COMPARISON OF CLINICAL EFFICACY OF POLYDOCARYL FOAM SCLEROTHERAPY WITH CONVENTIONAL SURGERY FOR VARICOSE VEINS IN LOWER EXTREMITIES

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ABSTRACT

Objective*: To investigate the clinical efficacy of polydocartanol foam sclerotherapy and conventional surgery in the treatment of varicose veins in lower extremities.*

Methods: *112 cases of VVLE patients hospitalized in the vascular surgery department of our hospital from September 2017 to August 2019 were included and divided into experimental group and control group according to different surgical methods, with 56 cases in each group. Both groups of VVLE patients received routine preoperative surgical examination and epidural anesthesia, in which the control group received conventional surgical treatment (high ligation and stripping of the great saphenous vein), and the experimental group received polydocartanol foam sclerosis. The operative time, length of hospital stay, intraoperative blood loss, subjective feeling improvement, postoperative pain (whether there is local pain, whether to take painkillers), and incidence of symptoms were observed and analyzed in each group.*

Results: *Compared with the control group and experimental group, the operative time, hospital stay, and intraoperative blood loss were significantly reduced (P<0.05). Compared with the control group, there was no statistically significant difference in the subjective feelings of VVLE patients in the experimental group (P>0.05). Of the 56 VVLE patients in the experimental group (101 affected limbs), 32 (31.68%) had local pain, and 6 (10.71%) needed to take painkillers. Among the 56 patients with VVLE in the control group (105 affected limbs), 69 (65.71%) had local tenderness, and 21 (37.50%) needed a painkiller. The difference in the local pain rate and the painkiller rate between the two groups was statistically significant compared with the control group (P<0.05). In the experimental group, 3 (5.36%) cases of thrombophlebitis, 4 (7.14%) cases of skin pigmentation, and 3 (5.36%) cases of varicose vein residue occurred in VVLE patients, with a total incidence of 17.86%. In the control group, there were 6 (10.71%) cases of thrombophlebitis, 6 (10.71%) cases of skin pigmentation, 4 (7.14%) cases of varicose vein residue, and 7 (12.50%) cases of skin paresthesia, for a total of 41.07%. The difference in the postoperative complication rate between the two groups of VVLE patients was statistically significant (P<0.05).*

Conclusion: *Polydocaryl foam sclerotherapy can effectively promote the recovery of VVLE patients and relieve their pain with higher safety and reliability. Compared with traditional surgical treatment, polydocaryl foam sclerotherapy has significant advantages, strong practicability, and is expected to be a new treatment method to replace traditional surgery.*

Keywords: *Varicose veins of lower extremities, polydocaryl alcohol, foam sclerotherapy, high ligation of great saphenous vein.*

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Introduction

Varicose vein of lower extremity (VVLE) is a disease of the vascular surgical venous system, mainly manifested as Varicose great saphenous vein with different symptoms[(1)]. At present, the incidence of varicose veins in lower extremities in China is gradually increasing, and the incidence of varicose veins in females is significantly higher than that in males, which has a serious impact on the quality of life and aesthetic appearance of the legs of patients[(2)]. In the past, traditional surgery was mainly used to treat varicose veins in lower extremities. However, this operation can lead to severe trauma and many skin scars, slow postoperative recovery, and a high risk of complications. Conventional treatments have

gradually been replaced by many types of minimally invasive surgery[3]. Foam sclerotherapy is one of the most widely used surgical methods in clinical practice in recent years. It has the advantages of fewer postoperative complications and faster recovery, better early treatment effect, and higher safety and reliability[4]. Clinical studies have shown that foam sclerotherapy has therapeutic effects on all types of varicose veins in lower extremities and is a new treatment for varicose veins[5].

Polydocartanol is a hardener that can damage the epidermal cells in the veins. Thus, related venous atresia and blood flow recanalization are inhibited, causing the function of the atresia vein to be replaced by connective tissue and finally absorbed by the body, with an objective effect[6]. Therefore, this study will further explore the clinical efficacy of polydocartanol foam sclerotherapy and traditional surgery for lower extremity varicose veins.

Materials and methods

General information

Included: 112 cases of VVLE patients hospitalized in the vascular surgery department of our hospital from September 2017 to August 2019.

