论著·临床医学

达标的管腔预处理对下肢动脉硬化闭塞症患者药物洗脱支架12个月一期通畅率的影响

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[摘要] **目的** 探究达标的管腔预处理对下肢动脉硬化闭塞症(arteriosclerosis obliterans,ASO)患者药物洗脱支架(drug-eluting stents,DES)12个月一期通畅率的影响,并分析支架内再狭窄的独立预测因素。**方法** 采用回顾性队列研究设计,纳入2022年4月至2024年4月在重庆医科大学附属第一医院血管外科接受DES治疗的141例ASO患者为研究对象。根据经皮腔内血管成形术(percutaneous transluminal angioplasty,PTA)后血管夹层分级(国家心肺血液研究所,C型及以上为严重夹层)及残余狭窄率(≥30%为重度狭窄),将不存在严重夹层和重度残余狭窄的患者纳入达标组(n=59),其余患者纳入未达标组(n=82)。采用彩色多普勒血管超声或血管造影评估DES 12个月一期通畅率,通畅的标准定义为血管超声收缩期峰值流速比≤2.4或血管造影狭窄<50%。采用Kaplan-Meier法比较组间DES通畅率及无临床驱动的靶病变血运重建(clinically driven target lesion revascularization,CD-TLR)率差异。采用多因素Logistic回归分析DES再狭窄的危险和保护因素,评估PTA后夹层和残余狭窄对DES再狭窄的风险贡献度。**结果** PTA后94.3%(133/141)的患肢出现血管夹层,其中42.1%(56/133)为严重夹层;44.0%(62/141)存在重度管腔残余狭窄。Kaplan-Meier生存分析显示,达标组DES 12个月一期通畅率显著高于未达标组(HR=0.322,95%CI:0.132~0.789,P=0.013),而无CD-TLR率组间差异无统计学意义(HR=0.608,95%CI:0.187~1.937,P=0.407)。多因素Logistic回归分析显示,达标的管腔预处理(OR=0.228,95%CI:0.069~0.747,P=0.015)和Rutherford分类2~3类(OR=0.205,95%CI:0.058~0.725,P=0.014)是DES再狭窄的独立保护因素。严重夹层与重度残余狭窄共存组的DES通畅率显著低于无并发症组(P<0.001),且再狭窄风险达无并发症组的7.067倍(P<0.001)。**结论** 达标的管腔预处理可有效改善DES 12个月一期通畅率,并与Rutherford分类2~3类为支架内再狭窄的独立保护因素,术中应竭力避免同时出现严重夹层与重度残余狭窄。

[关键词] 下肢动脉硬化闭塞症;球囊血管成形术;药物洗脱支架;夹层
[中图法分类号] R181.32;R543.5;R619 [文献标志码] A

Effect of adequate vessel preparation on 12-month primary patency rate of drug-eluting stents in patients with lower extremity arteriosclerosis obliterans

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[**Abstract**] **Objective** To investigate the impact of adequate lumen preparation on the 12-month primary patency rate of drug-eluting stents (DES) in patients with lower extremity arteriosclerosis obliterans

