

· 临床研究 ·

髂静脉支架在下肢深静脉血栓形成治疗中的应用

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【摘要】目的 评价髂静脉支架在急性期下肢深静脉血栓形成伴有髂静脉狭窄或者闭塞的治疗中的应用效果。**方法** 回顾性分析2016年1月至2018年1月山东省潍坊市人民医院收治并行腔内治疗的急性下肢深静脉血栓形成伴髂静脉狭窄或闭塞患者80例。根据手术是否行髂静脉支架植入治疗,分为观察组45例和对照组35例。观察组通过置入下腔静脉滤器+导管接触性溶栓(CDT)+髂静脉支架治疗;对照组采用置入下腔静脉滤器+CDT治疗。对比2组患者术后效果、患肢消肿率、静脉通畅率分别为及流行病学和经济研究-生活质量/症状(VEINES-QOL/SYM)问卷调查评分。采用SPSS 18.0统计软件进行统计分析。**结果** 术前,2组大腿、小腿周径差比较,差异均无统计学意义(均 $P>0.05$);术后,2组大腿、小腿周径差及消肿率比较,差异均有统计学意义(均 $P<0.05$)。随访1、3、6、12个月后,观察组静脉通畅率分别为45例(100.0%)、43例(95.5%)、41例(91.1%)及41例(91.1%),对照组分别为29例(82.8%)、27例(77.1%)、26例(74.2%)及25例(71.4%),差异均有统计学意义(均 $P<0.05$)。观察组与对照组的下肢深静脉血栓后遗症发生率分别为0(0.00%)与4例(11.43%),差异有统计学意义($P<0.05$)。观察组与对照组的DVT复发率分别为4例(8.89%)与5例(14.28%),差异无统计学意义($P>0.05$)。治疗前,2组患者VEINES-QOL/SYM评分比较,差异均无统计学意义(均 $P>0.05$);治疗后,2组患者VEINES-QOL/SYM评分比较,差异均有统计学意义(均 $P<0.05$)。**结论** 髂静脉支架在急性期下肢深静脉血栓形成伴有髂静脉狭窄或者闭塞的治疗中的应用效果优于单纯置管溶栓。

【关键词】 下肢深静脉血栓形成; 髂静脉狭窄; 髂静脉闭塞; 下腔静脉滤器; 髂静脉支架; 置管溶栓

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Application of iliac vein stent in treatment of deep venous thrombosis in lower extremities

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【Abstract】 Objective To evaluate the efficacy of iliac vein stent in the treatment of acute deep venous thrombosis (DVT) in the lower limbs with iliac vein stenosis or occlusion. **Methods** A retrospective analysis was made of 80 patients hospitalized for acute DVT in the lower extremities with iliac vein stenosis or occlusion at Weifang People's Hospital of Shandong Province from January 2016 to January 2018. According to the implantation of iliac vein stent, they were divided into observation group ($n=45$) and control group ($n=35$). The observation group underwent implantation of inferior vena cava filter, catheter-directed thrombolysis (CDT), and iliac vein stent; the control group were treated with an inferior vena cava filter and CDT. The two groups were compared for the postoperative effect, detumescence rate of the affected limbs, venous patency rate, and scores on Venous Insufficiency Epidemiological and Economic Study on Quality of Life/Symptoms (VEINES-QOL/Sym) questionnaire. Statistical analysis was performed using SPSS statistics 18.0. **Results** Before operation, circumference differences in the thigh and calf between the two groups were not statistically significant ($P>0.05$ for both); after operation, circumference differences in the thigh and calf and difference in the detumescence rate between the two groups was statistically significant ($P<0.05$ for all). The observation group had higher venous patency rates than the control group at 1, 3, 6, and 12 months of follow-up [45(100.0%) vs 29(82.8%), 43(95.5%) vs 27(77.1%), 41(91.1%) vs 26(74.2%), and 41(91.1%) vs 25(71.4%) respectively], the differences being statistically significant ($P<0.05$ for all). There was a statistically significant difference in the incidence of sequelae of DVT between the observation group and the control group [0(0.00%) vs 4(11.43%), $P<0.05$]. There was no significant difference in the rate of thrombosis recurrence between the two groups [4(8.89%) vs

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5(14.28%), $P>0.05$]. VINESES-QOL/SYM questionnaire scores of the two groups were not significantly different before the treatment ($P>0.05$) but were significantly different after the treatment ($P<0.05$). **Conclusion** Implantation of iliac vein stent is more effective than catheter-directed thrombolysis in the treatment of DVT of the lower extremity with iliac vein stenosis or occlusion.

