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· 专题研究 ·

紫杉醇涂层球囊与普通球囊治疗腘动脉硬化闭塞症效果的倾向性评分匹配分析

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摘要

背景与目的: 药物涂层球囊 (DCB) 作为一种新的介入治疗技术已逐渐广泛应用, 但目前主要集中在冠脉血管领域, 在外周血管的应用研究相对较少, 尤其是针对跨关节的腘动脉的研究更是罕见。因此, 本研究比较 DCB 与普通球囊 (CB) 用于腘动脉硬化闭塞症中的近期疗效与远期预后, 探讨 DCB 在该领域中的应用价值。

方法: 回顾性分析 2014 年 3 月—2020 年 4 月河北医科大学第一医院血管外科行介入球囊扩张治疗的 65 例腘动脉硬化闭塞症患者临床资料, 其中 29 例行 DCB 治疗 (DCB 组), 36 例行 CB 治疗 (CB 组)。采用 1:1 倾向性匹配 (PSM) 方法对两组患者进行匹配, 比较匹配后两组患者术后的腘动脉通畅率、踝肱指数 (ABI) 指标、Rutherford 分级情况及截肢、血栓形成、血管内再狭窄等终点事件的发生情况。

结果: 两组共 21 对匹配成功, 匹配后两组患者术前临床资料均衡可比 (均 $P>0.05$)。匹配后, 两组患者术后 3、6 个月时腘动脉通畅率及 ABI 比较差异无统计学意义 (均 $P>0.05$), 术后 12 个月, DCB 组腘动脉通畅率、ABI 明显高于 CB 组 (65.71% vs. 49.55%; 0.71 vs. 0.55, 均 $P<0.05$), 而 Rutherford 分级明显优于 CB 组 ($P<0.05$); DCB 组患者术后 1 年截肢、血栓形成、血管内再狭窄等终点事件的总发生率低于 CB 组 (23.81% vs. 57.14%, $P<0.05$); Log-rank 检验结果显示, 两组患者术后随访期间终点事件发生情况差异有统计学意义 ($\chi^2=5.654$, $P<0.05$)。

结论: DCB 与 CB 治疗腘动脉硬化闭塞症的近期疗效相当, 但远期 DCB 能够明显提高术后腘动脉通畅率、减少终点事件的发生。

关键词

闭塞性动脉硬化; 腘动脉; 药物洗脱支架; 倾向性评分

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Efficacy of paclitaxel-coated balloon versus common balloon for popliteal arteriosclerosis obliterans: a propensity score matching analysis

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Abstract

Background and Aims: Drug-coated balloon (DCB) as a new interventional therapeutic technique has been increasingly used. However, it is currently mainly used in the field of coronary artery disease therapy, while studies on its application in peripheral vascular diseases are relatively limited, and especially rare in popliteal artery that spans the joint. Therefore, this study was performed to compare the short-term efficacy and long-term outcomes of using DCB versus common balloon (CB) in the treatment of popliteal arteriosclerosis obliterans, and investigate the application value of DCB in this field.

Methods: The clinical data of 65 patients with popliteal arteriosclerosis obliterans undergoing interventional balloon dilatation in the Department of Vascular Surgery of the First Hospital of Hebei Medical University from March 2014 to April 2020 were retrospectively analyzed. Of the patients, 29 cases were treated with DCB (DCB group) and 36 cases were treated with CB (CB group). The two groups of patients were matched with propensity score matching (PSM) method at a 1:1 ratio. After match, the postoperative patency rate of the popliteal artery, ankle-brachial index (ABI) and Rutherford classification as well as the occurrence of endpoint events such as amputation, thrombosis formation and intravascular restenosis were compared between the two groups of patients.

