站式”介入治疗时,DSA引导可缩短手术时间,除DRT的发生有增加趋势外,可取得与TEE引导一致的安全性和有效性。

[**关键词**] 心房颤动;“一站式”介入治疗;数字减影血管造影;经食道超声;左心耳封堵

[**中图法分类号**] R445;R540.46;R541.75 [**文献标志码**] A

Safety and efficacy of “one-stop” interventional therapy for non-valvular atrial fibrillation under DSA/TEE guidance

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[**Abstract**] **Objective** “One-stop” interventional therapy for non-valvular atrial fibrillation (NVAF)

[**基金项目**] 重庆市自然科学基金面上项目(CSTB2024NSCQ-MSX0771)

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引用格式:唐西芝,柴虹,陈兴华,等. 非瓣膜性房颤在DSA/TEE引导下行“一站式”介入治疗的安全性及有效性研究[J]. 陆军军医大学学报,2026,48(08):1092-1099. DOI:10.16016/j.2097-0927.202601030.

Citation:TANG X Z, CHAI H, CHEN X H, *et al*. Safety and efficacy of “one-stop” interventional therapy for non-valvular atrial fibrillation under DSA/TEE guidance[J]. J Army Med Univ, 2026, 48(08):1092-1099. DOI:10.16016/j.2097-0927.202601030.

traditionally relies on transesophageal echocardiography (TEE) guidance, which carries limitations including anesthesia requirements and esophageal injury risks. Whether digital subtraction angiography (DSA) combined with transthoracic echocardiography (TTE) guidance can balance therapeutic efficacy with procedural simplification remains unclear. This study aims to compare the safety and efficacy of "one-stop" procedure for NVAF under different imaging guidance modalities. **Methods** Based on predefined inclusion and exclusion criteria, this retrospective cohort study was conducted on consecutive NVAF patients undergoing combined "one-stop" interventional therapy in Department of Cardiology of our hospital between August 1, 2014 and July 31, 2024. According to intraoperative guidance methods, they were divided into the DSA combined with TTE group (DSA group, n=77) and the DSA combined with TEE group (TEE group, n=209). Relevant clinical data of the patients were collected from the hospital big data intelligent platform medical record system, including gender, age, comorbidities, and results of TTE and TEE examinations. Postoperative follow-up included atrial fibrillation recurrence, stroke, bleeding, device-related thrombosis (DRT), cardiac tamponade, hospitalization due to heart failure, and cardiac death. The safety and efficacy of the "one-stop" procedure were compared between the 2 groups. **Results** There were 286 patients enrolled in this study, including 170 males and 116 females, with 77 in the DSA group and 209 in the TEE group. All patients completed at least 6 months of follow-up, with a mean duration of 36.49±14.26 months. No statistically significant differences were observed in baseline characteristics between the 2 groups (P>0.05). The DSA group demonstrated shorter mean procedural time (202.4±39.3 *vs* 214.1±33.4 min, P=0.013). The incidence of DRT was higher in the DSA group than in the TEE group (3.9% *vs* 1.4%), though the difference was not statistically significant (P=0.411). Atrial fibrillation recurrence occurred in 10 patients (13.0%) in the DSA group and 19 patients (9.1%) in the TEE group, with no significant intergroup difference. Regarding clinical endpoints, no significant differences were observed between the 2 groups in terms of stroke, major bleeding, cardiac tamponade, heart failure rehospitalization, or cardiac death. Kaplan-Meier survival curve analysis revealed no statistical differences between the 2 groups in composite endpoints, such as major adverse cardiovascular events (MACE), and in the efficacy composite endpoint, including atrial fibrillation recurrence, heart failure rehospitalization, stroke, or transient ischemic attack. **Conclusion** For NVAF patients undergoing one-stop procedures, DSA guidance can shorten procedural time and achieve comparable safety and efficacy to TEE guidance, with the exception of a trend toward increased DRT incidence.

