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大隐静脉改良射频消融术治疗大隐静脉曲张的疗效分析

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· 技术与方法 ·

大隐静脉改良射频消融术治疗大隐静脉曲张的疗效分析



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[摘要] **目的** 比较大隐静脉改良射频消融术 (radiofrequency ablation, RFA) 联合硬化剂注射与大隐静脉高位结扎和剥脱术 (high stripping and ligation, HSL) 联合硬化剂注射治疗大隐静脉曲张的疗效。**方法** 选择南通大学附属医院介入与血管外科组 2022 年 5 月至 2024 年 3 月收治的 220 例接受大隐静脉曲张手术的患者 (252 条患肢), 根据手术方式分为 RFA 组 (大隐静脉改良 RFA 联合硬化剂注射治疗, 110 例患者 125 条患肢) 和 HSL 组 (HSL 联合硬化剂注射治疗, 110 例患者 127 条患肢)。比较 HSL 组和 RFA 组疗效、手术时间、术中出血量、术后下床活动时间和术后并发症情况。分别通过视觉模拟评分 (visual analogue scale, VAS)、静脉临床严重程度评分 (venous clinical severity score, VCSS)、慢性静脉功能不全问卷 14 项 (chronic venous insufficiency questionnaire-14 item, CIVIQ-14) 评估患者疼痛程度、疾病严重程度及生活质量。**结果** 两组患者治疗总有效率差异无统计学意义, RFA 组疗效等级分布优于 HSL 组 ($P=0.044$)。与 HSL 组相比, RFA 组手术时间缩短、手术切口减少、术中出血量减少、术后更早下床活动 ($P<0.01$), 总并发症发生率更低 ($P=0.006$)。RFA 组术后 1 个月 VAS、VCSS、CIVIQ-14 评分低于 HSL 组 ($P<0.01$)。术后随访 6 个月, 两组复发率差异无统计学意义。**结论** 与 HSL 联合硬化剂注射相比, 大隐静脉改良 RFA 联合硬化剂注射治疗大隐静脉曲张具有创伤小、恢复快、并发症少、术后生活质量高等优点, 值得临床推广应用。

[关键词] 大隐静脉曲张; 改良射频消融术; 高位结扎和剥脱术; 并发症

[中图分类号] R 543.6 **[文献标志码]** A

Analysis of the therapeutic effect of modified radiofrequency ablation on great saphenous vein varicosity

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[Abstract] **Objective** To compare the efficacy of modified radiofrequency ablation (RFA) combined with sclerosing agent injection and high stripping and ligation (HSL) combined with sclerosing agent injection in the treatment of great saphenous vein varicosity. **Methods** A total of 220 patients (252 affected limbs) who underwent surgery for great saphenous vein varicosity at Affiliated Hospital of Nantong University from May 2022 to March 2024 were selected. They were divided into RFA group (110 patients and 125 affected limbs treated with modified RFA combined with sclerosing agent injection) and HSL group (110 patients and 127 affected limbs treated with HSL combined with sclerosing agent injection) according to the surgical methods. The treatment effect, surgical time, bleeding during the surgery, time to get out of bed after surgery, and various postoperative complications were compared between the two groups. The pain level, disease severity, and the quality of life were measured using the visual analog scale (VAS), venous clinical severity score (VCSS) and chronic venous insufficiency questionnaire-14 item (CIVIQ-14), respectively. **Results** There was no statistically significant difference in the total effective rate between the two groups of patients, but the distribution of efficacy levels in the RFA group was better than that in the HSL group ($P=0.044$). Compared with the HSL group, the RFA group had shorter surgery time, fewer incisions during surgery, less bleeding during the surgical process, shorter time to get out of bed after surgery ($P<0.01$), and a lower overall complication rate ($P=0.006$). The RFA group had lower postoperative VAS, VCSS, and CIVIQ-14 scores than the HSL group 1 month after surgery ($P<0.01$). During 6 months of postoperative follow-up, the recurrence rates were similar between the two groups. **Conclusions** Compared with HSL combined with sclerosing agent injection, the modified RFA combined with sclerosing agent injection for the great saphenous vein varicosity has the advantages of less trauma, faster recovery, fewer complications, better postoperative quality of life, and is worthy of clinical

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promotion and application.