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(ASO) and to identify risk and protective factors for in-stent restenosis. **Methods** A retrospective cohort study was conducted on 141 patients who underwent DES implantation for ASO at the Department of Vascular Surgery of the First Affiliated Hospital of Chongqing Medical University between April 2022 and April 2024. According to post-percutaneous transluminal angioplasty (PTA) dissection grade [severe dissection is defined as type C or higher based on National Heart, Lung, and Blood Institute (NHLBI) criteria] and residual stenosis rate (severe stenosis is defined as ≥30%), the patients were categorized into an adequate preparation group (no severe dissection or severe residual stenosis; n=59) and an inadequate preparation group (n=82). DES primary patency at 12 months was assessed by color Doppler ultrasonography or angiography, defined as a peak systolic velocity ratio ≤2.4 on duplex ultrasound or angiographic stenosis <50%. Kaplan-Meier analysis was used to compare intergroup differences in DES patency rate and freedom from clinically driven target lesion revascularization (CD-TLR). Multivariate logistic regression analysis was employed to identify risk and protective factors for DES restenosis and to evaluate the risk contributions of post-PTA dissection and residual stenosis to DES restenosis. **Results** Post-PTA, vascular dissection occurred in 94.3% (133/141) of treated limbs, among which 42.1% (56/133) were severe dissections, and severe residual stenosis was present in 44.0% (62/141) of limbs. Kaplan-Meier analysis revealed that the 12-month primary patency rate was significantly higher in the adequate preparation group than the inadequate group (*HR*=0.322, 95%*CI*: 0.132~0.789, *P*=0.013), while no significant difference was found in the rate of freedom from CD-TLR (*HR*=0.608, 95%*CI*: 0.187~1.937, *P*=0.407). Multivariate logistic regression analysis identified adequate lumen preparation (*OR*=0.228, 95%*CI*: 0.069~0.747, *P*=0.015) and Rutherford category 2~3 (*OR*=0.205, 95%*CI*: 0.058~0.725, *P*=0.014) as independent protective factors against DES restenosis. The patency rate in the subgroup with coexisting severe dissection and residual stenosis was significantly lower than that in the uncomplicated group (55.6% *vs* 89.8%, *P*<0.001), with a 7.067-fold increased risk of re-stenosis (95%*CI*: 2.424~20.602, *P*<0.001). **Conclusion** Adequate lumen preparation significantly improves the 12-month primary patency rate of DES. It, along with Rutherford category 2~3, serves as an independent protective factor against in-stent restenosis. Concurrent severe dissection and significant residual stenosis should be actively avoided during the procedure.

[**Key words**] arteriosclerosis obliterans; balloon angioplasty; drug-eluting stents; dissection

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下肢动脉硬化闭塞症(arteriosclerosis obliterans,ASO)是动脉粥样硬化在下肢动脉的局部表现,其特征性病理改变为动脉内膜粥样斑块形成、管腔狭窄或闭塞,从而导致受累肢体出现慢性缺血的一系列临床症状,如间歇性跛行、静息痛、溃疡甚至坏疽等,严重影响患者生活质量。根据全球疾病负担研究,40~70岁和>70岁人群的ASO患者数量分别为5 640万例和5 700万例[1]。ASO的患病率随着老龄化程度不断加深呈上升趋势[2]。

经皮腔内血管成形术(percutaneous transluminal angioplasty,PTA)是治疗ASO的基础术式。对于长病变、慢性完全闭塞或严重钙化等复杂病变,单纯行PTA治疗效果并不理想,需支架植入维持管腔通畅。药物洗脱支架(drug-eluting stents,DES)在ASO治疗中有较高的安全性和可靠性[3-4],12个月一期通畅率明显高于裸支架[5],但支架内再狭窄仍是支架治疗策略面临的一大挑战。有研究指出,PTA导致的血管扩张不充分和限流夹层会影响支架长期通畅率[6]。通过血管预处理优化管腔、清除钙化,有助于支架展开和药物在血管壁的沉积[7]。然而,目前还缺乏针对下肢动脉PTA后,血管夹层和管腔残余狭窄严重程度与DES治疗结局关系的研究,理论上,不达标的管腔预处理(如存在严重夹层或重度残余狭窄)可能通过破坏血流动力学、阻碍药物均匀释放等途径,导致DES再狭窄风险增高,管腔预处理策略也有待完善。

本研究旨在探究下肢动脉病变PTA后,血管夹层和残余狭窄对DES治疗效果的影响,预测DES再狭窄的危险和保护因素,为建立规范化、以临床结局为导

向的管腔预处理标准提供关键理论依据,以期改进管腔预处理策略、降低支架再狭窄和二次干预需求、改善患者生活质量和肢体预后。

1 方法

1.1 研究设计

本研究为回顾性队列研究,共纳入2022年4月至2024年4月于重庆医科大学附属第一医院血管外科使用DES治疗ASO的141名患者(共141条患肢)为研究对象。

纳入标准:①慢性、有症状的下肢缺血,定义为Rutherford 2~6类;②狭窄、再狭窄或闭塞性病变位于原生血管中;③血管造影评估狭窄程度≥70%;④参考血管直径3~7 mm(以匹配研究用DES的可用尺寸);⑤病变长度30~210 mm(以涵盖具有临床意义的短段至长段弥漫性病变);⑥膝下至少有1条血管通畅(狭窄<50%)并达足部动脉弓;⑦根据跨大西洋多学会共识Ⅱ(TransAtlantic Inter-Society Consensus Ⅱ,TASC Ⅱ)分级标准,病变属于B~D型。