[Key words] deep venous thrombosis of lower extremity; iliac vein stenosis; iliac vein occlusion; inferior vena cava filter; iliac vein stent; catheter-directed thrombolysis

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深静脉血栓形成(deep venous thrombosis, DVT)常发生于下肢,发生率可达20%~40%^[1]。目前,导管接触性溶栓(catheter-directed thrombolysis, CDT)为临床首选的溶栓方法^[2]。但对于合并髂静脉压迫综合征(Cokett综合征或May-Thurner综合征)的患者,单独的CDT抗凝治疗效果欠佳^[3],腔内方式解除髂静脉狭窄对于深静脉血栓形成的治疗尤为重要。本研究旨在探讨髂静脉支架在下肢深静脉血栓形成治疗中的应用,报道如下。

1 对象与方法

1.1 研究对象

回顾性分析2016年1月至2018年1月山东省潍坊市人民医院收治并行腔内治疗的急性下肢DVT伴髂静脉狭窄或闭塞患者80例,其中男例43例,女性37例。根据手术是否行髂静脉支架植入治疗,分为观察组(45例)和对照组(35例)。本研究经本院医学伦理委员会批准,并与患者或家属签署知情同意书。

纳入标准:(1)年龄>25岁;(2)发病时间在14 d以内;(3)血浆D-二聚体 $\geq 500 \text{ ng/ml}$;(4)超声检查证实急性下肢DVT;(5)随诊材料完整;(6)口服抗凝药物 ≥ 12 个月;(7)CDT治疗后造影符合髂静脉狭窄者(狭窄>50%)。排除标准:(1)怀孕或哺乳期妇女;(2)活动性出血或有高度出血风险患者;(3)易栓症;(4)肝肾功能不全者;(5)合并影响抗凝治疗的严重疾病;(6)血液系统疾病患者;(7)CDT治疗后造影符合髂静脉狭窄者(狭窄<50%)。

1.2 方法

对照组采用下腔静脉滤器+CDT治疗(图1,2)。观察组采用下腔静脉滤器+CDT+髂静脉支架治疗(图3,4)。所有患者均常规植入Cordis可回收滤器,CDT治疗5~7 d。治疗结束后行下腔静脉滤器取出术。观察组在CDT治疗结束后经造影明确髂静脉狭窄位置行髂静脉支架植入,同时行腔静脉滤器取出。先充分预扩张髂静脉狭窄闭塞处,后置入

Wallstent支架(美国Boston Scientific公司),定位于髂静脉狭窄闭塞处,髂总及髂外静脉支架一般选择直径12~14 mm,股总静脉选择直径在10~12 mm。对于髂总静脉与下腔静脉交界处的病变,支架进入下腔静脉的长度控制在1 cm以内^[4,5]。在近股总静脉或者合并股总静脉的病变,明显影响血流,则需要跨髂关节植入支架。

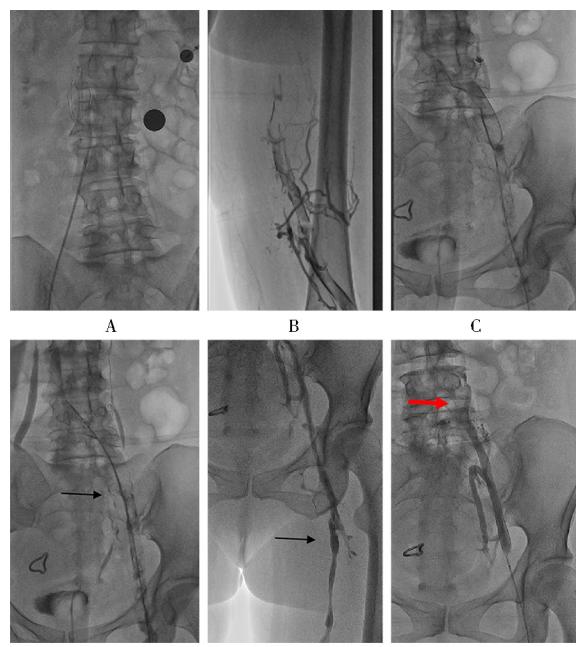


图1 对照组左下肢DVT

Figure 1 DVT of left lower extremity in control group

A: inferior vena cava filter; B: femoral vein thrombosis; C: iliac vein thrombosis; D: CDT; E: external iliac, femoral vein imaging after CDT; F: obvious stenosis of common iliac vein after CDT. DVT: deep venous thrombosis; CDT: catheter-directed thrombolysis.