Inclusion criteria:

• All patients are consistent with the VVLE diagnostic criteria in the 7th edition of Wong Kars Si Surgery;

• All diagnoses were confirmed as VVLE by Doppler ultrasonography and other examinations;

• Clinical manifestations presented include acid distention and discomfort, itchy skin, muscle spasms, and others;

• All agreed to undergo minimally invasive surgery, which requires strong aesthetic requirements, and informed consent was obtained;

• An application was submitted to the ethics committee of the hospital and has been approved.

Exclusion criteria:

• Previous history of deep vein thrombosis;

• VVLE caused by congenital causes;

• Or presence of cardiovascular, cerebrovascular diseases, or autoimmune diseases.

One hundred twelve cases of VVLE were divided into an experimental group and a control group according to different surgical methods. Among them, 56 patients were in the experimental group, 30 males and 26 females with an average age of 51.51 (±11.11) years and disease course of 13.02 (±8.31) years were enrolled.

The control group comprised 56 patients, 25 males and 31 females, with an average age of 53.11 (±13.31) years and a course of disease of 10.71 (±138.31) years. No statistically significant difference was observed in general data between the two groups of VVLE patients (P>0.05).

Methods

Both groups of VVLE patients underwent routine preoperative surgical examination and epidural anesthesia. VVLE patients in the control group were treated with traditional surgery (high ligation and stripping of the great saphenous vein). A supine position was taken, inguinal oval fossa was selected for incision, subcutaneous tissue of the partial branch of the great saphenous vein root was separated, oval hole and bone saphenous confluence were fully exposed, and the main trunk of great saphenous vein was ligated at high level, and superficial venous mass of large saphenous vein was stripped. The VVLE patients in the experimental group were treated with polydocarbol foam sclerosis. The puncture position was selected before the operation, and the total dose was controlled within 20 ml at each puncture point. According to the preoperative mark, 1~20 ml foam sclerotherapy was injected into the superficial varicose vein mass.

Observation index

• The operative time, hospital stay, and intraoperative blood loss of VVLE patients in the two groups were recorded and analyzed.

• One month after surgery, the subjective feeling improvement of patients in the two groups of VVLE was observed, mainly including skin pruritus, lower extremity acid distention and heaviness, which were divided into two levels of no improvement or significant improvement.

• After surgery, the two groups of VVLE patients were compared as to whether there was local pain and whether they took analgesic drugs.

• The complications of the two groups of VVLE patients were observed, including thrombophlebitis, skin pigmentation, skin paresthesia, and varicose vein residue.

Statistical methods

The measurement data of operation time, hospitalization time, and intraoperative blood loss of VVLE patients in each group were (x±s) expressed. A comparison between the two groups was performed using a t-test. The incidence of postoperative

complications and other counting data of VVLE patients were expressed in n(%).

A χ^2 test was used between the two groups, and analysis of observation data using SPSS18.0 revealed statistically significant results (P<0.05).

Results

Comparison of operative time, hospital stay, and intraoperative blood loss of VVLE patients in each group

Compared with the control group, the operative time, hospital stay, and intraoperative blood loss of the experimental group of VVLE patients were significantly reduced (P<0.05). See Table 1.

Group	n	Operative Time (Min)	Intraoperative Blood Loss (Ml)	Hospital stay (d)
Experimental group	56	42.44±5.65	16.88±4.47	5.38±0.54
Control group	56	57.25±6.73	42.21±7.96	7.77±1.21
t		12.612	20.763	13.498
P		<0.001	<0.001	<0.001

Table 1: Comparison of operative time, hospital stay, and intraoperative blood loss of VVLE patients in each group (x±s).

Analysis of the improvement degree of subjective feeling of VVLE patients in each group

Compared with the control group, there was no statistically significant difference in the subjective feelings of VVLE patients in the experimental group (P>0.05). Results are shown in Table 2.

Group	n (Affected limbs)	Obvious improvement	No/slight improvement
Experimental group	101	81(80.20)	20(19.80)
Control group	105	86(81.90)	19(18.10)
χ^2	0.098		
P	0.765		

Table 2: Analysis of improvement degree of subjective feeling of VVLE patients in each group [n (%)].

Analysis of postoperative pain of VVLE patients in each group

Among the 56 VVLE patients in the experimental group (101 affected limbs), 32 (31.68%) had local pain, and 6 (10.71%) needed to take painkillers. Of the 56 patients with VVLE in the control group (105 affected limbs), 69 (65.71%) had local tenderness, and 21 (37.50%) needed a painkiller.

The difference in local pain rate and painkiller rate between the two groups was statistically significant compared with the control group (P<0.05). See Table 3.