[**Key words**] atrial fibrillation; "one-stop" interventional treatment; digital subtraction angiography; transesophageal echocardiography; left atrial appendage occlusion

Supported by the General Project of Natural Science Foundation of Chongqing (CSTB2024NSCQ-MSX0771). Corresponding author: LI Huakang, E-mail: lihuakang1980@tmmu.edu.cn

心房颤动(atrial fibrillation, AF)是临床上常见的心律失常,缺血性卒中是其致残、致死的主要原因。全球疾病负担研究显示[1]:我国≥45岁人群AF相关卒中年龄标化发病率已升至65.3/10万,且仍以每年2.1%的速度上升,给社会带来严重的负担。尽管口服抗凝药(oral anticoagulants, OAC)可使卒中相对风险下降,但长期应用面临出血风险升高、药物间相互作用,以及患者用药依从性不佳等挑战[2]。并且真实世界数据显示,我国老年AF患者高出血评分(HAS-BLED≥3)患者比例高达42%,1年OAC持续服用率仅28.7%,颅内出血风险随年龄呈指数级增加[3]。

症状管理和卒中预防是AF治疗的核心。经导管射频消融虽可改善部分AF患者的临床症状[4],但消融术后仍旧存在一定的复发率,且高血栓栓塞风险患者仍需要长期口服OAC预防脑卒中。左心耳封堵(left atrial appendage occlusion,LAAO)通过机械隔离达到预防血栓栓塞的目的,已被多项临床研究证实可显著降低非瓣膜性房颤(non-valvular atrial fibrillation, NVAF)患者卒中风险[5-7]。"一站式"介入手术通过同期行射频消融和左心耳封堵达到节律控制和卒中预防的双重目的,SWAANS等[8]首次尝试了高卒中风险且OAC禁忌的AF患者同期接受"一站式"介入治疗,证实了其可行性,随后多项临床研究亦验证了该手术的安全性与有效性[9-11,16]。

经典LAAO要求采用全麻和经胸超声心动图(transthoracic echocardiography,TTE)引导下进行,但是,随着经验累积、器械迭代发展,LAAO的手术风险不断降低,全身麻醉、TEE检测等措施在一些情况下反而可能会增加患者的相关风险,增加手术及康复的时间和费用。ZHANG等[10]的研究指出,在局部麻醉下仅采用数字减影血管造影(digital subtraction angiography,DSA)引导行Watchman装置LAAO手术,较TEE+DSA(全身麻醉)可缩短手术时间约8.69 min,且未显著增加主要不良事件发生率,同时可避免TEE相关的食管/口咽损伤等并发症。CHEN等[9]的研究表明,"一站式"介入治疗的成功主要取决于规范的手术操作及严格把握手术适应症,而与术中是否常规联合使用TEE引导无关,这也为在该术式中探索更简化的影像引导策略提供了循证医学依据。目前DSA引导LAAO的循证证据多局限于单纯LAAO[10-12],而"一站式"介入治疗的研究较少,并且局限于小样本研究[13-14]。本研究回顾性分析本中心DSA/TEE引导行"一站式"介入治疗的资料,来进一步验证DSA引导下行"一站式"介入治疗的安全性和有效性。

1 资料与方法

1.1 研究人群

采用队列研究设计,回顾性收集了2014年8月1日至2024年07月31日在陆军军医大学第一附属医院心血管内科住院并行"一站式"介入治疗的NVAF患者为研究对象。

纳入标准:①符合NVAF诊断标准;②符合LAAO手术指征并成功进行LAAO的患者,植入封堵器类型为Watchman左心耳封堵器;③临床资料完整,包括人口学特征、临床病史、实验室检查及影像学资料,并完成6个月以上随访。排除标准:①临床资料缺失的患者;②植入封堵器为其他类型的患者;③瓣膜型房颤患者,以及接受过瓣膜手术的患者;④合并先天性心脏病的患者;⑤严重肝肾功能不全者;⑥目前存在明显感染状态的患者;⑦近3个月有输血史、严重的血液系统疾病者;⑧甲亢、晚期恶性肿瘤恶病质等导致全身代谢功能异常的患者;⑨3个月内接受过大型手术;⑩未按要求完成随访者。所有患者均签署手术知情同意书,本研究获得陆军军医大学第一附属医院伦理委员会批准[(B)KY2024323)]。