Results: Twenty-one pairs of patients in the two groups were successfully matched. The clinical data were balanced and comparable between the two groups after match (all $P>0.05$). After match, the popliteal artery patency rate and ABI at 3 and 6 months after surgery showed no significant difference between the two groups (all $P>0.05$). At 12 months after surgery, the popliteal artery patency rate and ABI were significantly higher in DCB group than those in CB group (65.71% vs. 49.55%; 0.71% vs. 0.55%, both $P<0.05$), and the Rutherford classification in DCB group was significantly superior to that in CB group ($P<0.05$). At one year after surgery, the overall incidence of endpoint events that included amputation, thrombosis formation and intravascular restenosis in DCB group was significantly lower than that in CB group (23.81% vs. 57.14%, $P<0.05$). The Log-rank test showed that there was a significant difference in the incidence of endpoint events between the two groups of patients ($\chi^2=5.654$, $P<0.05$).

Conclusion: DCB offers a similar CB short-term efficacy as CB in the treatment of popliteal arteriosclerosis obliterans, but DCB can significantly improve the popliteal artery patency rate and reduce the occurrence of endpoint events in long-term postoperative period.

Key words

Arteriosclerosis Obliterans; Popliteal Artery; Drug-Eluting Stents; Propensity Score

CLC number: R654.3

随着我国人口老龄化的不断加剧，周围血管病的发生率逐年增加。在下肢动脉中股腘动脉是

周围血管病变的好发部位，常以股腘动脉硬化闭塞症多见^[1]。随着血管介入技术的不断发展，球囊

血管成形术在治疗周围血管硬化闭塞症方面取得了不错的疗效。但应用普通球囊 (common balloon, CB) 后的患者在术后6个月至1年内血管再狭窄、血栓形成发生率较高,极大影响患者的身体健康和生命安全^[2]。近年来关于药物涂层球囊 (drug-coated balloon, DCB) 应用的报道越来越多,但主要集中在冠脉血管领域,对于外周血管应用DCB的研究多集中在股动脉方面,对于腘动脉狭窄时应用DCB的研究较少。腘动脉因其位置特殊,属于跨膝关节病变,腘动脉置入支架后,由于膝关节的反复屈伸运动,容易导致动脉内支架两端内膜增生,以及支架内疲劳折损,从而导致血管闭塞,传统CB也可能因为该部位运动频繁,血液发生湍流,导致血栓形成风险增加^[3]。开放性手术由于创伤大,且患病人群多为老年人,手术耐受性较差,风险较大。CB扩张后易发生血管内再狭窄;DCB的引入可能为这一难点提供新的解决方案。为此笔者团队回顾近5年来实施的介入球囊扩张治疗腘动脉硬化闭塞症患者的临床资料,分析DCB在该病中的应用价值,现报告如下。

1 资料与方法

1.1 临床资料

回顾性分析河北医科大学第一医院血管外科2014年3月—2020年4月收治的65例腘动脉硬化闭塞症行血管介入球囊扩张治疗患者的临床资料,其中行DCB治疗29例(DCB组),行CB治疗36例(CB组)。男36例,女29例,年龄67~80岁。本研究经医学伦理委员会审核批准。纳入标准:(1)年龄60~80岁;(2)单侧单个或多个腘动脉病变(3~15 cm的狭窄或<10 cm的闭塞);(3)Rutherford分级2~5级;(4)伴有不同程度的跛行或缺血性静息痛;(5)临床资料完整,术后坚持完成1年的随访;(6)存在开放手术禁忌证。排除标准:(1)髂动脉或股动脉病变严重经介入处理不成功,或残留狭窄率>30%者,膝下三支动脉病变严重经处理仍不能至少开通一支的患者;(2)支架内再狭窄者、存在动脉瘤、急性血栓形成;(3)合并恶性肿瘤者;(4)预计生存期不足1年者;(5)术中内膜下开通、支架放置病例以及被迫应用补救性支架的患者;(6)临床资料缺失或没有完成1年随访者。