排除标准:①存在严重合并症,且预期寿命<12个月;②手术期间在目标血管使用过斑块切除术、激光或其他减容装置;③使用药物涂层球囊治疗或未进行球囊血管成形术的直接支架植入治疗;④通过内膜下血管成形术开通的病变;⑤目标血管中存在动脉瘤;⑥随访期间非标准用药;⑦医学图像数据丢失。

对纳入的患者进行12个月随访,评估DES一期通畅率和无临床驱动的靶病变血运重建(clinically driven target lesion revascularization,CD-TLR)率。根据PTA后血管造影观察到的夹层分级和管腔残余狭窄率,将病变全程扩张后残余狭窄率均<30%且无C型及以上分型夹层定义为达标的管腔预处理[8],并据此将患者分为达标组和未达标组。本研究的"达标状态"是PTA后的自然结果,用于分析不同血管基础条件对DES预后的影响,而非评价特定操作技术的优劣。本研究经重庆医科大学附属第一医院伦理委员会批准[2025年科研伦审(2025-249-01)]。

1.2 介入治疗

手术入路选择患肢对侧股总动脉逆行穿刺,或者在明确患肢同侧股总动脉及股浅动脉近端无病变时,采用顺行穿刺。使用2.0%利多卡因进行局部麻醉后穿刺,并置入6 F或7 F动脉鞘,经鞘进行全身肝素化。在球囊血管成形术前后,对目标血管进行造影,明确病变位置、长度和钙化程度。根据患者血管具体情况行PTA,球囊-血管比设定为1∶1,若进行逐级扩张首球囊选择参考血管直径的50%~70%,每次递增1 mm,球囊充盈时间≥120 s。管腔预处理均采用普通球囊。手术中力求支架完全覆盖目标病变。根据术中支架贴壁及伸展情况,术者决定是否行后扩张。支架均选用Eluvia DES(美国Boston Scientific公司),其直径为6或7 mm,长度有40、60、80、100和120 mm。

手术成功的标准为:将指定的研究支架成功输送并部署到目标病变,经干预医生评估残余血管造影狭窄<30%,且术后24 h内未发生死亡、截肢、CD-TLR、需要手术干预的目标肢体缺血以及手术血管修复等重大不良事件(major adverse events,MAE)。

1.3 图像分析

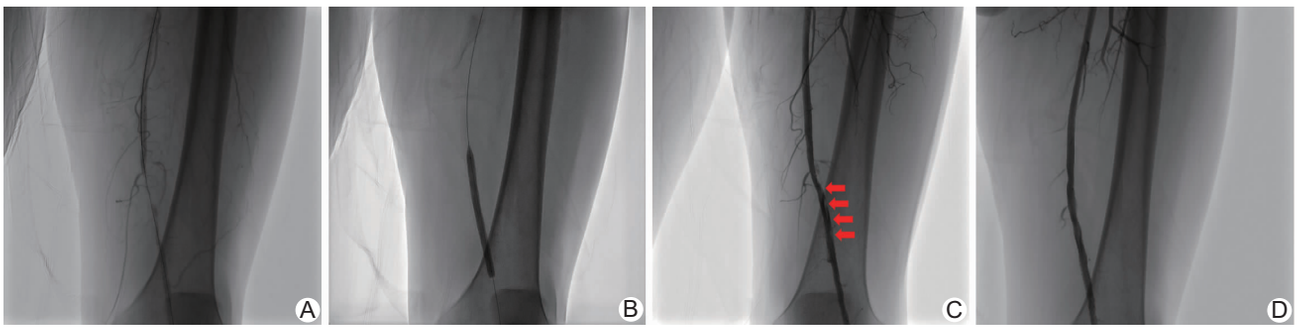
运用血管造影系统定量分析软件,对PTA前后获取的血管造影图像分析。由2名从事血管介入工作>5年、年均独立完成下肢动脉介入手术>100例的重庆医科大学附属第一医院血管外科医师采用双盲法独立评估血管夹层及残余狭窄严重程度,若判断结果存在分歧,则由1名具有>10年介入经验的高年资副主任(或主任)医师仲裁达成一致。采用国家心肺血液研究所(National Heart, Lung, and Blood Institute,NHLBI)血管造影夹层分级量表对夹层进行定义[9]。若单个病变存在多种明显的夹层分级,则选取最差的级别进行分析,其中严重的血管夹层定义为C型或更高类型。将非夹层节段管腔直径损失定义为残余狭窄,若病变扩张后残余狭窄率≥30%视为重度残余狭窄(图1)。根据外周动脉钙化评分系统(Peripheral Arterial Calcium Scoring System,PACSS)对钙化程度进行分级,分为无钙化(0级)、轻度钙化(1~2级)和重度钙化(3~4级)[10]。