1.2 "一站式"介入治疗的适应证和禁忌证

适应证:①NVAF(TTE检测排除中度以上二尖瓣狭窄或机械心脏瓣膜置换术后患者);②CHA2DS2-VASc评分≥2分,或HAS-BLED评分≥3分;③年龄≥60岁(对于有卒中/TIA发作史或合并巨大型ASD患者,年龄适当放宽);④有口服抗凝药禁忌证或不愿长期服用抗凝药者;⑤房颤导管消融术后复发或不适合行导管消融术的房颤患者。禁忌证:①术前TEE或心脏CT造影(cardiac CT angiography,CCTA)检查发现左心房或左心耳内血栓形成者;②术前TEE检查提示左心耳解剖结构复杂(如LAA开口过小或过大等),现有技术和设备条件下不适合行LAAO者;③术前TTE检查提示LVEF<30%,或心包积液量≥10 mm、且原因不明者;④经TTE检查确定为瓣膜性房颤患者;⑤合并有需心脏外科处理的其他心脏疾病者(如需外科手术治疗的先心病或严重冠心病等);⑥严重肝肾功能不全或有其他心血管介入手术禁忌证者。

1.3 左心耳封堵器械及三维标测系统

本研究所用左心耳封堵装置为Watchman左心耳封堵器(美国波科公司)生产。

1.4 临床资料收集与分组方法

1.4.1 临床资料收集内容及来源 从医院大数据智能平台病历系统收集患者的资料,包括:①病史资料:年龄、性别、合并的基础疾病(如高血压病、冠心病等)、CHA_2DS_2-VA评分、HASBLED评分;②辅助检查资料:血常规、肝功、肾功、凝血功能、TTE结果、TEE检查结果等;③手术相关资料:封堵器大小、有无残余分流等;④术后随访资料。

1.4.2 影像引导方式的定义与分组 根据术中引导手术方式的不同,将完成"一站式"手术的患者分为2组:DSA联合TTE组(简称DSA组,n=77)与DSA联合TEE组(简称TEE组,n=209例)。

1.5 DSA组与TEE组的手术操作方法及麻醉方式

依照本科室导管室常规操作方法使用CARTO标测系统进行射频消融术(catheter ablation,CA)[15]。在DSA组中,手术仅在局部麻醉下进行,使用DSA+TTE完成全部评估。通过CA建立的股静脉通路送入LAAO输送鞘及猪尾导管。封堵器释放前后,在DSA引导下行RAO 30°/CRAN 20°、CAU 20°、RAO 30°/CAU 20°三个角度进行造影,评估左心耳开口、封堵器位置及是否存在残余漏,用TTE评估有无心包积液及封堵器有无明显突出。TEE组患者依照我科导管室LAAO常规操作方法进行[16]。所有"一站式"手术均由接受本中心统一培训的副主任医师完成,人员构成稳定,术者经验和技术水平高度同质化。本研究中所

记录的手术时间仅指从股静脉穿刺开始至封堵器释放结束的纯操作时间,不包括麻醉准备、麻醉诱导及苏醒时间。

1.6 术后随访方案及抗栓治疗方案

术后随访时间为术后30 d、45~60 d、3个月、6个月和12个月,以后每年随访1次。随访内容:①自觉症状:包括有无心血管死亡、脑卒中/TIA/系统性栓塞、大出血、心力衰竭等;②复查心电图、TTE(45~60 d随访时加做TEE),观察封堵器位置有无移位、有无器械相关血栓(device-related thrombosis,DRT)、形成及残余分流。随访期间进行统一的规范化节律控制和抗栓治疗方案。

1.7 主要与次要疗效及安全性终点定义

主要终点为AF复发和卒中。AF复发定义为术后3个月后出现持续时间≥30 s的AF;前3个月为"空白期",此期间发作不计入复发[17]。卒中(缺血性或出血性)通过颅脑CT或MRI确诊。次要终点包括全因死亡、心衰再住院、心源性死亡、TIA、大出血、LAAO相关事件(残余分流、DRT)。

1.8 统计学分析

所有统计分析使用SPSS 27软件完成。符合正态分布的连续变量以$\bar{x}\pm s$表示,不符合正态分布变量以$M(P_{25},P_{75})$表示,分类变量以百分比表示。生存分析采用Kaplan-Meier法,组间比较使用log-rank检验。$P<0.05$认为差异有统计学意义。