[Key Words] great saphenous vein varicosity; modified radiofrequency ablation; high stripping and ligation; complication

大隐静脉曲张是常见的血管外科疾病，主要由浅静脉反流和深静脉回流障碍引起的静脉压升高导致。患者早期无明显症状，随病情发展，出现下肢酸胀、沉重感、水肿、色素沉着等^[1]。大隐静脉曲张的治疗方法有多种，根据病情严重程度和患者具体情况可选择保守治疗和手术治疗。保守治疗适用于静脉曲张处于早期阶段、症状轻的患者；对于C2级以上患者，推荐手术治疗。目前，手术仍是治疗大隐静脉曲张的最有效方法^[2]。大隐静脉曲张常见的手术治疗方法包括大隐静脉高位结扎和剥脱术（high stripping and ligation, HSL）、静脉腔内射频消融术（radiofrequency ablation, RFA）、静脉腔内激光治疗术。

HSL能在短期内有效改善患者的血流动力学状况，但存在创伤较大、手术时间长、术后康复慢等不足^[3]。RFA因创伤小、术后康复快等特点，逐渐应用于大隐静脉曲张^[4-5]。但是，目前大隐静脉RFA手术须在彩超引导下进行，且仅用于膝上大隐静脉近端主干。本研究将RFA用于全长大隐静脉，联合硬化剂注射治疗大隐静脉曲张，并与HSL联合硬化剂注射治疗效果相比，探讨改良RFA的有效性和安全性。

1 资料与方法

1.1 一般资料 选择2022年5月至2024年3月在南通大学附属医院介入与血管外科诊治的大隐静脉曲张患者220例（共252条患肢）。纳入标准：（1）年龄18~80岁；（2）临床-病因学-解剖学-病理生理（CEAP）分级^[2]为C2~6；（3）术前均行下肢深静脉造影排除深静脉梗阻及狭窄；（4）无泡沫硬化剂过敏史。排除标准：（1）既往同侧静脉曲张手术史；（2）患肢深静脉血栓病史；（3）随访资料不全。患者在硬化剂注射治疗基础上，接受改良RFA手术治疗（RFA组），或HSL手术治疗（HSL组）。本院在2022年3月3日开始开展改良RFA手术，排除团队开展改良RFA手术初期（学习阶段）的前30例患

者。RFA组有110例患者125条患肢；HSL组有110例患者127条患肢。

1.2 手术方法 HSL和RFA手术均由同一血管外科团队完成。该团队手术经验丰富，年均完成静脉曲张手术300例以上，其中RFA≥40%。主刀医师独立完成至少50例HSL或30例RFA。

1.2.1 RFA组 患者取平卧位，经静脉吸入复合麻醉后，在患者患肢腹股沟韧带下方，定位股动脉搏动点正下方约2 cm处，再向内侧偏移1.5 cm，作一长约0.5 cm的横行切口；分离并离断大隐静脉主干部分，在近心端用4号丝线缝扎及7号丝线结扎，在远心端用7号丝线结扎（图1A）；在内踝前方作一0.2 cm横行切口，分离出大隐静脉主干并离断，用4号丝线缝扎离断处远心端。采用奥林巴斯软性双极RFA针从足踝部大隐静脉近心端从下向上全程通过大隐静脉主干至腹股沟处大隐静脉远心端（图1B）。调节RFA主机功率：18 W，固定温度120℃，1 cm/(2.5~6.0) s，变频模式。大隐静脉主干走行处皮肤以湿盐水纱布覆盖降温，并以双手施压配合RFA，以闭合大隐静脉主干。若大隐静脉主干闭合不满意，可重复治疗1~2次。对于小腿段侧支曲张静脉团，以点式切口（约0.3 cm长）剥脱。对于小腿端残留的直径小于3 mm的曲张静脉，用1%聚多卡醇注射液通过Tessari法制备硬化剂，多点穿刺注射，硬化剂剂量根据静脉曲张范围及程度调整，每个注射点不超过10 mL，总量不超过20 mL。治疗后严密止血，并观察皮肤有无过敏反应及烫伤等，确认无异常后用可吸收缝线缝合伤口。

1.2.2 HSL组 患者取平卧位，采用静脉吸入复合麻醉，同上述步骤离断患者患肢腹股沟及足踝内侧大隐静脉后，将静脉剥脱导丝从足踝部大隐静脉主干近心端从下向上全程通过大隐静脉主干至腹股沟处大隐静脉远心端，在腹股沟处用7号丝线结扎固定大隐静脉主干和剥脱导丝。将导丝从腹股沟处向足踝方向缓慢抽动，内翻式完整剥