1.4 药物治疗

患者在干预前24 h开始服用抗板药物;术后4~6 h皮下注射1支低分子肝素。所有患者术后服用至少60 d的双重抗血小板治疗方案,60 d后持续服用至少1种抗板药物,主要包括氯吡格雷、阿司匹林、西洛他唑等。

1.5 随访

在植入DES后1、3、6和12个月,通过彩色多普勒超声或动脉造影评价支架的通畅性。主要通畅性的评估标准定义为在不存在CD-TLR或旁路的情况下,彩色多普勒超声检查收缩期峰值流速比≤2.4或动脉造影狭窄<50%[11]。此外,随访内容还包括临床和血流动力学改善情况、步行功能和相关生活质量。



A：Pre-PTA showing occlusion of the mid-to-distal segment of the superficial femoral artery；B：PTA showing the diseased vessel；C：Post-PTA showing severe dissection（NHLBI grade ≥C）and significant residual stenosis（≥30%），red arrows indicate severe dissection and significant residual stenosis；D：Post-DES implantation angiography demonstrating optimal stent apposition and a patent lumen

图1 下肢动脉硬化闭塞症患者药物洗脱支架植入术的数字减影血管造影图像

Figure 1 Digital subtraction angiography of DES implantation in a patient with ASO

1.6 研究终点

主要有效性结果为12个月(±30 d)支架通畅。主要安全终点是12个月时的无事件生存期，定义为未发生临床事件委员会裁定的MAE，且Rutherford分类[12]未恶化2个类别或达到5类、6类。CD-TLR定义为：因彩色多普勒超声或血管造影发现显著再狭窄或再闭塞，并伴有复发性缺血症状，而进行的任何再介入治疗。当再次介入无法挽救缺血肢体时，进行大截肢(定义为踝关节以上的肢体切除)。在12个月内需要再次介入或大截肢的情况均自动归类为再狭窄。次要结局包括持续临床改善，即不存在持续性或恶化性跛行、静息痛、溃疡或组织损失，Rutherford分类改善(降低)≥1个类别。

1.7 统计学分析

采用SPSS 27.0软件进行统计学分析。通过描述性统计对患者和病变特征以及临床结果进行总结。对于连续变量，根据其分布是否接近正态性，选用独立样本t检验或Mann-Whitney U检验进行分析，并分别以$\bar{x}\pm s$或$M(P_{25},P_{75})$表示。分类变量以例(%)呈现，采用χ^2检验或Fisher确切概率法进行比较，等级资料(如Rutherford分级、钙化程度)采用Mann-Whitney U检验比较，亚组多重比较采用Bonferroni校正，根据比较次数(k=3)调整显著性水平(α'=0.05/3≈0.017)。运用Kaplan-Meier方法分析一期通畅率及12个月内无CD-TLR的情况；采用多因素Logistic回归分析方法，探究DES再狭窄的独立预测因素，并通过方差膨胀因子(VIF<5)评估变量共线性；同时评估夹层和残余狭窄率对DES再狭窄的风险贡献程度，其中独立变量通过比值比(odds ratio，OR)及95%CI进行精准量化表示。当P<0.05时，认为差异具有统计学意义。