1.2 治疗方案

所有手术操作均在数字血管造影机(飞利浦-FD20)上进行,术前确定腘动脉病变近心端情况及远心端血管因素影响,术前两组患者均给予阿司匹林100 mg/d和氯吡格雷75 mg/d,口服至少3 d;符合手术条件后根据解剖学特点选择常规股动脉顺行或逆行穿刺方式,置入6 F动脉鞘,应用VER导管及0.35导丝或0.014导丝,小心通过腘动脉病变部位,直至远端动脉真腔,导入CB逐级扩张,扩张时间2 min,直至目标直径,后造影显示残余狭窄<30%,且无限流性夹层,定义为扩张成功。DCB组:在此手术基础上,导入DCB,药涂层球囊直径:末次扩张球囊直径为1:1。两组患者术后均长期给予阿司匹林100 mg/d以及6个月的氯吡格雷75 mg/d,若置入支架则使用氯吡格雷时间再延长3个月。

1.3 临床资料收集

收集两组患者性别、年龄、BMI、基础疾病(糖尿病、高血压、高脂血症、慢性肾功能不全)、Rutherford分级^[4](分为0~6级,0级无临床症状;1级有轻度间歇性可行;2级中度间歇性跛行;3级重度间歇性可行,不能完成踏车试验,运动后踝动脉压<50 mmHg;4级出现缺血性静息痛,足背动脉、胫后动脉几乎不能够触及;5级出现组织小块缺损,非愈合性溃疡;6级出现大块组织缺损,出现肢体坏疽的现象)、吸烟史、饮酒史、腘动脉狭窄程度^[5](使用CTA检查腘动脉狭窄,I级属轻度斑块浸润,狭窄在25%以下,II级狭窄为26%~50%,III级狭窄为50%~75%,IV级狭窄为>75%至完全闭塞)、入院时踝肱指数^[5](ankle-brachial index, ABI)(ABI计算:患者仰卧,用12 cm×40 cm气袖分别置于双侧踝部及上臂,用多普勒听诊器协助测取足背或胫前动脉、胫后动脉以及肱动脉收缩压,两者之比即为ABI。正常ABI≥0.97,0.9~0.97为临界值)、腘动脉通畅率^[5](术后彩色超声多普勒检测腘动脉通畅率,CTA检查示腘动脉腔狭窄缩小>50%,未再狭窄)等临床资料。

1.4 随访指标

分别于术后3、6、12个月采用多普勒彩超测算腘动脉通畅率;测量ABI。于术后12个月对所有患者进行Rutherford分级评定;终点事件:截肢、血栓形成、血管内再狭窄(标准为靶血管病变血管再狭窄>50%)。

1.5 研究方法

本研究为回顾性研究，采用倾向性评分匹配法（propensity score matching, PSM）匹配DCB组和CB组。基本原理和步骤为将DCB和CB定义为因变量，以各组的临床资料为协变量，通过多因素Logistic回归估计倾向性评分分值，采用1:1匹配法进行匹配，利用匹配后的新样本对比干预效应。

1.6 统计学处理

采用SPSS 19.0软件进行数据分析，计量资料采用均数±标准差($\bar{x} \pm s$)表示，组间比较采用 t 检验；计数资料采用例(百分比)[n (%)]表示，组间比较采用 χ^2 检验；等级资料采用秩和检验；

$P < 0.05$ 时差异具有统计学意义。

2 结果

2.1 PSM前后两组患者临床资料比较

PSM前两组患者在糖尿病、Rutherford分级、ABI方面差异有统计学意义(均 $P < 0.05$)。经倾向性1:1匹配65例患者中21对匹配成功(卡钳值为0.08)；匹配后两组患者在糖尿病、ABI及性别、年龄、BMI、Rutherford分级等资料方面比较差异无统计学意义(均 $P > 0.05$)(表1)。

表1 PSM前后两组患者临床资料比较

Table 1 Comparison of clinical data between the two groups of patients before and after PSM

