Advances in Clinical Medicine 临床医学进展, 2023, 13(11), 18366-18373
Published Online November 2023 in Hans. https://www.hanspub.org/journal/acm
https://doi.org/10.12677/acm.2023.13112579

Hans汉斯

药物涂层球囊在Supera支架治疗下肢动脉闭塞病变中的附加价值

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收稿日期：2023年10月25日；录用日期：2023年11月19日；发布日期：2023年11月27日

摘　要

目的：评估药物涂层球囊能否进一步提高Supera支架在复杂股腘动脉闭塞病变中的治疗效果。方法：收集2019年1月至2022年10月期间接受Supera支架治疗的下肢动脉疾病患者资料，根据是否联合使用DCB，将所有患者分为观察组和对照组，观察组为Supera支架联合使用DCB治疗(n = 59)，对照组为单纯使用Supera支架治疗(n = 97)，比较两组患者的一期通畅率，技术成功率，临床成功率，死亡率和再干预率等。结果：平均随访时间为36.5 ± 10.1个月。两组患者基线特征相似，无明显统计学差异。观察组和对照组分别有74.1%和68.0%的患者累及腘动脉(P > 0.05)，观察组技术成功率为96.6%，对照组为93.8% (P > 0.05)，观察组12个月时的一期通畅率为81.4%，对照组为84.5%，两组无统计学差异(P > 0.05)。两组患者死亡率、卢瑟福分级改变也无明显统计学差异(P > 0.05)，观察组有6.8%的患者接受了再干预，低于对照组的10.3%，但在统计学上两组差别无意义(P > 0.05)。结论：Supera支架联合DCB的治疗策略是安全的，但较单独使用Supera支架策略并未表现出明显优势。还需要进一步的研究来在更大的患者队列中证实这些结果。

关键词

外周动脉疾病，血管腔内治疗，股动脉，腘动脉，Supera支架，药物涂层球囊

Additional Value of Drug-Coated Balloon in Supera Stent Treatment for Occlusive Lesions of Lower Limb Arteries

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Received: Oct. 25th, 2023; accepted: Nov. 19th, 2023; published: Nov. 27th, 2023

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文章引用: 唐兴义, 邱德强, 郭明金. 药物涂层球囊在 Supera 支架治疗下肢动脉闭塞病变中的附加价值[J]. 临床医学进展, 2023, 13(11): 18366-18373. DOI: 10.12677/acm.2023.13112579

Abstract

Objective: To evaluate whether drug-coated balloon can further improve the efficacy of Supera stent in the treatment of complex femoral and popliteal artery occlusion. Methods: The data of patients with arterial disease of lower extremities treated with Supera stent from January 2019 to October 2022 were collected. According to the combination of DCB, all patients were divided into observation group and control group. The observation group was treated with Supera stent combined with DCB (n = 59), and the control group was treated with Supera stent alone (n = 97). The primary patency rate, technical success rate, clinical success rate, mortality and re-intervention rate were compared between the two groups. Results: The mean follow-up time was 36.5 ± 10.1 months. The baseline characteristics of the two groups were similar, and there was no significant statistical difference. 74.1% and 68.0% of the patients in the observation group and the control group involved the popliteal artery respectively (P > 0.05). The technical success rate was 96.6% in the observation group and 93.8% in the control group (P > 0.05). The primary patency rate was 81.4% in the observation group and 84.5% in the control group. There was no statistical difference between the two groups (P > 0.05). There was no significant difference in mortality and Rutherford classification between the two groups (P > 0.05). 6.8% of the patients in the observation group received re-intervention, which was lower than 10.3% in the control group, but there was no significant difference between the two groups (P > 0.05). Conclusion: The strategy of Supera stent combined with DCB is safe, but it does not show obvious advantage over the strategy of Supera stent alone. Further studies are needed to confirm these results in a larger cohort of patients.