2 结果

2.1 患者特征与术中并发症

跛行患者(Rutherford分类2~3级)占41.84%，严重肢体缺血患者(Rutherford分类4~6级)占58.16%；病变长度中位数为88.62(65.45，119.90) mm，最长达208.20 mm，最短为30.86 mm；慢性完全闭塞患者有64例(45.39%)；41.84%(59/141)的患肢存在重度钙化。86.52%(122/141)的患肢植入单个DES；21.28%(30/141)的病例进行了后扩张，48.94%(69/141)的病例采用了逐级扩张。手术成功率为97.16%(137/141)，4次失败是由于植入支架后残余狭窄仍>30%。达标组与未达标组临床基线特征对比分析显示，达标组糖尿病患者显著多于未达标组[49.2% *vs* 28.0%；风险差异(risk difference，RD)=0.212，95%CI：0.049~0.362，χ^2=6.565，P=0.010]；达标组患者血管钙化程度显著低于未达标组(Z=1.989，P=0.047)，见表1。但糖尿病患病(RD=0.033，95%CI：−0.114~0.161，χ^2=0.206，P=0.650)和血管钙化程度(P=0.810)与DES通畅率无显著相关性，提示在该样本中糖尿病和血管钙化程度不是影响支架长期通畅性的混杂因素。94.3%(133/141)的患肢在PTA后出现血管夹层，其中42.1%(56/133)为严重夹层(C型及以上)；44.0%(62/141)的患肢存在PTA后重度管腔残余狭窄(≥30%)。随访12个月期间，未发现支架断裂病例。

2.2 达标组DES 12个月一期通畅率显著高于未达标组

DES总体12个月一期通畅率为78.7%，其中达标组显著高于未达标组[89.8%(53/59) *vs* 70.7%(58/82)；RD=0.191，95%CI：0.056~0.310，χ^2=7.472，P=

表1 2组样本基线对比[$\bar{x}\pm s$,$M(P_{25},P_{75})$,例(%)]

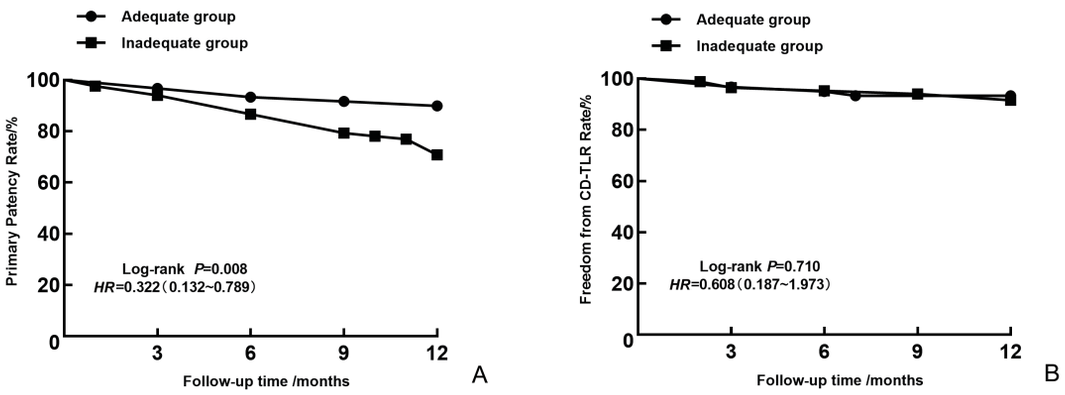
Table 1 Baseline characteristics of the 2 groups [$\bar{x}\pm s$, $M(P_{25},P_{75})$, n(%)]