离大隐静脉主干，在大隐静脉主干走行处皮肤表面持续进行加压止血。同手术方法对小腿段侧支曲张静脉团剥脱、穿刺注射及缝合伤口。

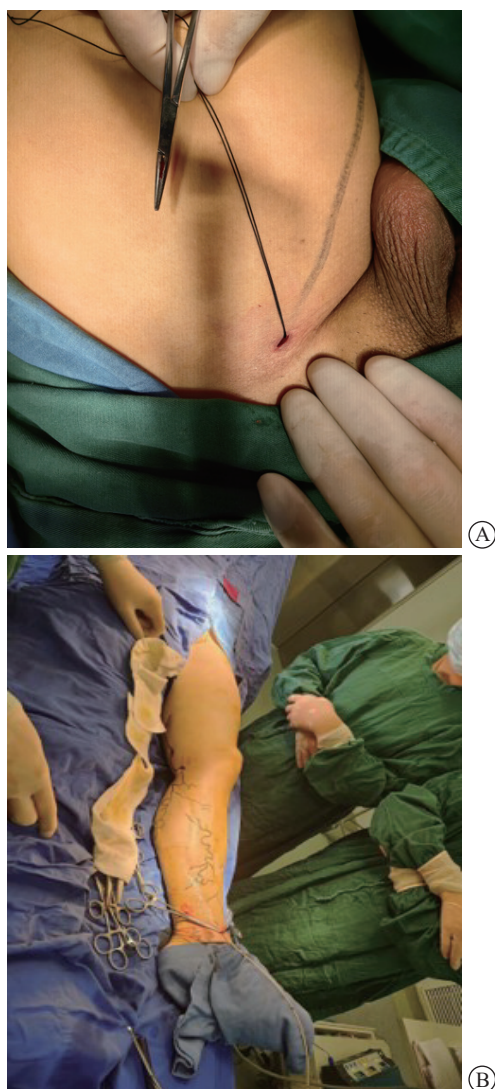


图1 大隐静脉曲张改良 RFA 手术

Figure 1 Modified RFA surgery for great saphenous vein varicosity

A: Dissection of the main trunk of the great saphenous vein through a small incision in the inguinal region; B: The radiofrequency ablation guide wire passes the entire main trunk of the great saphenous vein. RFA: radiofrequency ablation.

1.3 术后处理 术后 72 h 内，除伤口换药外持续穿戴二级医用静脉曲张弹力袜；72 h 后白天穿戴，夜间睡觉时脱离。返回病房后皮下注射低分子肝素，以预防下肢深静脉血栓形成。出院后口服利伐沙班（每日 5 mg，共 5 d）和地奥司明（0.9 g/次，每日 2 次，服用 60 d）。

1.4 观察指标 （1）疗效：术后 1 个月，肉眼未发现静脉曲张，彩超未发现反流，同时无相关症状，评估为显效；肉眼观察到微小静脉曲张，临床症状显著改善，评估为有效；肉眼观察到明显静脉曲张，症状未改善，评估为无效^[6]。治疗总有效率 = （显效 + 有效）/ 总例数 × 100%^[7]。

（2）手术指标：手术时间、术中出血情况、切口数量以及术后离床活动时间。（3）术后并发症：创面感染、皮下血肿、感觉异常、深静脉血栓等。

（4）疼痛程度：术前和术后 1 个月采用视觉模拟评分（visual analogue scale, VAS）评估，总分 10 分，分值越高表明疼痛越严重^[8]。

（5）疾病严重程度：术前和术后 1 个月采用静脉临床严重程度评分（venous clinical severity score, VCSS）评估，总分 30 分，分值越高表明症状越严重^[9]。

（6）生活质量：术前和术后 1 个月采用慢性静脉功能不全问卷 14 项（chronic venous insufficiency questionnaire-14 item, CIVIQ-14）评估，总分 100 分，分值越低表明生活质量越高^[10]。（7）术后早期复发：术后 6 个月在门诊复查，经 B 超或彩色多普勒超声发现病变处直径 > 12 mm 的血管未闭合，可见浅静脉迂曲扩张或大隐静脉及其交通支再通，诊断为大隐静脉曲张复发^[11]。

1.5 统计学处理 采用 SPSS 27.0 处理数据。符合正态分布的计量资料以 $\bar{x} \pm s$ 表示，两组间比较采用成组 t 检验，治疗前后比较采用配对 t 检验。不符合正态分布的计量资料以 $M(P_{25}, P_{75})$ 表示，两组间比较采用非参数检验。计数资料以 $n(\%)$ 表示，组间比较采用卡方检验。检验水准（ α ）为 0.05。

2 结果

2.1 基线资料 结果（表 1）显示：两组患者性别、年龄、病程、BMI、合并症、CEAP 分级差异无统计学意义。

2.2 疗效 结果（表 2）显示：术后 1 个月，两组疗效差异无统计学意义（ $\chi^2 = 3.124$, $P = 0.077$ ）。Mann-Whitney U 检验分析显示，RFA 组疗效等级分布优于 HSL 组（ $U = 7\ 345$, $P = 0.044$ ），RFA 组显效比例更高。