Keywords

Peripheral Artery Disease, Endovascular Treatment, Femoral Artery, Popliteal Artery, Supera Stent, Drug-Coated Balloon

1. 引言

外周动脉疾病(Peripheral artery disease，PAD)已成为全球日益严重的健康问题。糖尿病发病率的上升以及吸烟等风险因素增加了发生动脉粥样硬化的可能性[1]。PAD 主要影响下肢动脉股腘区，其血管腔内治疗已得到广泛接受，已成为治疗的主要手段[2]。然而，对于中长段(>5 cm)股腘动脉闭塞病变的腔内治疗，仍具有相当大的挑战性[3] [4] [5] [6] [7]。尽管已有多种类型的支架在股浅动脉和腘动脉中进行了测试，但这些结果绝大多数都不令人满意，这可能是由于它们无法适应复杂的股腘动脉的解剖生理特性[8] [9] [10]。

Supera 外周支架(Abbott Vascular, Santa Rosa, CA, USA)是一种编织型的镍钛合金支架。从已发表的研究来看，Supera 支架在下肢动脉粥样硬化的人群中表现出良好的临床结果，一期通畅率可达 86%，支架断裂率为 0%，12 个月时 89%的患者无需进行再干预[11] [12] [13] [14] [15]。另一方面，药物涂层球囊(Drug coated balloon, DCB)的使用已经证明了其抑制内膜增生的能力以及降低术后支架内再狭窄

发生率(in-stent restenosis, ISR)的功效[16]-[22]。然而联合使用 DCB 是否能进一步提高 Supera 支架的通畅率值得怀疑。

2. 方法

2.1. 研究设计和研究对象

这是一项回顾性的单中心研究。收集了 2019 年 1 月至 2022 年 10 月期间接受 Supera 支架治疗的下肢动脉疾病患者资料，对所有患者的术前、术中及随访数据进行回顾性分析。

纳入标准：1) 年龄 ≥18 岁的男性或非孕妇；2) 下肢动脉闭塞性病变累及股腘动脉；3) 有术前 CTA 影像数据。

排除标准：1) 患有严重合并症，或预计生存期 < 6 个月的受试者；2) 既往接受过下肢动脉手术的患者；3) 严重肾功能衰竭(eGFR < 30 mL/min/1.73m^2)；4) 动脉瘤或夹层引起的闭塞。

这项研究得到了相应的生物医学研究伦理委员会的批准。

2.2. 影像测量和分析

所有患者均接受了 CTA 术前评估，并进行了影像学三维重建。至少两名医生独立识别图像并比较其结果。主要评估病变部位、程度及血管具体情况，包括病变长度及直径变化，准确评估膝下流出道情况、附壁血栓及严重钙化情况。

2.3. 主要终点和定义

该研究的主要终点是一期通畅率，其定义为再狭窄没有 > 50%，表现为收缩期峰值速度比 < 2.5，无需再次干预。次要终点包括技术成功率、技术成功率、死亡率和再干预率。

技术成功的定义是指定义为支架能够顺利放置在病变区域，术后通过血管造影实现残留狭窄 ≤30%，通过超声显示 ≤50% [23]。临床成功被定义为卢瑟福类别中至少 1 级的改善[24]。

2.4. 随访方案

随访包括术后的体格检查和影像学检查。如果获得临床症状(间歇性跛行；静息痛；伤口不愈合)并且超声提示再狭窄(狭窄 > 50%；低流速)证实，则使用计算机断层扫描血管造影或常规血管造影。

2.5. 统计分析

连续变量以平均值 ± 标准差表示，而分类变量以数字(百分比)表示。使用卡方检验(分类变量)、t 检验(连续变量)对所有基线特征、解剖参数、术中数据和临床结果进行比较。P 值 < 0.05 被认为具有统计学差异。使用 SPSS 软件(26.0 版；IBM Corporation，Armonk，NY，USA)分析数据。

3. 结果

3.1. 基线特征和病变特征

共纳入了 156 名接受了 Supera 治疗的下肢动脉疾病患者。平均随访时间为 36.5 ± 10.1 个月。有 97 名患者仅接受 Supera 治疗，59 名患者接受 Supera 联合 DCB 治疗。其中，男性 111 例，女性 45 例，平均年龄 73.8 ± 11.0 岁。

基线特征如表 1 所示。影响下肢动脉闭塞的危险因素普遍存在，但糖尿病、高血压、心脏病方面无统计学差异(P > 0.05)。两组的其他人口统计学特征和合并症也相似(P > 0.05)。