Variables	Inadequate group(n=82)	Adequate group(n=59)	$\chi^2/t/Z$	P
Male	65(79.3)	46(78.0)	0.035	0.852
Age/years	75.170±11.530	72.760±10.403	1.261	0.209
Hypertension	55(67.1)	39(66.1)	0.015	0.904
Diabetes mellitus	23(28.0)	29(49.2)	6.565	0.010
Coronary artery disease	20(24.4)	16(27.1)	0.134	0.714
Hyperlipidemia	24(29.3)	18(30.5)	0.025	0.874
Chronic kidney disease	13(15.9)	11(18.6)	0.189	0.664
Smoking history	46(56.1)	39(66.1)	1.434	0.231
Alcohol history	24(29.3)	18(30.5)	0.025	0.874
Cerebrovascular disease	7(8.5)	4(6.8)	0.004	0.948
Endovascular history	25(30.5)	21(35.6)	0.407	0.524
Right limb	38(46.3)	30(50.8)	0.279	0.597
Rutherford classification			0.651	0.515
2~3	30(36.6)	29(49.2)		
4	26(31.7)	11(18.6)		
5~6	26(31.7)	19(32.2)		
TASC Ⅱ classification			0.564	0.572
B	39(47.6)	33(55.9)		
C	36(43.9)	18(30.5)		
D	7(8.5)	8(13.6)		
Chronic total occlusion	40(48.8)	24(40.7)	0.909	0.340
Lesion length/mm	89.27(70.53,119.41)	87.45(56.85,126.90)	1.082	0.279
Calcification			1.989	0.047
None	6(7.3)	7(11.9)		
Mild	36(43.9)	33(55.9)		
Severe	40(48.8)	19(32.2)		
Ankle brachial index	0.403±0.132	0.441±0.145	1.633	0.105

0.006],但2组在12个月内无CD-TLR率差异无统计学意义(P=0.396,图2)。Cox比例风险回归分析显示,达标的管腔预处理显著降低了支架再狭窄风险[风险比(hazard ratio, HR)=0.322,95%CI:0.132~0.789,P=0.013,图2]。多因素Logistic回归分析证实,达标的管腔预处理(OR=0.228,95%CI:0.069~0.747,P=0.015)和Rutherford分类2~3类(OR=0.205,95%CI:0.058~0.725,P=0.014)是12个月内DES再狭窄的独立保护因素(图3)。

2.3 严重夹层合并重度残余狭窄显著降低DES通畅率并倍增再狭窄风险

对未达标组患者进行亚组分析,根据PTA后并发症类型将患者分为仅严重夹层组(n=19)、仅重度残余狭窄组(n=27)、严重夹层合并重度残余狭窄组(n=36)组。其组间DES一期通畅率存在显著差异[仅严重夹层组78.9%(15/19)、仅重度残余狭窄组85.2%(23/27)、严重夹层合并重度残余狭窄组55.6%(20/36);χ^2=7.349;P=0.025]。经Bonferroni校正多重比较后(校正后α=0.017),仅严重夹层组与仅重度残余狭窄组(P=0.70)、仅严重夹层组与严重夹层合并重度残余狭窄组(P=0.086)的DES通畅率差异均无统计学意义,而仅重度残余狭窄组与严重夹层合并重度残余狭窄组的DES通畅率差异有统计学意义(P=0.012)。以无并发症组为对照(n=59),Logistic回归分析显示,严重夹层与重度残余狭窄共存时,DES再狭窄风险显著升高(OR=7.067,95%CI:2.424~20.602,P<0.001),而单独存在严重夹层(OR=2.356,95%CI:0.587~9.447,P=0.227)或重度残余狭窄(OR=1.536,95%CI:0.396~5.965,P=0.535)时,风险增加但差异无统计学意义(表2)。



A: Survival curves for primary patency rate of DES; B: Survival curves for freedom from CD-TLR

图 2 下肢动脉硬化闭塞症患者行药物洗脱支架置入术后12个月的Kaplan-Meier生存分析

Figure 2 Kaplan-Meier survival analysis at 12 months after DES implantation in patients with ASO