表 1 两组大隐静脉曲张患者基线资料比较

Table 1 Comparison of baseline data between the two groups of patients with great saphenous vein varicosity				
Index	HSL group (n=110)	RFA group (n=110)	χ^2/t	P
Age/year	63.73±8.572	62.96±11.046	0.574	0.567
Male n(%)	52(47.3)	54(49.1)	0.073	0.787
Course of disease/year	9.52±3.557	10.44±3.513	-1.926	0.055
BMI/(kg•m ⁻²)	24.79±3.705	25.45±3.463	-1.354	0.177
Complication n(%)	40(36.36)	42(38.18)	0.711	1.000
Hypertension	20(18.18)	21(19.09)		
Diabetes	12(10.91)	11(10.00)		
Hyperlipidemia	5(4.55)	6(5.45)		
Arrhythmia	2(1.82)	2(1.82)		
Kidney disease	1(0.91)	2(1.82)		
CEAP grading n(%)			2.203	0.699
C2	26(23.64)	29(26.36)		
C3	52(47.27)	50(45.45)		
C4	26(23.64)	22(20.00)		
C5	4(3.64)	8(7.27)		
C6	2(1.82)	1(0.91)		

HSL: high stripping and ligation; RFA: radiofrequency ablation; BMI: body mass index; CEAP: Clinical-Etiology-Anatomic-Pathophysiologic classification system.

表 2 两组大隐静脉曲张患者疗效比较

Table 2 Comparison of efficacy between the two groups of patients with great saphenous vein varicosity				
Group	Significant effect	Effective	Invalid	Total effective n(%)
HSL group (n=110)	88(80.00)	10(9.09)	12(10.91)	98(89.09)
RFA group (n=110)	96(87.27)	9(8.18)	5 (4.55)	105(95.45)

HSL: high stripping and ligation; RFA: radiofrequency ablation.

2.3 手术情况及术后下床活动时间 结果 (表 3) 中出血量和切口数减少, 术后下床活动时间更早显示: 与 HSL 组比较, RFA 组手术时间缩短, 术 (P<0.01) 。

表 3 两组大隐静脉曲张患者手术情况及术后下床活动时间比较

Table 3 Comparison of surgery situation and time to get out of bed after surgery between the two groups of patients with great saphenous vein varicosity				
Group	Operative time/min	Intraoperative bleeding volume/mL	Number of incisions	Postoperative time to get out of bed/h
HSL group (n=110)	49.91±12.228	51.35±6.580	10.05±1.549	12.04±1.556
RFA group (n=110)	42.36±10.617	23.15±4.002	7.04±1.608	5.96±1.544
t	4.887	37.280	14.176	29.057
P	<0.01	<0.01	<0.01	<0.01

HSL: high stripping and ligation; RFA: radiofrequency ablation.

2.4 术后并发症 结果 (表 4) 显示: 与 HSL 组 (χ²=7.565, P=0.006) 比较, RFA 组患者术后总并发症发生率更低 2.5 术后疼痛情况、疾病程度和生活质量 结果

(表5)显示:两组患者术前VAS、VCSS和CIVIQ-14评分差异无统计学意义;术后1个月,VAS、VCSS和CIVIQ-14评分均降低,RFA组术后VAS、VCSS和CIVIQ-14评分低于HSL组($P<0.01$)。

2.6 早期复发情况 术后随访6个月,RFA组复发3例(2.73%),HSL组复发4例(3.64%)。两组早期复发率差异无统计学意义($\chi^2=0.148$, $P=0.701$)。

表4 两组大隐静脉曲张患者术后并发症比较
Table 4 Comparison of postoperative complications between the two groups of patients with great saphenous vein varicosity

Group	Wound infection	Subcutaneous hematoma	Paresthesia	Deep vein thrombosis	Total
HSL group (n=110)	6(5.45)	9(8.18)	5(4.55)	2(1.82)	22(20.00)
RFA group (n=110)	2(1.82)	4(3.64)	2(1.82)	0	8(7.27)

HSL: high stripping and ligation; RFA: radiofrequency ablation.