Group	n (Affected limbs)	Local pain		Take painkillers	
		With	Without	Require	Not Required
Experimental group (n = 56)	101	32 (31.68)	69 (68.32)	6 (10.71)	50 (89.29)
Control group (n = 56)	105	69 (65.71)	36 (34.29)	21 (37.50)	35 (62.50)
χ^2		23.857		10.980	
P		<0.001		0.001	

Table 3: Analysis of postoperative pain of VVLE patients in each group [n (%)].

Risk analysis of postoperative complications of VVLE patients in each group

In the experimental group, 3 (5.36) cases of thrombophlebitis, 4 (7.14%) cases of skin pigmentation, and 3 (5.36%) cases of varicose vein residue occurred in VVLE patients, with a total incidence of 17.86%. In the control group, there were 6 (10.71%) cases of thrombophlebitis, 6 (10.71%) cases of skin pigmentation, 4 (7.14%) cases of varicose vein residue, and 7 (12.50%) cases of skin paresthesia, for a total of 41.07%. The difference in the postoperative complication rate between the two groups of VVLE patients was statistically significant (P<0.05). See Table 4.

Group	n	T	P	Skin paresthesia	Varicose vein residue	Complication rate
Experimental group	56	3 (5.36)	4 (7.14)	0 (0.00)	3 (5.36)	10 (17.86)
Control group	56	6 (10.71)	6 (10.71)	7 (12.50)	4 (7.14)	23 (41.07)
χ^2						7.261
P						0.007

Table 4: Risk analysis of postoperative complications of VVLE patients in each group.
Note: T: Thrombophlebitis; P: Pigmentation.

Discussion

Many treatment methods exist for VVLE, among which the high ligation and stripping of the great saphenous vein belong to the traditional classic operation, and the clinical effect is worthy of affirmation. However, it has disadvantages such as a long operation time and many surgical incisions, which make it difficult for people to accept[7]. With the improvement of people's aesthetic requirements,

the treatment of VVLE has gradually become minimally invasive. In recent years, phlebology has continuously been developing, and foam-hardening therapy has emerged[8]. Clinical studies have shown that a foam sclerosing agent's physical properties can overcome the restrictions of liquid sclerotherapy to the maximum extent. At present, foam hardening preparations have become the research focus of relevant scholars in the Americas, among whom some scholars have repeatedly described their experience in the application of foam-hardening preparations in their articles and highly praised its prospects for therapeutic application[9]. In addition, relevant studies at home and abroad have confirmed that the clinical effect of foam sclerotherapy in the treatment of VVLE is similar to that of intravenous cava ablation and traditional surgical treatment to a certain extent[10].

Polydocaryl alcohol is a foam hardener widely used in the world. In 2015, it entered the medical field in China. Its main active ingredient is polydocaryl alcohol, which can be mixed with air in a certain proportion and can be made into drugs with a stable structure. Clinical studies have shown that the amount of polydocaryl alcohol foam hardening liquid is small, and the amount entering deep veins is also minimal, so it has a high safety[12]. Studies have shown that polypolycartanol is similar to sodium myristyl sulfate in the treatment of varicose veins in spider webs[13,14]. Studies on the treatment of varicose veins in lower extremities by polydocarylation have shown that there were still 2 patients with residual varicose veins after surgery, and that the residual varicose veins were found to disappear after foam sclerosis one month later and reach complete closure, indicating that the varicose veins could be reused in a short period of time[15].

In this study, we first collected and analyzed the operative time and other relevant data of the two groups of VVLE patients and found that compared with the control group and experimental group, the operative time, hospital stay, and intraoperative blood loss of VVLE patients were significantly reduced. It is suggested that polydocaryl foam-hardening is beneficial to the recovery of VVLE patients and the reduction of operative time and intraoperative blood loss. In this study, we found that there was no statistical significance in the improvement of subjective feelings of patients in the two groups, suggesting that the two surgical methods can significantly improve the clinical symptoms of VVLE patients and reduce their burden.

We also found that the local pain in the experimental group was significantly reduced compared with that in the control group, and the use of analgesic drugs was also significantly reduced. It is suggested that the foam sclerotherapy with polypolyol could significantly relieve common pain and reduce trauma. In addition, this study found that the risk of complications in the experimental group was significantly lower than that in the control group, suggesting that polydocaryl foam sclerosis could significantly control the incidence of complications in patients with VVLE, with higher safety and reliability. However, in this study, we found that there were still a small number of varicose veins locally in 3 patients in the experimental group, which we speculated might be related to the unreasonable design of the puncture site before surgery.