Table 1. Baseline characteristics
表 1. 基线特征

	观察组(N = 59)	对照组(N = 97)	P
年龄(岁)	71.98 ± 10.35	74.96 ± 11.28	0.665
性别			
男	45 (76.3)	66 (68.0)	0.271
女	14 (23.7)	31 (32.0)	0.271
吸烟史			
活跃吸烟者	14 (23.7)	25 (25.8)	0.775
戒烟超过 1 年	5 (8.5)	11 (11.3)	0.567
从不吸烟	36 (61.0)	46 (47.4)	0.099
高血压	43 (72.9)	61 (62.9)	0.199
心脏病	25 (42.4)	37 (38.1)	0.601
糖尿病	36 (61.0)	49 (50.5)	0.202
肾脏疾病	6 (10.2)	12 (12.4)	0.676
脑血管病	18 (30.5)	25 (25.8)	0.521
患肢部位			
左下肢	39 (66.1)	50 (51.5)	0.075
右下肢	22 (37.3)	49 (50.5)	0.108
病变的解剖位置			
仅股浅动脉	15 (25.9)	31 (32.0)	0.421
股浅动脉和腘动脉	43 (74.1)	66 (68.0)	0.421
病变长度(毫米)	116.7 ± 77.0	144.7 ± 93.2	0.120
膝下流出道数量			
0	6 (10.2)	10 (10.3)	0.978
1	13 (22)	26 (26.8)	0.505
2	14 (23.7)	16 (16.5)	0.266
3	26 (44.1)	45 (46.4)	0.777
卢瑟福分级			
1	12 (20.3)	17 (17.5)	0.661
2	3 (5.1)	3 (3.1)	0.530
3	11 (18.6)	18 (18.6)	0.989
4	10 (16.9)	20 (20.6)	0.573
5	7 (11.9)	19 (19.6)	0.209
6	14 (23.7)	20 (20.6)	0.648

注：分类变量以 n (%)表示。连续变量以平均 ± 标准差表示。P < 0.05 差别有统计学意义。

在解剖特征方面，观察组病变长度为 116.7 ± 77.0 cm，对照组病变长度为 144.7 ± 93.2 cm，观察组有74.1%的患者病变累及腘动脉，对照组为 68.0%，两组患者的解剖学特征和卢瑟福分级均无明显差异(P > 0.05)。

3.2. 围手术期和随访结果

围手术期和随访结果如表 2 所示。观察中 96.6%的患者取得了技术成功，而对照组中的这一比例为93.8%，两组无统计学差异(P > 0.05)。在临床预后分析中，观察组 12 个月时的一期通畅率为 81.4%，对照组为 84.5%，在统计学上两组差别无意义(P > 0.05)。另一方面，观察组的支架内再狭窄发生率为 16.9%，对照组为 23.7% (P > 0.05)。观察组有 6.8%的患者接受了再干预，低于对照组的 10.3%，但在统计学上两组差别无意义(P > 0.05)。两组之间的住院天数、全因死亡率和临床成功率没有显着差异。

Table 2. Perioperative and follow-up results
表 2. 围手术期和随访结果

	观察组(n = 59)	对照组(n = 97)	P
技术成功	57 (96.6)	91 (93.8)	0.443
手术时间(分钟)	105.3 ± 64.6	103.0 ± 49.1	0.506
支架内再狭窄	10 (16.9)	23 (23.7)	0.316
截肢	1 (1.7)	5 (5.2)	0.276
一期通畅率			
≤3 个月	55 (93.2)	92 (94.8)	0.673
≤6 个月	51 (86.4)	89 (91.8)	0.289
≤12 个月	48 (81.4)	82 (84.5)	0.605
死亡率	9 (15.3)	19 (19.6)	0.494
随访时间(月)			
住院天数(天)			
卢瑟福分级术后变化			
2	1 (1.7)	1 (1.0)	0.721
1	2 (3.4)	5 (5.2)	0.606
0	22 (37.3)	28 (28.9)	0.274
−1	13 (22.0)	17 (17.5)	0.488
−2	2 (3.4)	2 (2.1)	0.611
−3	10 (16.9)	21 (21.6)	0.476
−4	10 (16.9)	23 (23.7)	0.316
再干预率	4 (6.8)	10 (10.3)	0.454