术后选择华法林或利伐沙班抗凝治疗。对于VTE患者,拜瑞妥与传统抗凝方案疗效相当^[6],服用华法林患者根据国际标准化比值(international normalized ratio, INR)调整至2.0~2.5;利伐沙班应用参考急性深静脉血栓形成患者临床指南。所有住院患者出院时均复查彩色多普勒超声,随访12个月,评估髂静脉通畅程度及临床症状变化。观察患

者患肢沉重感、肿胀、静脉曲张、色素沉着及溃疡等一般情况和 DVT 的复发情况及下肢深静脉血栓后遗症 (post-thrombotic syndrome, PTS) 的发生率。

1.3 评价方法

1.3.1 效果评价 (1) 治愈: 患肢肿胀和疼痛等症状自觉消失, 复查彩色多普勒检查示血流通畅, 完全再通; 患肢消肿, 基本恢复正常。(2) 有效: 患肢肿胀和疼痛等症状自觉减轻; 患肢消肿, 但未恢复正常; 复查彩色多普勒检查示官腔内有残留血栓, 为部分再通。(3) 无效: 患肢肿胀、疼痛等症状未完全消失; 患肢无消肿; 彩色多普勒检查示无血流信号, 官腔内充满血栓, 仅靠侧支血管回流, 为完全不通。

1.3.2 患肢消肿率 分别以双侧大腿(髌骨上缘上 15 cm)及小腿(髌骨下缘下 15 cm)进行周径测量。周径差为患侧与健侧大腿和小腿周径的差值。患肢消肿率 = (治疗前周径差 - 治疗后周径差) / 治疗前周径差。

1.3.3 静脉通畅率评价 彩色多普勒超声患肢每段静脉(髂总静脉、髂外静脉、股总静脉、股浅静脉、腘静脉、胫后及肌间静脉)完全通畅 0 分, 部分通畅 1 分, 不通畅 2 分。静脉通畅率 = (治疗前静脉通畅评分 - 治疗后静脉治疗评分) / 治疗前静脉通畅评分^[7]。

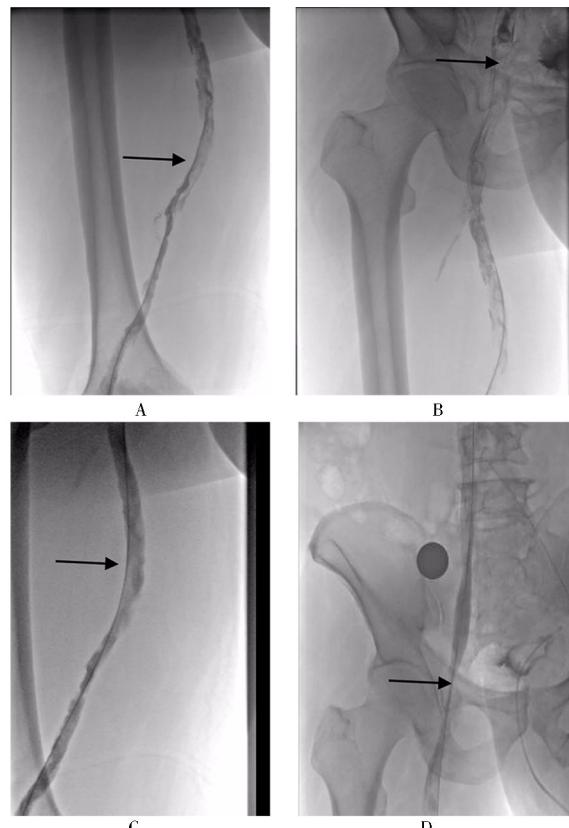


图 2 对照组右下肢 DVT

Figure 2 DVT of right lower extremity in control group
A: thrombus of femoral vein; B: thrombus of external iliac vein; C: femoral vein imaging after CDT; D: obvious stenosis of external iliac vein after CDT.

DVT: deep venous thrombosis; CDT: catheter-directed thrombolysis.