In sum, polydocartanol foam sclerotherapy can effectively promote the recovery of VVLE patients and relieve their pain with higher safety and reliability. Compared with traditional surgical treatment, polydocartanol foam sclerotherapy has significant advantages and strong practicability and is expected to be a new treatment method to replace traditional surgery.

References

1) Nierlich P, Enzmann FK, Metzger P, Dabernig W, Akhavan F, et al. Arm vein versus small saphenous vein for lower extremity bypass in the absence of both great saphenous veins. Ann Vasc Surg 2020; 12: 24.
2) Yu WS, Liu J, Yang HW, Wang ZH, Xia YD, et al. Application of the Trivex system in the treatment of primary severe superficial varicose veins of the lower extremity. J Interventional Med 2019; 2: 146-149.
3) Kheirelseid EAH, Crowe G, Sehgal R, Liakopoulos D, Bela H, et al. Systematic review and meta-analysis of randomized controlled trials evaluating long-term outcomes of endovenous management of lower extremity varicose veins. J Vasc Surg Venous Lymphat Disord 2018; 6: 256-270.
4) Brittenden J. Randomized clinical trial comparing endovenous laser ablation, radiofrequency ablation, foam sclerotherapy and surgical stripping for great saphenous varicose veins (Br J Surg 2011; 98: 1079–1087). British J Surg 2017; 98: 1088-1089.
5) Huegel U, Baumgartner I. Implementation of new endovenous treatments in therapy for lateral embryonic veins. J Vasc Surg Cases Innov Tech 2019; 5: 243-247.

6) Mohammed AS, Mahmood WI, Ghafor K. TGA, rheological properties with maximum shear stress and compressive strength of cement-based grout modified with polycarboxylate polymers. Constr Build Mater 2019; 235: 1175.
7) Woźniak W, Kielar M, Mlosek RK, Ciostek P. Comparative analysis of five-year outcomes of lower extremity varicose vein therapy using monopolar and segmental radiofrequency ablation. Int Angiol 2018; 37: 321-325.
8) Zhao MP, Han XQ, Wang WM, Chen G, Sheng YG, et al. Efficacy analysis of one-stop hybrid operation on iliac vein compression syndrome combined with lower extremity varicose veins. Chin J Interventional Radiol (Electronic Edition) 2019; 11: 78-89.
9) Venermo M, Saarinen J, Eskelinen E, Vähäaho S, Saarinen E, et al. Randomized clinical trial comparing surgery, endovenous laser ablation and ultrasound-guided foam sclerotherapy for the treatment of great saphenous varicose veins. Br J Surg 2016; 103: 1438-1444.
10) Yang Y, Xia Y. Polycarboxyl metal-organic framework UiO-66-(COOH) 2 as efficient desorption/ionization matrix of laser desorption/ionization mass spectrometry for selective enrichment and detection of phosphopeptides. J Nanoparticle Res 2019; 21: 1-12.
11) Li SS, Song YL, Yang HR, An QD, Xiao ZY, et al. Modifying alginate beads using polycarboxyl component for enhanced metal ions removal. Int J Biol Macromol 2020; 158: 493-501.
12) Heathman CR, Grimes TS, Jansone-Popova S, Roy S, Bryantsev VS, et al. Influence of a Pre-organized N-Donor Group on the Coordination of Trivalent Actinides and Lanthanides by an Aminopolycarboxylate Complexant. Chemistry 2019; 25: 2545-2555.
13) Luo SJ, Ding JS, Wang PQ, Wang Z, Ma XQ, et al. Carboxyl of Poly (D, L-lactide-co-glycolide) Nanoparticles of Perfluorooctyl Bromide for Ultrasonic Imaging of Tumor. Contrast Media Mol Imaging 2018; 2018: 2957459.
14) Cai Q, Li X, Zhu W. High Molecular Weight Biodegradable Poly (ethylene glycol) via Carboxyl-Ester Transesterification. Macromolecules 2020; 53: 2177-2186.
15) Liu ZJ, Chen XM, Cheng JS. Crystal structure of poly-[(μ2-(carboxylatomethyl) ((3-nitrophenyl) sulfonyl) amido-κ3N:O:O') (μ2-4,4'-bipyridine-κ2N: N') nickel (II)], C18H14NiN4O6S. Zeitschrift für Kristallographie - New Crystal Structures 2019; 234: 242.

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