资料	匹配前		t/χ^2	P	匹配后		t/χ^2	P
	DCB组($n=29$)	CB组($n=36$)			DCB组($n=21$)	CB组($n=21$)		
性别[n (%)]								
男	16(55.17)	20(55.56)	0.298	0.585	13(61.90)	12(57.14)	0.099	0.753
女	13(44.83)	16(44.44)			8(38.10)	9(42.86)		
年龄(岁, $\bar{x} \pm s$)	73.58±6.49	73.44±5.91	0.108	0.914	74.92±7.88	74.38±6.43	0.245	0.808
基础疾病[n (%)]								
糖尿病	3(10.34)	13(36.11)	4.017	0.045	2(9.52)	3(14.29)	0.000	1.000
高血压	10(34.48)	22(61.11)	0.012	0.911	8(38.10)	9(42.86)	0.099	0.753
Rutherford分级[n (%)]								
2	6(20.69)	8(22.22)	5.415	0.014	4(19.05)	5(23.81)	0.733	0.865
3	10(34.48)	17(47.22)			7(33.33)	6(28.57)		
4	8(27.59)	10(27.78)			8(38.10)	8(38.10)		
5	5(17.24)	1(2.78)			2(9.52)	2(9.52)		
腠动脉狭窄程度(% , $\bar{x} \pm s$)	87.24±7.55	86.91±6.40	0.229	0.819	85.82±5.77	85.73±6.12	0.049	0.961
腠动脉闭塞长度(cm, $\bar{x} \pm s$)	5.89±1.32	6.01±1.43	0.351	0.727	5.41±1.07	5.54±1.10	0.481	0.632
入院时ABI($\bar{x} \pm s$)	0.37±0.12	0.30±0.11	2.901	0.004	0.29±0.11	0.30±0.09	0.322	0.749
胆固醇(mmol/L, $\bar{x} \pm s$)	4.35±1.42	4.40±0.71	0.185	0.854	4.33±0.57	4.38±0.61	0.274	0.785
甘油三酯(mmol/L, $\bar{x} \pm s$)	2.12±0.48	2.09±0.37	0.285	0.777	2.14±0.28	2.13±0.31	0.109	0.913
低密度脂蛋白(mmol/L, $\bar{x} \pm s$)	0.96±0.26	0.99±0.28	0.443	0.659	0.98±0.17	0.96±0.19	0.359	0.721
血糖(mmol/L, $\bar{x} \pm s$)	5.81±0.33	5.78±0.57	0.251	0.802	5.41±0.66	5.39±0.72	0.094	0.926
病变分布[n (%)]								
P1	11(37.93)	13(36.11)	0.120	0.889	8(38.10)	9(42.86)	0.103	0.922
P2	16(55.17)	19(52.78)			12(57.14)	11(52.38)		
P3	2(6.90)	4(11.11)			1(4.76)	1(4.76)		

2.2 PSM后两组患者随访Rutherford分级比较

术后12个月DCB组Rutherford分级明显低于CB组，差异具有统计学意义($P < 0.05$)(表2)。

2.3 PSM后两组患者随访ABI指数比较

两组患者术后3、6个月时ABI差异无统计学意义(均 $P > 0.05$)，术后12个月DCB组ABI明显高于CB组($P < 0.05$)(表3)。

表2 PSM后两组患者随访Rutherford分级比较 [n=21, n (%)]

Table 2 Comparison of Rutherford classification between the two groups of patients after PSM [n=21, n(%)]

组别	Rutherford 分级			
	2	3	4	5
DCB组	10(47.62)	10(47.62)	1(4.76)	0(0.00)
CB组	6(28.57)	8(38.10)	6(28.57)	1(4.76)
Z	8.444			
P	0.038			

表3 PSM后两组患者随访ABI指数比较 (n=21, $\bar{x} \pm s$)

Table 3 Comparison of follow-up ABI index between the two groups of patients after PSM (n=21, $\bar{x} \pm s$)

组别	术后时间		
	3个月	6个月	12个月
DCB组	0.91±0.14	0.78±0.11	0.71±0.14
CB组	0.90±0.13	0.76±0.12	0.55±0.09
t	0.239	0.563	4.405
P	0.812	0.577	0.000

2.4 PSM后两组患者随访腘动脉通畅率比较

两组患者术后3、6个月复查腘动脉通畅率比较差异无统计学意义 (均 $P>0.05$), 术后12个月DCB组腘动脉通畅率高于CB组 ($P<0.05$) (表4)。