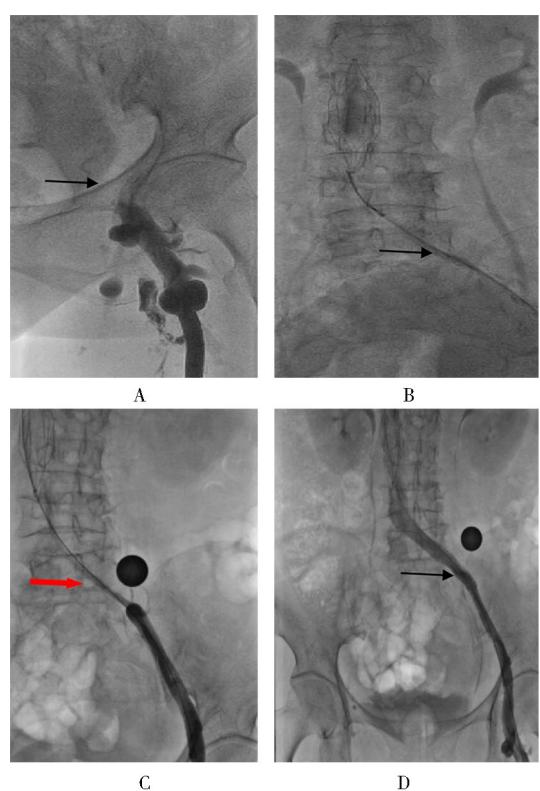


图 3 观察组左下肢 DVT

Figure 3 DVT of left lower extremity in observation group
A: no development of iliofemoral vein; B: CDT; C: obvious stenosis of common iliac vein after CDT; D: smooth blood flow after implantation of common iliac vein. DVT: deep venous thrombosis; CDT: catheter-directed thrombolysis.

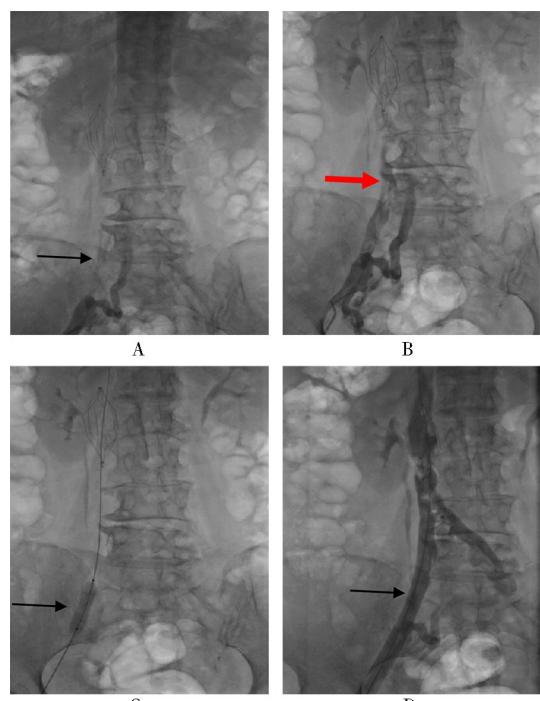


图 4 观察组右下肢 DVT

Figure 4 DVT of right lower extremity in observation group
A: no development of common iliac vein before CDT; B: obvious stenosis of common iliac vein after CDT; C: balloon dilation of common iliac vein; D: smooth blood flow of common iliac vein after CDT. DVT: deep venous thrombosis; CDT: catheter-directed thrombolysis.

1.3.4 流行病学和经济研究-生活质量/症状问卷调查评分^[8,9] (1) 经济研究-生活质量/症状(venous insufficiency epidemiological and economic studies—the quality of life/symptom, VEINES-QOL/SYM)是关于人的生存质量评分,包括:急性下肢深静脉血栓形成本身对患者心理的影响;下肢肿胀、沉重及皮肤颜色改变对生活工作的干扰;下肢静脉血栓治疗效果对患者的影响;抗凝药物对患者的影响等。(2) VEINES-SYM 是关于患肢主观症状的评分,包括:长时间站立以及行走后下肢是否有沉重感及酸胀感;是否出现色素沉着及皮肤瘙痒等。

1.4 统计学处理

采用 SPSS 18.0 统计软件进行统计分析。计数资料以例数(百分率)表示,组间比较采用 χ^2 检验,若理论频数值<1 则采用 Fisher 确切概率法。计量资料以均数±标准差($\bar{x}\pm s$)表示,采用 t 检验。以 $P<0.05$ 为差异有统计学意义。