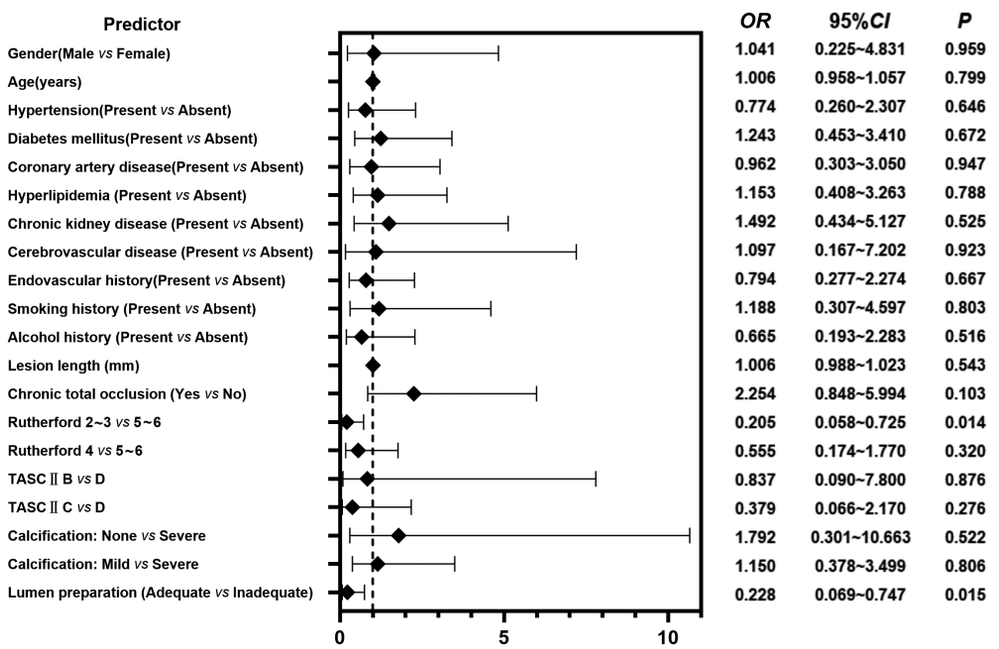


图 3 影响12个月一期通畅率的多因素Logistic回归分析及森林图

Figure 3 Multivariable logistic regression analysis and forest plot for predictors of 12-month primary patency rate.

表2 未达标组中不同并发症类型对药物洗脱支架通畅率影响的比较

Table 2 Comparison of DES patency among different complication types in the inadequate group

Group	*n*	Patency rate/%	$\beta(SE)$	*OR*(95%*CI*)	*P*
Dissection only	19	78.9	0.857(0.709)	2.356(0.587~9.447)	0.227
Residual stenosis only	27	85.2	0.429(0.692)	1.536(0.396~5.965)	0.535
Both complications	36	55.6	1.955(0.546)	7.067(2.424~20.602)	<0.001
No complications	59	89.8	-	1.000	-

3 讨论

3.1 达标的管腔预处理是提高DES长期通畅率的关键举措

本研究证实,达标的管腔预处理(定义为PTA后无C型及以上夹层且残余狭窄<30%)可显著提高ASO患者DES 12个月一期通畅率(89.8% *vs* 70.7%, *P*=0.006)。这一结果可能扭转了"DES可补偿PTA不足"的传统认知,同时为临床提供了管腔预处理的质量标准。未达标的管腔预处理会导致DES贴壁效果不佳及局部血流动力学异常,进而明显增加支架内再次狭窄的风险[13-14]。在本项研究中,通过Cox比例风险回归分析(*HR*=0.322,95%*CI*:0.132~0.789,*P*=0.013)与多因素Logistic回归分析(*OR*=0.228,95%*CI*:0.069~0.747,*P*=0.015)共同证明了该结论。研究显示,DES 12月一期总通畅率仅为78.7%,低于既往研究报道(85.4%~96.4%)[4-5,15],可能与本研究纳入患者血管条件较差(如重度钙化比例较高)有关。即便如此,达标组12个月一期通畅率(89.8%)与文献结果相当,也体现出管腔预处理达标的重要性。多因素分析表明,Rutherford分类2~3类是DES再狭窄的独立保护因素(*OR*=0.205,95%*CI*:0.058~0.725,*P*=0.014),提示对于症状较重的患者,达标的管腔预处理具有更重要的临床意义。因此,应将达标的管腔预处理视为DES疗效的基础。

3.2 严重夹层与残余狭窄的协同效应显著倍增再狭窄风险

本研究显示,当严重夹层与重度残余狭窄共存时,DES再狭窄风险协同性激增(*OR*=7.067),远高于单一病变(*OR*=2.356和1.536)。这提示夹层与残余狭窄之间的病理协同是造成DES失效的关键因素。其机制可能与严重夹层和重度残余狭窄造成血流动力学严重紊乱,对血管壁损伤级联放大有关[14]。残余狭窄导致血液湍流,增加血管壁损伤及炎症反应,血管夹层暴露出的胶原触发血小板聚集,而夹层腔隙及残余狭窄区域药物涂层无法有效接触血管壁,造成药物传递障碍[13],形成了"损伤、炎症、药物失效"的正反馈,加速了支架再狭窄。这解释了严重夹层与重度残余狭窄共存组患者12个月一期通畅率仅为55.6%,显著低于仅存在重度残余狭窄组的85.2%(*P*=0.012)。综上,严重夹层合并重度残余狭窄应被视为DES再狭窄的高风险表型,该类患者需强化抗血小板治疗并密切随访。

