

Effects of Combining Lumbrokinase and PGE1 in Treating Senior Patients with Peripheral Arteriosclerosis Obliterans

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[Abstract] **OBJECTIVE:** To observe the therapeutic effects of combining enteric-coated lumbrokinase and PGE1 in treating patients with peripheral arteriosclerosis obliterans of old age. **METHODS:** Sixty-two patients of peripheral arteriosclerosis obliterans (ASO) were divided into two groups randomly and treated with lumbrokinase enteric-coated capsules and PGE1, or prostaglandin E1 alone. Patients were monitored for changes in symptoms, blood parameters, ABI, and severity of peripheral arteriosclerosis by ultrasound before and after treatment. **RESULT:** The treatment effectiveness rate in the lumbrokinase plus PGE1 group and in the PGE1 alone group were 93.5% and 71% respectively, and the difference was statistically significant ($P < 0.05$). **CONCLUSION:** Lumbrokinase enteric-coated capsules plus PGE1 a better option than PGE1 alone in the treatment of ASO.

[Key words] Peripheral arteriosclerosis obliterans; Lumbrokinase enteric-coated capsules, Alprostadil

Peripheral arteriosclerosis obliterans has become a common disorder for seniors over the years. In recent years, we have been using lumbrokinase with PGE1 to treat peripheral arteriosclerosis obliterans of old age, and the results are quite promising.

1. Information and Method

1.1 Clinical information:

All 62 cases of peripheral arteriosclerosis obliterans (ASO) had been diagnosed based on the criteria set out by China Integrated Western and Chinese Medicine Committee on peripheral vessels disease. There were 46 male cases and 16 female cases with the age ranging from 60 to 85 years. There were 44 cases with hypertension, 32 cases with diabetes, 25 cases with heart disease, 39 cases with high blood cholesterol and 6 cases with cerebral infarction history. The breakdown of patients according to disease severity: 6 cases of stage I, 42 cases of stage II, 14 cases of stage III in which there were 12 cases of 1st level of stage III and 2 cases of 2nd level of stage III. All observations and measurements were done on the more severe side of the lower extremities in all 62 cases. The cases are divided randomly into treatment group and control group. The average ages of both groups were 68 and 68.4 years with average course of disease of 2 years. Both groups were statistically comparable.

1.2 Treatment method:

Control group: the most commonly used treatment of intravenous injection of PGE1, 20 µg once per day for 15 days, with concurrent oral intake of Aspirin 100mg once a day for 3 months.

Treatment group: Intravenous injection of PGE1, 20 µg once per day for 15 days with concurrent oral intake of lumbrokinase 0.46g tid after meal for 3 months.

Other medications such as blood pressure lowering medication, anti-cholesterol medication and blood sugar lowering medications were given to patients as indicated in both groups.

2. Results

2.1 Clinical effectiveness:

According to the revised standard set out by Chinese integrated Western and Chinese medicine on professional peripheral vessels disease committee: Excellent: pain disappeared, ulcer healed, blood circulation restored to normal or improved substantially, the maximal walking distance was about 1000m. Good: pain disappeared or alleviated, ulcer healed or reduced, blood circulation improved, the maximal walking distance was about 400-500m. Poor: Pain reduced, no change in ulcer, no obvious improvement in blood circulation and maximal walking distance. Ineffective: no benefits from the treatment resulting in amputation. Among all 62 cases, there were only 7 cases (4 in treatment group and 3 in control group) showing erythematous skin and venous pain during intravenous infusion of PGE1, but symptoms were resolved after the infusion rate was reduced or switching the injection site. Four cases had digestive discomfort after taking lumbrokinase for 3 to 6 days, but symptoms were alleviated after GI protective medication was added. Of the 31 cases in the treatment group, the results were considered excellent in 16 cases, good in 12 cases and poor in 2 cases. In the control group, the results were considered excellent in 8 cases, good in 14 cases and poor in 9 cases.

2.2 The comparison of blood ApoA, ApoB, HDL-C and Lp(a) between two groups before and after treatment:

Group	n		LP(a)	HDL-C	ApoA	ApoB
Treatment	31	Before	81.9±41.8	0.696±0.189	1.192±0.181	1.736±0.275
		After	43.55±30.51*Δ	0.913±0.178*Δ	1.402±0.170*Δ	1.449±0.258*Δ
Control	31	Before	84.52±46.87	0.695±0.199	1.187±0.181	1.752±0.288
		After	62.35±39.24	0.801±0.189	1.293±0.174	1.577±0.239

*Intra-group comparison before and after treatment, $P < 0.001$

ΔInter-group comparison before and after treatment, $P < 0.05$

2.3 The comparison of ankle brachial index (ABI) and degree of stenosis between two groups before and after treatment:

Group	n		ABI	Degree of Stenosis	
				PSV(cm/s)	PSV Ratio
Treatment	31	Before	0.675±0.123	145.19±20.43	1.760±0.362
		After	0.807±0.114* Δ	122.61±19.09* Δ	1.396±0.348* Δ
Control	31	Before	0.665±0.125	154.55±20.26	1.771±0.366
		After	0.736±0.120	134.29±19.37	1.586±0.352

*Intra-group comparison before and after treatment, $P < 0.001$

Δ Inter-group comparison before and after treatment, $P < 0.05$

PSV=Peak Systolic Flow Velocity at the stenosis

PSV Ratio= Peak Systolic Flow Velocity at the stenosis/PSV 1-2 cm above the stenosis

3. Discussion

This research combined lumbrokinase with PGE1 to treat ASO because lumbrokinase is a multi-enzyme complex containing two types of enzymes, plasminogen activator and fibrinolytic agent. It also contains tPA-like enzymes that can enter into blood via intestinal absorption. Therefore, lumbrokinase can achieve the purpose of treating ASO by dissolving blood clots directly, activating fibrinolytic system, inhibiting platelet aggregation and dilating blood vessels. PGE1 is the most effective and extensively used medication for ASO. It can prevent arteriosclerosis, protect endothelium, modify TXA2/PGI2 ratio, inhibit platelet aggregation and improve blood circulation. Therefore, it works not only on ASO, but also works on arteriosclerotic complications in coronary artery, cerebrovascular, and kidney diseases as well as in diabetes. This research shows that combining lumbrokinase with PGE1 has a better clinical effectiveness than applying PGE1 alone, and the combination can achieve treatment goal through multi-targeted, multi-leveled, and both local and systemic circulatory effects. This combination treatment is an effective and convenient treatment protocol with minimal side effects for ASO in seniors.

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