2 结果

2.1 2组患者基本资料比较

2组患者基本资料比较,差异均无统计学意义($P>0.05$),具有可比性(表1)。

2.2 2组患者术后疗效比较

观察组治愈 41 例(91.1%)、有效(未愈)4 例(8.9%)、无效 0 例(0.0%);对照组治愈 26 例(74.3%)、有效(未愈)9 例(25.7%)、无效 0 例(0.0%)。

观察组的治愈率高于对照组,差异有统计学意义($\chi^2=4.095, P=0.043$)。2组患者治疗总有效率均为 100%。观察组患者支架植入前进行球囊扩张时大多数出现腰痛,术后均恢复。2组患者均未发生症状性肺栓塞、瘀斑及出血等并发症。

2.3 2组患者患肢消肿率比较

术前,2组大腿、小腿周径差比较,差异均无统计学意义(均 $P>0.05$)。术后,2组大腿、小腿周径差及消肿率比较,差异均有统计学意义(均 $P<0.05$;表2)。

2.4 2组患者静脉通畅率比较

随访 1、3、6、12 个月后,观察组静脉通畅率明显高于对照组,差异均有统计学意义(均 $P<0.05$;表3)。

2.5 2组患者 PTS 发生率和血栓复发率比较

所有患者术后均随访 12 个月。观察组:无 PTS 发生;下肢 DVT 复发患者 4 例,其中 2 例复发患者尚有行走后下肢酸胀及水肿,但较轻,不影响工作。对照组:发生 PTS 患者 4 例,下肢 DVT 复发患者 5 例,其中 PTS 4 例患者和复发 DVT 1 例患者下肢酸胀、沉重仍较明显,影响正常活动。

观察组与对照组的 PTS 发生率分别为[0(0.00%) 和 4 例(11.43%)] ,差异有统计学意义($P<0.05$)。观察组与对照组的 DVT 复发率分别为[4 例(8.89%) 和 5 例(14.28%)] ,差异均无统计学意义(均 $P>0.05$)。

表 1 2组患者基本资料比较

Table 1 Comparison of basic data between two groups

Group	n	Gender (male/female, n)	Previous thrombotic risk factor [n (%)]					Thromboembolic site	
			Idiopathic	Trauma surgery	Advanced aged (> 70 years old)	Lumbago and leg pain	Estrogen and progesterone	Central type/ Mixed type	Left side/Right side/Both side
Observation	45	25/20	11(24.4)	15(33.3)	11(24.4)	6(13.3)	2(4.4)	20/25	40/4/1
Control	35	18/17	8(22.9)	10(28.6)	9(25.7)	5(14.3)	3(8.6)	16/19	33/2/0
χ^2		0.136	0.039	0.215	0.027	0.024	0.079	0.016	-
P value		0.718	0.874	0.656	0.902	0.901	0.804	0.917	0.835*

* Fisher exact probability method.

表 2 2组患者双侧大腿及小腿周径差及消肿率比较

Table 2 Comparison of bilateral thigh and bilateral calf circumference difference and detumescence between two groups ($\bar{x}\pm s$)

Group	n	Bilateral thigh			Bilateral calf		
		Circumference difference before treatment (cm)	Circumference difference after treatment (cm)	Detumescence rate (%)	Circumference difference before treatment (cm)	Circumference difference after treatment (cm)	Detumescence rate (%)
Observation	45	9.64±2.18	1.50±0.80	83.14±7.60	3.65±2.12	0.88±0.76	75.68±12.29
Control	35	9.75±3.27	3.01±1.17	65.34±2.30	3.92±1.37	2.18±0.67	52.41±17.25
t		0.612	4.625	7.453	0.741	6.041	8.426
P value		0.059	<0.001	<0.001	0.060	<0.001	<0.001

2.6 2组患者生活质量评估

治疗前,2组患者VEINES-QOL/SYM评分比较,差异均无统计学意义(均 $P>0.05$)。治疗后,2组患者VEINES-QOL/SYM评分比较,差异均有统计学意义(均 $P<0.05$;表4)。