2 结果

2.1 2组患者基线资料无显著差异

一共286例NVAF患者入选本研究,其中男性170例,女性116例,DSA组77例,TEE组209例,2组患者的性别、年龄、身高、体重、CHA_2DS_2-VA评分、HAS-BLED评分、房颤类型(持续性)、心力衰竭、卒中、糖尿病、高血压、吸烟史、饮酒史等,差异无统计学意义,见表1。

表1 2组NVAF患者术前基线特征比较[$\bar{x}\pm s$, 例(%)]

Table 1 Baseline characteristics of NVAF patients in the 2 groups before procedure [$\bar{x}\pm s$, n(%)]

Baseline characteristics	DSA(n=77)	TEE(n=209)	t/χ^2	P
Male	48(62.34)	122(58.37)	0.367	0.545
Age /years	72.8±9.8	73.3±7.8	−0.383	0.702
Height /cm	161.2±7.5	161.2±6.6	0.015	0.988
Weight /kg	65.2±11.6	64.6±10.7	0.438	0.662
CHA_2DS_2-VA score	2.83±1.07	2.67±1.12	1.092	0.276
HAS-BLED score	3.57±1.36	3.68±1.51	−0.595	0.553
Type of AF (Persistent)	43(40.19)	107(51.96)	0.487	0.485
Heart failure	61(79.22)	158(75.60)	0.416	0.521
Stroke	11(14.29)	45(21.53)	0.416	0.171
Diabetes	13(16.89)	40(19.14)	0.191	0.663
Hypertension	60(77.92)	177(84.69)	1.894	0.059
Smoking history	24(31.17)	68(32.53)	0.049	0.826
Drinking history	33(42.86)	82(39.23)	0.308	0.579

NVAF: non-valvular atrial fibrillation; TEE: transesophageal echocardiography; TTE: transthoracic echocardiography; DSA: digital subtraction angiography; AF: atrial fibrillation

2.2 2组术前试验室检查指标无显著差异

2组患者术前凝血功能(PT、PT-INR、Fbg、TT、APTT、D-dimer)、血常规(Hct、RBC、Hb、PLT)及肝功能(AST、ALT)指标比较,差异均无统计学意义,见表2。

表2 2组NVAF患者术前实验室检查指标比较[$\bar{x}\pm s$, 例(%)]

Table 2 Preoperative laboratory indicators of NVAF patients in the 2 groups [$\bar{x}\pm s$, n(%)]

Baseline characteristics	DSA(n=77)	TEE(n=209)	t/χ^2	P
PT/s	12.8±5.1	12.8±3.4	−0.015	0.988
PT-INR	1.13±0.47	1.13±0.31	−0.149	0.882
Fbg/(g/L)	3.0±0.9	2.8±0.8	−1.924	0.055
TT/s	24.5±22.4	21.9±17.2	−1.044	0.298
Prothrombinactivity/%	87.1±26.9	82.9±26.0	−1.201	0.231
APTTratio	30.5±9.2	29.9±5.4	−0.679	0.498
D-dimer/(μg/L)	16.1±29.9	43.8±170.5	−0.682	0.158
Hct/%	40.0±4.5	40.9±5.3	1.433	0.153
RBC/$\times10^{12}$L^{-1}	4.37±0.62	4.45±0.54	1.032	0.303
Hb/(g/L)	133.1±14.6	135.2±17.1	0.975	0.330
PLT/($\times10^9$L^{-1})	184.5±71.8	171.6±53.0	−1.660	0.098
AST/(U/L)	25.9±14.8	29.2±14.8	1.660	0.098
ALT/(U/L)	22.9±17.4	26.4±20.4	1.337	0.182

2.3 2组术前心脏及食道超声参数无显著差异

2组患者的术前心脏超声及食道超声比较:左心耳宽度0°、左心耳深度0°、左心耳宽度45°、左心耳宽度135°、左心耳深度135°、室间隔厚度、右心室内径、横径、肺动脉内径、左室舒张末容积、左心室射血分数等均无统计学差异,见表3。

2.4 DSA组手术时间显著短于TEE组,封堵器参数无差异

2组患者封堵器尺寸、在0°、45°、90°及135°角度下的封堵器宽度、封堵器压缩比、住院天数等,差异均无统计学意义。但DSA组的手术时间显著短于TEE组[(202.4±39.3)min *vs* (214.1±33.4) min,P=0.013],见表4。

表3 2组NVAF患者术前心脏超声及食道超声指标比较[$\bar{x}\pm s$, 例(%)]