表4 PSM后两组患者随访腘动脉通畅率比较 (% , $\bar{x} \pm s$)

Table 4 Comparison of popliteal artery patency rate between the two groups of patients after PSM (% , $\bar{x} \pm s$)

组别	术后时间		
	3个月	6个月	12个月
DCB组	91.23±7.46	86.44±6.11	65.71±5.14
CB组	91.35±7.28	82.76±9.12	49.55±5.09
t	0.053	1.536	10.237
P	0.958	0.132	0.000

2.5 PSM后两组患者随访期间终点事件发生情况比较

术后1年, DCB组患者血管内再狭窄、血栓形成及截肢比例均少于CB组, 上述差异均无统计学意义 ($P>0.05$); 但总发生率DCB组明显低于CB组 (23.81% vs. 57.14%, $P<0.05$) (表5); Log-rank 检验结果显示两组患者术后发生终点事件方面存在统计学差异 ($\chi^2=5.654$, $P<0.05$) (图1)。

表5 PSM后两组患者随访期间终点事件发生情况比较 [n=21, n (%)]

Table 5 Comparison of endpoint events between the two groups after PSM [n=21, n (%)]

组别	截肢	血管内再狭窄	血栓形成	总计
DCB组	2(9.52)	2(9.52)	1(4.76)	5(23.81)
CB组	4(19.05)	5(23.81)	3(14.29)	12(57.14)
χ^2	0.194	0.686	0.276	4.842
P	0.659	0.408	0.599	0.028

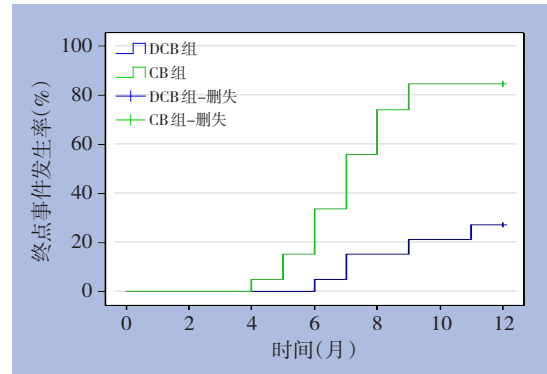


图1 两组患者随访终点事件发生风险曲线图

Figure 1 Follow-up risk curve of endpoint events for the two groups of patients

3 讨论

外周动脉疾病的治疗重点是针对存在生活质量下降的间歇性跛行和严重肢体缺血病变的管理。介入腔内手术被各大指南推荐用于存在严重肢体缺血或影响生活质量的跛行患者的治疗中^[6]。随着介入腔内技术的不断发展, 2015年更新的外周动脉疾病管理指南已经推荐将腔内治疗作为股腘动脉病变的首选治疗方案^[7-8]。关于股腘动脉硬化闭塞症临床常采用旁路移植术, 该手术虽在临床中为治疗腘动脉的标准, 但此类手术开口大、发症多, 又因患者接受能力、开放手术禁忌、花费等问题所限, 临床应用越来越少。后期采用CB技术, 对于合并血管钙化患者辅以血管内支架治疗^[9-10]。对于股浅动脉硬化闭塞症的患者, 采用CB效果较好, 但对于跨膝关节的腘动脉, 研究^[11]发现, 由于解剖位置特殊, 在应用CB后患者随访过程中发展其血管再狭窄、血栓形成率高, 远期疗效不理想; 而对于腘动脉内置入支架的患者, 由于膝关节反复活动, 支架存在折断情况。Rastan等^[12]报道腘动脉支架术24个月通畅率(64.2%)较

低，支架断裂率4.6%。后虽有“仿生”SUPERA支架应用于股腘动脉病变，考虑到目前尚缺乏可靠的循证学证据，还有支架断裂的报道等，所以腘动脉病变的处理仍以尽可能不置入支架为首要选择^[13-14]。