3.3 支架重叠及末端部位是再狭窄发生的高危区域

尽管达标组总体通畅率较高(89.8%),但再狭窄多发生在支架重叠及末端区域。支架重叠区域由于金属负荷增加导致持续性炎症反应和内皮愈合延迟,增加了再狭窄风险[16-17]。同时扰乱血流并影响药物均匀分布,减弱了对平滑肌细胞增生的抑制作用[18-19]。支架末端与正常血管交界处易因支撑力不足而发生弹性回缩与微小夹层,裸露的胶原可促进血栓形成[20-21]。建议术中应用血管内超声或光学相干断层扫描精确指导支架贴壁和定位,以减少支架边缘再狭窄风险[21-22]。

3.4 获得达标管腔预处理的技术路径

为实现达标的管腔预处理,应优化球囊扩张策略、联合减容技术并在血管内成像引导下操作。相关研究表明,中心导丝路径[23]、使用长球囊扩张病变血管[24]和增加球囊扩张时间[25-26]能够有效降低严重夹层及残余狭窄的发生率。本研究还发现,采用逐级球囊扩张技术相较参考血管直径球囊直接扩张,发生严重夹层和重度残余狭窄的风险均显著更低,可能与逐级施加压力更温和有关,但仍需进一步研究证明结论的可靠性。联合斑块旋切或激光消融等减容技术,有助于以更低的球囊压力获得达标的管腔预处理[27]。此外,血管造影在评估斑块和夹层方面存在局限性,建议术中应用血管内连续成像技术,精准评估病变、指导干预,进一步减少严重夹层及重度残余狭窄的发生[28-30]。

3.5 影像学再狭窄与临床再干预的分离现象

本研究观察到影像学再狭窄(狭窄>50%)与CD-TLR之间存在分离现象:尽管达标组一期通畅率显著高于未达标组,但2组免于CD-TLR率差异无统计学意义。该现象提示,部分患者虽发生影像学再狭窄,却未出现显著缺血症状,可能与侧支循环代偿[31]、个体缺血耐受差异等因素相关。例如,糖尿病患者因周围神经病变对缺血感知可能减弱[32]。因此,对无症状性再狭窄患者,可优先采取密切随访而非立即干预;在评价DES疗效时,应结合影像学结果与临床症状综合判断。

本研究存在一定局限性:首先,患者均来自同一医疗中心,纳入标准可能引入选择偏倚,且回顾性数据收集可能受病历记录完整性的影响,导致信息偏倚;其次,尽管整体样本量(*n*=141)满足主要终点分析需求,但亚组分析的样本量较小(如严重夹层与残余狭窄共存组仅36例),可能降低统计效力;另外,12个月的随访可能不足以评估DES的长期通畅率。未来需通过多中心、前瞻性、大样本及长时间随访研究巩固结论。最后,本研究依赖血管造影评估夹层和残余狭窄,虽通过双盲独立判读与仲裁机制控制主观偏差,但二维成像的固有局限可能产生夹层低估风险及

残余狭窄量化误差,弱化组间差异,同时研究未采用量化指标(如Kappa值)评估判读一致性,仍存在主观性风险。

本研究结果表明,达标的管腔预处理可显著提高DES 12个月一期通畅率,与Rutherford分类2~3类为多因素分析证实的DES再狭窄的独立保护因素。严重夹层与重度残余狭窄共存会大幅增加再狭窄风险,而且支架重叠及末端是再狭窄好发部位,提示应注重精准支架置入与贴壁评估。此外,影像学再狭窄与临床干预需求之间分离,评价疗效时应结合影像与症状综合判断。综上,达标的管腔预处理是改善DES远期疗效的关键,推荐术中积极采用影像引导、逐级扩张及减容等技术以实现优质预处理。

利益冲突 本文所有作者声明不存在利益冲突

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