

ANALYSIS OF CLINICAL EFFICACY OF INTERVENTIONAL THERAPY ON LOW EXTREMITY THROMBOANGIITIS OBLITERANS PATIENTS

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ABSTRACT

Objective: To investigate the clinical efficacy of interventional therapy on low extremity thromboangiitis obliterans in clinical practice.

Methods: We selected 100 low extremity thromboangiitis obliterans patients who went to this hospital for treatment between January 2016 and December 2017 as subjects, and, divided them randomly into two groups, i.e. the treatment group (n=50) and the control group (n=50). Patients in the control group received the conventional conservative treatment, while those in the treatment group received the interventional therapy, and clinical efficacy was compared.

Results: After treatment, ameliorations in varying degrees were seen in blood flow volume, blood flow velocity, ankle-brachial index, transcutaneous oxygen pressure, inner diameter of arteria dorsalis pedis in patients of two groups, but effectiveness rate in the treatment group was better than that in the control group ($p<0.05$). Meanwhile, incidence rate of the patients in the treatment group was significantly lower than that in the control group ($p<0.05$).

Conclusion: In clinical treatment of low extremity thromboangiitis obliterans, interventional therapy can improve the condition of patients, increase the total effectiveness of clinical treatment and decrease the incidence rate of complications, which, thus, is worthy being promoted in clinical practice.

Keywords: Interventional therapy, low extremity thromboangiitis obliterans, clinical research.

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Introduction

Thromboangiitis obliterans (TAO) involves initially the middle- or small-sized arteries in limbs (mainly the lower limbs), and then the vessels, and induces intraluminal thrombus, stenosis and occlusion of lumen to cause ischemia and pains in limbs; in some severe cases, patients may experience ulcer or necrosis of limbs⁽¹⁻³⁾, and delayed treatment may easily contribute to gangrene or amputation⁽⁴⁾. Thus, timely diagnosis and treatment are critical to the improvement of prognosis of patients.

In this study, we investigated the efficacy of interventional therapy on low extremity thromboangiitis obliterans, and significant effectiveness was obtained. Detailed information of this study is reported as follows.

Data and methods

General data

100 patients with low extremity thromboangiitis obliterans who received treatment in this hospital between January 2016 and December 2017 were

enrolled as subjects, and were confirmed through arteriography. Patients had following signs in varying degrees: numbness, intermittent claudication, low skin temperature on the affected side and sensation of chill⁽³⁾. Patients with hepatic or renal dysfunctions, blood diseases, abnormal cardiac or pulmonary functions or mental diseases were excluded.

All patients had one-side lesions, and stages of ischemia in low limbs are shown as follows: 51 patients in Stage 1, 28 in Stage 2 and 21 in Stage 3. These patients were divided randomly into two groups, i.e. the control group (n=50) and the treatment group (n=50). In the control group, there were 41 males and 9 females aged between 30 and 68 years old with an average of 44.8 years old; disease course of patients ranged from 3 months to 6 years, with an average of 1.4 years. In the treatment group, there were 42 males and 8 females aged between 32 and 69 years, with an average of 44.9 years old; disease course ranged from 2 months to 6 years, with an average of 1.5 years. Comparisons of the age, gender, disease course and severity of disease between two groups showed that differences had no statistical significance ($p>0.05$).

Methods

For patients in the control group, conservative treatment was performed with Huangqi Tongmai decoction (Huangqi 50 g, salvia miltiorrhiza 20 g, achyranthes root 15 g, cassia twig 15 g, Radix Rehmanniae Praeparata 15 g, Angelica sinensis 12 g, dogwood 12 g, Radix Paeoniae Alba 12 g, leech 10 g, Cassia Twig 8 g, Asarum sieboldii 5 g, liquorice 4 g and 5 Jujubes). Decoction was taken in water service twice a day, and additionally, 50 mg aspirin was also taken orally once a day.