随着对DCB相关机制的研究不断成熟，其也被广泛应用于血管内疾病中，起初在冠脉血管中应用，外周血管应用较少，近年来也逐渐应用于外周血管病变^[15-17]。目前，美国食品药品监督管理局已经批准了DCB用于下肢缺血性病变，但国内外对于DCB应用于下肢动脉病变的研究仍然较少，疗效有待进一步评估，且目前国内外关于DCB用于下肢动脉的研究多集中在股腘动脉上，而单纯针对腘动脉硬化闭塞症的研究较为罕见。此外，对于股腘动脉硬化闭塞症，既往研究多将其作为一个整体来进行研究，但由于腘动脉和股浅动脉解剖位置不同，两者轴向伸缩弯曲特点也对其预后产生一定影响。

笔者团队采用PSM方式针对性回顾对比了近5年本院收治的腘动脉硬化闭塞症分别采用DCB和CB患者的临床资料以及后期随访情况，结果显示，术后3、6个月随访时，两组患者的ABI和腘动脉通畅率并无较大差异，但在术后12个月随访时，DCB组的Rutherford分级、ABI和腘动脉通畅率明显优于CB组患者；笔者分析认为：DCB作为一种表面负载抗血管内皮增生药物的球囊，能够在置入后将涂层药物有效持续地扩散到血管壁，阻止细胞内微血管形成，达到限制内皮细胞增殖、阻止内膜增生目的^[18]；而本研究采用DCB的药物为紫杉醇，其主要抗内皮细胞增生机理为干扰内皮细胞的有丝分裂，进而阻止内膜增生，达到降低血管内再狭窄的风险。且关于紫杉醇DCB的研究，前期动物试验证实紫杉醇DCB在股浅动脉和膝下动脉病变中有确切的疗效^[19]；后期也有一些临床研究^[20-22]对比了紫杉醇DCB和CB降低外周血管病变治疗后再狭窄的疗效差异，结果均显示接受紫杉醇DCB的患者一期血管通畅率明显优于CB的患者，且能够降低靶血管重建的风险；特别是在晚期管腔丢失方面，紫杉醇DCB相比CB术后远期通畅率更高，维持时间更长。国外也有研究^[23-24]表明，与CB相比，紫杉醇DCB在治疗腘动脉硬化闭塞症后1年通畅率明显优于使用CB的患者（67.4% vs. 44.1%），但是CB后置入支架的患者1年

通畅率与DCB相当（67.4% vs. 65.1%）。

在安全性终点事件方面，紫杉醇DCB组患者安全性终点事件发生率明显低于CB组患者，但单项发生率并无差异笔者分析可能与样本量较小有关。且在一些研究^[25-29]中发现，相比于DCB，CB下肢动脉硬化闭塞症患者1年截肢率更高，血管再狭窄率也更高；本研究在PSM前有3例患者行CB+支架置入治疗，置入支架的原因在于球囊扩张后残余狭窄及限流性夹层，分析这3例患者的随访结果发现，其1年后腘动脉通畅率均达到了60%以上，但有1例患者出现支架在血管内断裂，这就提示临床医生在治疗过程中要警惕此类风险。韩国一项研究^[30]表明，对于P2、P3阶段的18例腘动脉硬化闭塞患者行支架内置入治疗后2年仅有4例患者没有出现支架断裂，因此说明腘动脉所处的位置极易受到膝关节的活动对置入的支架造成不利影响。

综上所述，与CB相比，紫杉醇DCB能够明显提高腘动脉硬化闭塞症术后远期血管通畅率，改善患者临床症状，安全可靠；另外紫杉醇DCB对于钙化明显的病变效果较差，特别为糖尿病患者，术中需置入支架预防再狭窄，本研究为CB和药物球囊的效果排除术中支架置入等患者，以避免其他医疗手段对研究结果的干扰。但本研究的不足之处在于非前瞻随机对照研究，科学性有限；且样本量较小，易犯II型统计学错误，后期仍需多中心、大样本系统进行多中心前瞻性研究进一步论证该结论。

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