Table 3 Preoperative transthoracic and transesophageal echocardiographic parameters of NVAF patients in the 2 groups [$\bar{x}\pm s$, n(%)]

Baseline characteristics	DSA(n=77)	TEE(n=209)	t/χ^2	P
Left atrial diameter /mm	41.7±5.5	41.1±5.6	1.143	0.255
Left ventricular diameter /mm	49.3±5.4	48.3±5.9	−0.371	0.711
Interventricular septal thickness /mm	10.8±2.1	10.6±2.1	0.417	0.677
Right ventricular diameter /mm	19.8±1.8	19.9±1.7	−0.360	0.719
Right atrial transverse diameter /mm	38.1±5.7	38.7±6.0	−1.058	0.291
Left ventricular end-diastolic volume /mL	116.5±27.0	116.3±29.2	−0.932	0.352
Left ventricular stroke volume /mL	69.3±15.6	67.1±15.4	−1.890	0.060
Left ventricular ejection fraction /%	59.7±8.2	58.8±9.6	−0.862	0.389
Left atrial appendage width at 0° /mm	20.5±0.8	20.7±0.8	−0.423	0.673
Left atrial appendage depth at 0° /mm	23.7±0.9	23.8±1.2	1.632	0.104
Left atrial appendage width at 45° /mm	19.8±0.7	19.9±0.9	0.358	0.720
Left atrial appendage depth at 45° /mm	23.6±1.0	23.8±1.1	0.810	0.419
Left atrial appendage width at 90° /mm	20.3±0.6	20.4±1.1	0.468	0.640
Left atrial appendage depth at 90° /mm	24.0±1.4	24.2±1.1	0.633	0.527
Left atrial appendage width at 135° /mm	21.2±0.8	21.3±1.0	0.559	0.577
Left atrial appendage depth at 135° /mm	24.0±1.2	24.1±1.1	1.089	0.277

表4 2组NVAF患者术中封堵器参数及手术时间比较[$\bar{x}\pm s$, 例(%)]

Table 4 Intraoperative occluder parameters and procedure time of NVAF patients in the 2 groups [$\bar{x}\pm s$, n(%)]

Baseline characteristics	DSA (n=77)	TEE (n=209)	t/χ^2	P
Device size/mm	27.6±2.3	27.5±3.1	−0.295	0.768
Device width at 0°/mm	21.62±0.46	21.70±3.16	0.231	0.817
Device compression ratio at 0°/%	20.08±1.49	19.85±5.72	−0.352	0.725
Device width at 45°/mm	21.60±0.46	21.68±3.11	0.231	0.817
Device compression ratio at 45°/%	19.83±0.00	19.83±5.61	0.000	1.000
Device width at 90°/mm	21.63±0.46	21.72±3.18	0.234	0.815
Device compression ratio at 90°/%	19.73±0.00	19.73±5.75	0.000	1.000
Device width at 135°/mm	21.69±0.47	21.78±3.22	0.225	0.809
Device compression ratio at 135°/%	19.49±0.00	19.49±6.01	0.000	1.000
Procedure time/min	202.4±39.3	214.1±33.4	2.496	0.013
Length of hospital stay/d	5.98±7.09	5.38±2.31	0.727	0.468

Procedure time includes only the pure operative time (from femoral venous puncture to the end of occluder release) and excludes anesthesia time

2.5 2组术后终末事件发生率无显著差异

所有患者均完成6个月以上随访,DSA组发生DRT 3例(3.9%),TEE组3例(1.4%),2组比较无统计学差异;DSA组AF复发10例(13.0%),TEE组19例(9.1%),差异亦无统计学意义。TEE组出现2例(1.0%)咽喉部损伤事件,DSA组0例,2者相比没有统计学差异。DSA组与TEE组在卒中、大出血、心包填塞、残余分流、心衰再住院、全因死亡及心源性死亡等主要不良事件发生率方面差异均无统计学意义,同时复合心脑血管事件(major adverse cardiovascular and cerebrovascular Events,MACE)(心源性死亡、大出血、心包压塞、DRT)、疗效复合终点(房颤复发、心衰再住院、卒中、TIA)无统计学差异,见表5。