3 讨 论

深静脉血栓形成并非少见,文献报道的实际发现率为35%~52%,经静脉造影证实有症状的DVT发病率为1.6%^[10]。Samama^[11]的统计资料发现:PE的发生率高达39%~41%,PTS发生率为20%~50%。临幊上绝大多数发生静脉血栓栓塞症的患者都存在一定程度左髂总静脉压迫,但从未被确诊过^[12]。左髂静脉的狭窄压迫不仅单纯由右髂总动脉导致,还包括左髂总动脉、左髂动脉及左髂内动脉等多重因素^[13]。右下肢DVT多为周围型、中央型或者混合型的血栓,也存在髂静脉狭窄的情况出现。国内研究表明在急性左下肢DVT经导管溶栓后,如造影发现有髂静脉受压狭窄或者残余血栓造成短段狭窄时,可应用经皮腔内血管成形术(percutaneous transluminal angioplasty, PTA);如扩张后局部仍有明显狭窄(>50%)可行支架植入术,术后应至少给予抗凝处理6个月^[14,15]。但是,CDT、PTA和支架植入后因异物的刺激、炎症反应或者病变狭窄段血管处理不彻底等因素可引起内膜增生、血栓形成,造成血栓复发,这是患者术后血栓复发、影响下肢静脉通畅率

的重要因素。VEINES-QOL/SYM问卷调查评分包括生活质量与临床症状两套评分系统,其在急性下肢DVT预后评估中得到广泛关注^[16]。VENIES-QOL主要反映患者生活质量,VENIES-SYM主要评价患者临床症状。

本中心对于中央型或混合型急性下肢DVT患者,若常规行下腔静脉滤器保护下腔静脉穿刺置管溶栓CDT后造影发现髂静脉狭窄或者闭塞,对部分患者(观察组)行髂静脉支架植入术,开通髂静脉血流,解除流出道梗阻,术后配合进一步的抗凝治疗,以期提高下肢深静脉的中远期通畅率,并降低PTS的发生率。本研究显示,观察组疗效优于对照组。随访12个月,观察组的静脉通畅率、临床治愈率均高于对照组,PTS发生率低于对照组;而2组患者血栓复发率差异无统计学意义($P>0.05$)。2组患者均有一定的DVT复发,均与后期出现了恶性肿瘤、抗凝药减量或者停用有关。对照组患者大部分髂静脉存在明显狭窄及大量侧支循环,临床症状愈明显,髂静脉病变越重。根据VEINES-QOL/SYM问卷调查评分,研究发现观察组患者生存质量和主观症状评分显著优于对照组($P<0.05$),提示患者临床症状严重程度、复发率及对工作生活的影响均明显降低。患者的精神心理得到宽慰,生活满意度更高。我们认为患者即使后期再出现髂静脉支架内狭窄、内膜增生及血栓形成,但是髂静脉周围的侧支循环已经形成,下肢静脉流出道的阻力明显减少,这是该组患

表3 2组患者随访1、3、6、12个月静脉通畅率比较

Table 3 Comparison of patency rate of vein between two groups at 1, 3, 6 and 12 months follow-up [n (%)]

Group	n	1 month	3 months	6 months	12 months
Observation	45	45(100.0)	43(95.5)	41(91.1)	41(91.1)
Control	35	29(82.8)	27(77.1)	26(74.2)	25(71.4)
χ^2		-	-	4.095	5.283
P value		0.005*	0.018*	0.043	0.036

* Fisher exact probability method.

表4 2组患者VEINES-QOL/SYM问卷评分比较

Table 4 Comparison of scores of VEINES-QOL/SYM questionnaire between two groups (points, $\bar{x}\pm s$)

Group	n	VEINES-QOL		VEINES-SYM	
		Before treatment	After treatment	Before treatment	After treatment
Observation	45	36.38±1.38	85.48±2.21	19.43±2.68	40.68±1.42
Control	35	37.25±1.85	70.09±2.18	18.93±1.42	31.71±2.38
t		0.521	3.765	0.898	5.287
P value		0.061	<0.001	0.378	<0.001

者PTS发生率低的重要因素之一。同时CDT能较好地消除血栓并保留静脉瓣膜功能。本研究的远期疗效结果与国内学者杨威等^[17]的结论基本一致,近期疗效优于单独的CDT。

综上,髂静脉支架在急性期下肢深静脉血栓形成伴有髂静脉狭窄的治疗中的应用效果优于单纯置管溶栓。该治疗方法可恢复静脉的通畅性,解除下肢静脉流出道梗阻,降低急性下肢DVT治疗后PTS的发生率和血栓复发率,明显改善下肢症状,提高患者生活质量,值得在临幊上推广应用。但本次研究为单中心研究,入组患者例数少,随访时间短,不代表大样本数据变化,其远期临床效果还需进一步随访观察。

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