For patients in the treatment group, they, according to the preoperative CTA, correspondingly took anterograde puncture through femoral artery and iliac, femoral arteriography using 4F catheter to clarify the thrombus and occlusion, range and collateral compensative capacity of lumen. Thrombectomy, thrombolysis, percutaneous transluminal coronary angioplasty and anticoagulant therapy were accordingly adopted; for patients with fresh thrombus in femoral or popliteal artery, 6F guiding catheter was used for suction-assisted thrombectomy; for patients with poor prognosis of thrombectomy, or patients in stage 1 with disease course > 14 d, or in stage 2 or 3, thrombolysis would be adopted directly. Thrombolysis was carried out by guiding wire in catheter that passed

through the occlusive or narrow part of artery, and the catheter was placed inside the thrombus; then, metal inner core was inserted and fixed inside the catheter; 20 mg recombinant tissue plasminogen activator dissolved in 20 mL normal saline was pumped through micro-pump for thrombolysis once per day for 3 consecutive days; during this period, angiography was performed once per day to observe the thrombolysis and reconstruction of lumen; for patients with significant stenosis, percutaneous transluminal coronary angioplasty was considered to perform through balloon dilation and stent implantation. During treatment, anticoagulation was conducted with heparin, and the coagulation time and plasma fibrinogen were monitored closely; meanwhile, medication was carried out for vascular dilation and improving the microcirculation. Moreover, patients were required to quit smoking, keep the affected limbs warm and receive symptomatic treatment; Buerger training was also conducted to establish the collateral circulation of affected limbs, and so did the anti-platelet treatment. Every month, continuous treatment was performed once, followed by three-month follow-up to compare the amelioration and clinical efficacy between two groups.

Criteria of clinical efficacy

According to openness of vessels and amelioration of disease, clinical efficacy on patients was divided into three categories, i.e. cure, effective and ineffective: a) Cure: Angiography showed normal blood supply in aorta, pulse in distal end, skin color and disappearance of ischemia, pains and intermittent claudication; b) Effective: Angiography showed partial recovery in blood supply in aorta and pulse in distal end, good recovery in skin color and partial improvement in diseases; c) Invalid: Angiography showed obstruction of aorta, anomaly in pulse in distal end, no amelioration in skin color, ischemia, pains or intermittent claudication, or aggravation in some cases. Total effectiveness rate was the total of percentages of cure and effective.

Statistical methods

SPSS 20.0 software was adopted for data analysis. Measurement data were presented as mean \pm standard deviation ($\bar{x} \pm s$). Comparisons of the measurement data and enumeration data were performed through t test and chi-square test. $p<0.05$ suggested that the difference had statistical significance.

Results

General data of patients

No statistical significance was identified in differences of age, gender, disease course and severity of patients between two groups ($p>0.05$), suggesting that the data were comparable (Table 1).

Item	Treatment group	Control group
Cases (n)	50	50
Gender (male/female)	42/8	41/9
Age (years)	32-69 (44.9)	30-68 (44.8)
Disease course	2 months-6 years (1.5 years)	3 months-6 years (1.4 years)
Stage of ischemia in low limb (n):		
Stage 1	25	26
Stage 2	14	14
Stage 3	11	10

Table 1: General data of patients in two groups.

Changes in blood flow velocity in external iliac vein, ABI, TcPO₂ and inner diameter of dorsal pedal artery in patients of two groups

In comparison with the levels before treatment, statistical significance was identified in differences of blood flow velocity in external iliac vein, ABI, TcPO₂ and inner diameter of dorsal pedal artery in patients in the treatment group after treatment ($p<0.01$ or 0.05); for patients in control group, only comparisons of blood flow velocity in external iliac vein and ABI with the level before treatment had statistical significance ($p<0.05$).

After treatment, comparison between the control group and the treatment group showed that the differences of blood flow velocity in external iliac vein, TcPO₂ and inner diameter of dorsal pedal artery had statistical significance ($p<0.05$; Table 2).

Item	Treatment group			Control group		
	Before	After	<i>p</i>	Before	After	<i>p</i>
Blood flow velocity in external iliac vein	21±2.6	37±1.9*	<0.01	20±2.4	28±2.1	<0.05
ABI	0.5±0.04	1.3±0.07	<0.01	0.5±0.06	1.0±0.03	<0.05
TcPO ₂	33±1.8	52±2.1*	<0.05	34±1.6	41±2.3	>0.05
Inner diameter of dorsal pedal artery	1.5±0.3	2.0±0.3*	<0.05	1.4±0.4	1.7±0.3	>0.05

Table 2: Changes in blood flow velocity in external iliac vein, ABI, TcPO₂ and inner diameter of dorsal pedal artery in patients of two groups.

Comparison of the clinical efficacy between two groups

Total effectiveness rate in the treatment group was significantly higher than that in the control group ($p<0.05$), while the incidence rate of the treatment group was 2.0% (1/50), significantly lower than 8.0% (4/50) in the control group ($p<0.05$; Table 3).