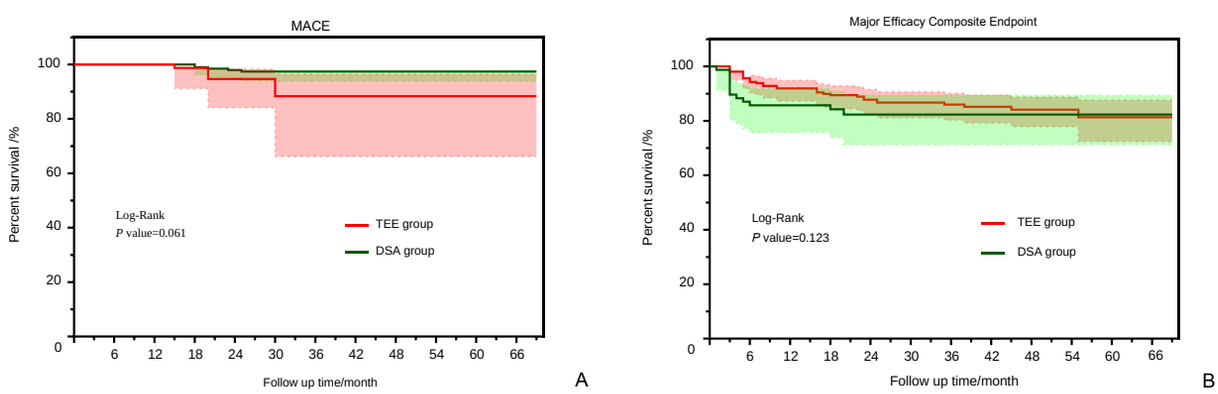
2.6 2组术后累积无事件生存率无显著差异

通过Kaplan-Meier法对2组患者术后结局进行分析,评估的终点包括主要MACE、DRT、疗效复合终点(房颤复发、心衰再住院、卒中、TIA)。生存曲线分析显示,DSA组与TEE组在主要疗效复合终点和MACE的累积无事件生存率上无显著差异,见图1。

表5 2组NVAF患者术后随访期间终末事件发生情况比较[$\bar{x}\pm s$,例(%)]

Table 5 Comparison of terminal events during follow-up between the 2 groups of NVAF patients [$\bar{x}\pm s$, n(%)]

Baseline characteristics	DSA (n=77)	TEE (n=209)	t/χ^2	P
Efficacy evaluation				
Atrial fibrillation recurrence	10 (13.0)	19 (9.1)	0.937	0.333
Transient ischemic attack (TIA)	0 (0)	0 (0)	-	-
Stroke	0 (0)	0 (0)	-	-
Heart failure rehospitalization	5 (6.5)	17 (8.1)	0.213	0.644
Total efficacy events	13 (16.9)	31 (14.8)	0.182	0.670
Safety evaluation				
All-cause death	3 (3.9)	4 (1.9)	0.926	0.336
Major bleeding	0 (0)	1 (0.5)	0.370	0.543
Device-related thrombosis (DRT)	3 (3.9)	3 (1.4)	1.659	0.198
Cardiac tamponade	0 (0)	1 (0.5)	0.370	0.543
Cardiac death	1 (1.3)	0 (0.0)	2.724	0.099
MACE	4 (5.2)	5 (2.4)	1.450	0.229
Complications				
Residual shunt	2 (2.6)	17 (8.1)	2.781	0.095
Throat injury	0 (0)	2 (1.0)	0.742	1



A: Survival curve of major adverse cardiovascular event (MACE); B: Survival curve of primary efficacy composite endpoint

图1 2组NVAF患者术后累积无事件生存率比较

Figure 1 Comparison of cumulative event-free survival rates after procedure between the 2 groups of NVAF patients