注：分类变量以 n (%)表示。连续变量以平均 ± 标准差表示。P < 0.05 差别有统计学意义。

4. 讨论

过去几年中，DCB 和 Supera 支架都已被报道在股腘动脉闭塞病变中有良好的治疗效果[3] [8] [22] [24]-[30]，但 Supera 支架联合使用 DCB 进行腔内治疗，能否进一步提高的治疗效果一直有所争议[3] [11]

[26] [31]。本研究报告了亚洲患者使用 Supera 支架联合 DCB 治疗有症状的股腘动脉闭塞患者的真实结果。

一项 RAPID 试验将 DCB 联合 Supera 支架与单独使用 Supera 支架的通畅率进行了比较，结果表明，与仅使用 Supera 支架策略相比，DCB 的支持并未提高通畅率[11]。PerProtocol 等人分析显示 Supera + DCB 组的 12 个月时的一期通畅率为 74.7%，而 Supera 组为 62.0% ($P > 0.05$)，研究结果支持上述实验。然而其他学者也有不同的看法。Prakash 等人的研究结果表明，与未联合使用 DCB 治疗的受试者相比，Supera 支架联合 DCB 治疗的受试者的再干预率频率显着降低[32]。这一结论与我们的研究结果不同。在我们的研究中，Supera 组 12 个月时的初次通畅率为 84.5%，而 Supera + DCB 组的初次通畅率为 81.4%，Supera 组中 10.3%的受试者进行了再干预，而 Supera + DCB 组中有 6.8%的受试者，这些差异没有统计学意义($P > 0.05$)。研究结果表明 DCB 无法进一步提高 Supera 支架在股腘动脉病变中的治疗效果。

另一方面，我们研究中的大多数患者是老年人，平均年龄为 73.8 ± 11.0 岁。超过一半的患者患有糖尿病(54.5%)，四分之一是活跃吸烟者(25.0%)。此外，大多数病灶有钙化，我们的平均病灶长度为 133.5 ± 87.8 mm，相对长于已发表文献中的病灶[33] [34] [35]。这些因素共同反映了本研究患者病灶的相对复杂性。在我们的研究中，12 个月总通畅率为 83.3%这与文献中报道的 12 个月初次通畅率为 79%至 88%的研究一致[12] [15] [25] [34]-[39]。这说明 Supera 支架可有效应对中长段股腘动脉钙化病变。同时，在随访期间没有观察到支架断裂情况。两组之间的卢瑟福分类变化没有显着差异。共有 28 人在随访期间死亡，观察组 9 人(15.3%)，对照组 19 人(19.6%)，两组全因死亡率无统计学差异($P > 0.05$)，其中 15 人因新冠病毒导致的心脏相关疾病而死亡，9 人死因呼吸衰竭，4 人死因脑血管疾病，没有发生围手术期、设备相关或手术相关的死亡。这说明尽管 DCB 联合 Supera 支架的策略仍是安全的。

这项研究有几个局限性。首先，本研究是一项回顾性研究，基于单中心的经验，可能因患者选择情况而存在偏差。其次，部分随访结果受到了新冠疫情的影响，比如死亡率等，导致了分析结果的偏差。第三，随访时间超过 3 年的患者数量有限。因此，需要更大规模的前瞻性研究来延长随访时间，以确定患者的长期预后结果。

5. 结论

综上所述，Supera 支架已被证明在复杂的外周动脉疾病中安全有效。它显示出良好的一期通畅率和免于再干预率。而且 Supera 支架联合 DCB 的策略相对于单独使用 Supera 支架的策略并没有表现出明显的临床优势。这还需要进一步的研究来在更大的患者队列中证实这些结果。

声　明

伦理批准：在涉及人类参与者的研究中进行的所有程序都符合机构和/或国家研究委员会的伦理标准，以及 1964 年赫尔辛基宣言及其后来的修正案或类似的伦理标准。

知情同意：被纳入研究的所有个体参与者均获得了知情同意。

利益冲突：所有的作者都声明他们没有利益冲突。

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