Group	n	Cure	Effective	Invalid	Total effectiveness rate (%)	Incidence rate (%)
Treatment group	50	31	19	0	50 (100.0)	1 (2.0)
Control group	50	21	22	7	43 (86.0)	4 (8.0)
<i>p</i>					<0.05	<0.05

Table 3: Comparison of the clinical efficacy of patients between two groups.

Discussion

Thromboangiitis obliterans is affected by various factors, including smoking, sex hormones or autoimmune, and in a chronic manner, peripheral vasculitis and occlusive lesions can gradually involve the middle- or small-sized veins in limbs, mostly the lower limbs; furthermore, non-inflamed inflammatory thrombus is found in affected veins, and patients manifest typical symptoms, including intermittent claudication, sensation of chill, numbness and stabbing pain in affected limbs and continuous pains in toes, which may aggravate at night. Clinical diagnosis is usually made according to the clinical symptoms, weakened or disappeared arterial pulse, ulcer or necrosis of limbs, arteriography or CTA; sensitive rate and detection rate of color Doppler ultrasound examination have been recognized in clinical practice, and this method shows promising value in diagnosis and differentiation of LEASD patients and vasculitis patients^(5,6). In thromboangiitis obliterans, affected arteries present non-infectious inflammatory changes, inflammatory hyperplasia in artery, stenosis or even secondary occlusion, thereby affecting the artery of shank, femoral artery and popliteal artery; characteristics of lesions mainly include the occluded arteries in limbs in an extensive range, obviously in the middle- and small-sized arteries, which may extend to the distal arteries; plus a long disease course, it is quite difficult to be cured in clinical practice.

With progression of disease, thromboangiitis obliterans manifests periodic features, including intraluminal thrombus that may easily lead to

ischemia, pains or intermittent claudication in patients, and delayed treatment may further induce necrosis or ulcer in limbs⁽⁷⁾. Thus, timely diagnosis and treatment are quite important for patients.

Clinically, treatment is usually carried out by conservative, mainly the Traditional Chinese Medicine, or surgery methods through vein-artery transformation, interventional therapy or embolectomy by arteriotomy^(8,9). Interventional therapy can directly act on the lesions, which can clarify the diagnosis and facilitate the treatment. Stages of ischemia in lower limbs are correlated with the efficacy of interventional therapy: A higher ischemic stage represents a poorer prognosis of interventional therapy^(10,11). Best outcomes are usually gained in patients in Stage 1, and their lumen can keep open for a long term with an excellent prognosis; for patients in Stage 2, interventional therapy is difficult in operation, and prognosis of patient is poor; as for patients in Stage 3, their lumen has been fully occluded, and therapy only gains a poor prognosis with a high incidence rate of stenosis after operation and a low limb preserved rate⁽¹²⁾.

We selected 100 low extremity thromboangiitis obliterans patients who went to this hospital for treatment between January 2016 and December 2017 as subjects, and, divided them randomly into two groups, i.e. the treatment group (n=50) and the control group (n=50). Patients in the control group received the conventional conservative treatment, while those in the treatment group received the interventional therapy, and clinical efficacy was compared. After treatment, ameliorations in varying degrees were seen in blood flow volume, blood flow velocity, ankle-brachial index, transcutaneous oxygen pressure, inner diameter of arteria dorsalis pedis in patients of two groups, but effectiveness rate in the treatment group was better than that in the control group ($p<0.05$). Meanwhile, incidence rate of the patients in the treatment group was significantly lower than that in the control group ($p<0.05$).

Thromboangiitis obliterans leads to insufficient collateral compensatory capacity, and a decrease in limb functions, while interventional therapy should open the anterior and posterior tibial artery to restore the blood supply in lower limbs maximally, thus increasing the cure rate and limb preserved rate⁽¹³⁾. In catheter system, catheter can be left in the external iliac artery of the affected limbs, and drug can be delivered to the targeted

vessels through catheter with a high drug concentration in local part, rapid onset of effect, and improved efficacy. Special attention should be paid to the opportunity and indications of percutaneous transluminal coronary angioplasty by balloon dilation and stent implantation, so as to avoid the detachment of thrombus, arterial embolism and aggravation in ischemia in limbs. During the interventional therapy, vasodilator therapy and methods to improve microcirculation should be considered at the same time, and patients are required to quit smoking, keep limbs warm, minimize the stimuli to affected limbs, be free from the raw or cold food, or spicy food, and take exercises to promote the blood circulation in limbs.

In clinical treatment of low extremity thromboangiitis obliterans, interventional therapy can improve the condition of patients, increase the total effectiveness of clinical treatment and decrease the incidence rate of complications, which, thus, is worthy being promoted in clinical practice.

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