3 讨论

3.1 DSA引导策略可获得与TEE引导相当的安全性与有效性

房颤是临床上常见的心律失常,“一站式”介入治疗是其重要的治疗手段,可同时达到节律控制和卒中预防的目的。近年来,随着“一站式”介入治疗的逐步开展,尤其2025年公布的OPTION研究结果证实:对于卒中风险高危的房颤患者,“一站式”介入治疗相比射频消融+口服抗凝药物可以显著降低非手术相关出血风险(56%),且在36个月内全因死亡、卒中及系统性栓塞的复合终点方面非劣效[18],同时《2025中国心房颤动管理指南》将心房颤动“一站式”介入治疗的推荐级别提到了IIa[19],这进一步奠定了“一站式”介入治疗在房颤治疗中的地位。随着“一站式”介入治疗在房颤患者中治疗地位的提高,如何确保在安全有效的前提下简化操作流程、提升患者舒适度,已成为临床关注的重要议题。本研究通过单中心回顾性分析,对在DSA+TTE和DSA+TEE 2种引导策略下行非瓣膜性房颤的“一站式”介入治疗进行了对比,证实除手术时间有统计学差异外,2种策略方式在房颤复发、心衰再住院、全因死亡、心源性死亡、卒中、大出血及心包

填塞等方面均无统计学差异,Kaplan-Meier生存曲线分析结果也显示,2种策略方式在安全性复合终点[MACE(主要不良心血管事件)、疗效复合终点(房颤复发、心衰再住院、卒中、TIA)]方面差异无统计学意义。这也为单纯DSA引导下行“一站式”介入治疗提供了依据。

3.2 DSA引导策略可避免TEE相关并发症,提升患者舒适度

既往食道超声检查因图像分辨高、对血栓检出的灵敏度及特异性均较高、能清楚地显示左心耳内部形态结构、精准指导选择合适的封堵器,一直被认为是房颤行LAAO治疗的“金标准”[20],但其常需在深度镇静或全身麻醉下进行,存在患者耐受性差、麻醉相关风险、食道损伤、部分患者可能无法耐受或拒绝接受食道超声检查等问题,这直接影响其接受LAAO治疗的依从性,限制了其在临床中的进一步推广[4]。OMURO等[21]的研究已证实,食道超声检查相关食管黏膜损伤发生率达6.1%,高龄患者为该损伤的独立危险因素。本研究中食道超声检查组有2例患者出现的咽喉部损伤,虽属轻度并发症,也进一步印证食道超声检查作为侵入性操作可能引发咽部刺激、恶心乃至黏膜损伤的已知风险,这也为探索更安全的替代引导方式提供了有力的循证依据。

3.3 DSA组DRT发生率有升高趋势但无统计学差异,可能与封堵器植入位置有关

作为LAAO的常见并发症,器械相关性血栓一直以来备受临床关注,本研究发现器械相关性血栓的发生率在DSA组为3.9%,在TEE组为1.4%,这与EWOLUTION试验2年随访报道的4.1%及多项荟萃分析得出的3.7%的发生率一致[22-23]。同时本研究发现DSA组器械相关性血栓的发生率虽高于TEE组,2者相比没有统计学差异,这与MENG等[14]报道的“一站式”介入治疗中单纯DSA引导与DSA+TEE引导2种方式器械相关性血栓发生风险相当相一致。既往研究还发现高凝、心包积液、肾功能不全、左心耳与肺静脉边缘的植入深度>10 mm、阵发性心房颤动均与器械相关性血栓的发生率有关[24],推测DSA组器械相关性血栓的发生率增高可能与封堵器的植入位置有关。

3.4 本研究结果与既往文献一致,支持DSA引导策略的临床可行性

目前DSA引导LAAO的循证证据多局限于单纯LAAO,而“一站式”介入治疗的研究较少。YUNIADI等[12]对DSA引导(无全身麻醉)与TEE(全身麻醉)引导下行单纯LAAO的研究表明:单纯DSA引导下和TEE引导下行LAAO的安全性和有效性相当。2023年MENG等[14]开展了一项回顾性临床研究,对比了“一站式”介入治疗中DSA引导与TEE引导2种方式,发现单纯DSA引导可取得与TEE引导相当的围术期安全性及长期临床疗效。这与本研究观察到的结论:经过6个月以上的随访,单纯DSA引导在全因死亡、心源性死亡、卒中、TIA、大出血、心包填塞及心衰再住院等主要安全性终点事件的与TEE引导相一致。

本研究为单中心回顾性队列研究,未来需开展多中心前瞻性研究来进一步验证这些结论,为单纯DSA引导非瓣膜性房颤患者行“一站式”介入治疗的安全性和有效性提供更多的循证医学证据。

利益冲突 本文所有作者声明不存在利益冲突

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(**收稿**:2026-01-10;**修回**:2026-02-16)
(编辑 栾 嘉)