表5 两组大隐静脉曲张患者手术前后疼痛评分、疾病程度和生活质量比较
Table 5 Comparison of VAS, VCSS, and CIVIQ-14 scores between the two groups of patients with great saphenous vein varicosity before and after surgery

Index	Point of time	HSL group (n=110)	RFA group (n=110)	t	P
VAS	Before treatment	6.04±1.602	6.07±1.578	-1.540	0.878
	1 month after treatment	5.20±1.652	2.91±1.594	10.021	<0.01
VCSS	Before treatment	13.62±3.469	14.40±3.338	-1.703	0.090
	1 month after surgery	6.55±2.954	5.50±2.489	2.863	0.005
CIVIQ-14	Before treatment	53.12±9.061	54.08±5.675	-0.910	0.364
	1 month after surgery	40.91±10.507	35.46±9.856	3.964	<0.01

HSL: high stripping and ligation; RFA: radiofrequency ablation; VAS: visual analogue scale; VCSS: venous clinical severity score; CIVIQ-14: chronic venous insufficiency questionnaire-14 item.

3 讨论

静脉曲张的治疗选择基于静脉功能不全的严重程度、术后并发症风险和患者个人因素。静脉曲张的治疗方式包括保守治疗和手术治疗。无症状静脉曲张患者可采用保守治疗方案进行治疗,包括药物治疗、加压疗法和生活方式改变;对于有症状患者,则建议手术,HSL是常用术式,可以提高患者生活质量^[12-14],但术中及术后疼痛明显,且术后易发生血肿、感染^[15]。目前,RFA逐渐成为治疗静脉曲张的首选方案。传统的RFA需在超声引导下经皮穿刺大隐静脉主干,于目标段周围注射肿胀液形成保护层,再通过分段射频加热实现静脉闭合;主要适用于膝上段主干,应用于小腿分支时需联合其他微创技术。RFA与

HSL治疗有效性和安全性相当^[16],但术后疼痛更轻、术后恢复更快^[17]。

本研究表明,在硬化剂注射治疗基础上,RFA与HSL对大隐静脉曲张的治疗总有效率差异无统计学意义。HSL能有效阻断血液反流,同时剥脱器能完全剥离曲张静脉,缓解瘀血造成的静脉回流受阻;RFA则利用射频主机配合专用的电极导管产生热能,破坏静脉内膜并促使其剥脱,同时使静脉管壁中层及壁内胶原变性,导致静脉逐渐发生纤维化进而闭塞^[18]。用手沿大隐静脉主干射频部位行适当按压,能满足大隐静脉主干不同部位的压力需求,同时有助于射频电极头端与静脉壁的贴和,从而更好地封闭大隐静脉主干。但是,电极导管具有热穿透能力,RFA治疗可能

导致皮肤和隐神经损伤^[19]。因此, RFA 治疗后患者可能出现患肢麻木等感觉异常, 此时可采用皮肤湿敷生理盐水纱布缓解。湿纱布覆盖有降温作用, 同时避免在大隐静脉主干周围注射麻醉肿胀液, 降低操作难度。

本研究还表明, 与 HSL 组相比, RFA 组患者手术切口少、出血少、时间短, 可以更早下床活动, 表明 RFA 较 HSL 手术创伤更小、患者术后恢复更快, 与既往研究^[17]结果相符; 术后 1 个月, RFA 组患者 VAS、VCSS、CIVIQ-14 评分均低于 HSL 组; RFA 组患者总并发症发生率低于 HSL 组, 且无深静脉血栓发生, 表明 RFA 治疗大隐静脉曲张更安全, 与既往研究^[20]相符。

本研究局限性: (1) 尽管已控制学习曲线的影响, 并由临床经验丰富的团队进行手术, 但单中心设计可能限制结论外推; (2) 未将采用的特定技术(小切口高位结扎主干、湿盐水纱布覆盖降温、主干全程射频消融)与国内外主流的、不进行高位结扎且仅处理膝上段大隐静脉主干的 RFA 方式进行对比分析; (3) 本研究目的为评估新技术能否降低早期复发率及短期技术稳定性, 仅随访术后 1 个月功能指标(疼痛、生活质量), 而未分析这些指标在术后 6 个月内的动态变化。

综上所述, 本研究在 RFA 过程中通过小切口高位结扎主干、湿盐水纱布覆盖降温、用手按压、主干全程射频消融等步骤, 实现大隐静脉主干压力可控, 联合硬化剂注射与 HSL 联合硬化剂注射治疗大隐静脉曲张效果相当, 同时该改良 RFA 手术时间更短、切口更少, 患者术后并发症更少、恢复更快、生活质量更高, 值得推广。未来将扩大样本量并延长随访时间, 以评估该改良 RFA 的长期疗效。

伦理声明 本研究符合《赫尔辛基宣言》基本原则。

利益冲突 所有作者声明不存在利益冲突。

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