

## ОПЫТ ПРИМЕНЕНИЯ МЕХАНОХИМИЧЕСКОЙ СКЛЕРООБЛИТЕРАЦИИ В ЛЕЧЕНИИ РЕЦИДИВА ВАРИКОЗНОЙ БОЛЕЗНИ ВЕН НИЖНИХ КОНЕЧНОСТЕЙ

© А.Д. Гаубов<sup>1,2</sup>, О. Нейматзода<sup>2</sup>, Ш.М. Буриева<sup>1</sup>, Е.Л. Калмыков<sup>1</sup>

ГОУ Таджикский государственный медицинский университет  
им. Абуали ибни Сино, Душанбе, Таджикистан (1)

ГУ Республиканский научный центр сердечно-сосудистой хирургии  
МЗ и СЗН РТ, Душанбе, Таджикистан (2)

**Цель.** Оценка эффективности механо-химической склерооблитерации при лечении рецидива варикозной болезни вен (ВБВ) нижних конечностей.

**Материалы и методы.** Проведен ретроспективный анализ результатов обследования и лечения 19 пациентов (17 женщин и 2 мужчин, средний возраст  $36,3 \pm 4,5$  лет) с рецидивами ВБВ, которым в качестве основного метода лечения была использована механо-химическая склеротерапия. Во всех случаях для механохимической облитерации поверхностных венозных стволов был использован катетер «Флебогриф». В качестве флебосклерозирующего препарата был использован 3% раствор натрия тетрадецилсульфата (фибровейн) объемом на одну процедуру не более 10 мл.

**Результаты.** Согласно классификации CEAP С2 класс имелся у 15 и С3 – у 4 пациентов. Рецидив ВБВ на одной нижней конечности был диагностирован у 17 (89,5%) пациентов, двухсторонний – у 2 (10,5%). В 6 (31,6%) наблюдениях рецидив возник спустя 5 лет и более от первой операции, у 8 (42,1%) пациентов – после 3-5 лет, у 5 (26,3%) – через 1-3 года. Диаметр варикозно расширенных вен до проведения лечения по данным цветного дуплексного сканирования (ЦДС) составлял  $7,9 \pm 0,8$  мм. Длительность выявленного сафенофemorального рефлюкса ( $n=10$ ) при оставленном стволе большой подкожной вены (БПВ) на бедре составила  $5,7 \pm 1,4$  с, протяженность –  $31,2 \pm 31,4$  мм. При оставленном стволе БПВ проводилась кроссэктомия в комбинации с механохимической склерооблитерацией. Также кроссэктомия была выполнена двум пациентам с повторным расширением ствола малой подкожной вены (МПВ) с последующей механохимической склерооблитерацией. В двух наблюдениях недостаточные перфоранты голени были лигированы из миниразрезов, еще в двух проводилась их пенная склерооблитерация. В течение 3 недель после проведения процедуры в 94,7% случаев регистрировался хороший результат в виде полной окклюзии склерозированных вен и отсутствие рефлюкса в них. Только в одном наблюдении отмечена неполная окклюзия склерозированной вены на бедре, что потребовало выполнение повторной процедуры. Отдаленные результаты были изучены у 19 пациентов, среди которых в 94,7% наблюдениях регистрировалась полная облитерация склерозированных вен и улучшения клинического течения хронического заболевания вен.

**Заключение.** Механохимическая склерооблитерация показала себя как эффективный метод лечения ВБВ нижних конечностей, являясь при этом малоинвазивной процедурой.

**Ключевые слова:** хроническая венозная недостаточность; варикозная болезнь; рецидив; механохимическая склеротерапия; результаты.



## EXPERIENCE OF APPLICATION OF MECHANOCHEMICAL SCLEROABLITERATION IN TREATMENT FOR RECURRENCE OF LOWER EXTREMITY VARICOSE VEIN DISEASE

A.D. Gaibov<sup>1,2</sup>, O. Nematzoda<sup>2</sup>, Sh.M. Burieva<sup>1</sup>, E.L. Kalmykov<sup>1</sup>

Ibn Sina Tajik State Medical University, Dushanbe, Tajikstan (1)  
Republican Scientific Center of Cardiovascular Surgery, Dushanbe, Tajikstan (2)

**Aim.** Evaluation of the effectiveness of mechanochemical scleroobliteration in treatment for recurrent lower extremity varicose veins (VVD).

**Materials and Methods.** A retrospective analysis of the results of examination and treatment of 19 patients (17 women and 2 men, average age  $36.3 \pm 4.5$  years) with recurrences of VVD, in whom mechanochemical sclerotherapy as the main method of treatment was used. In all cases, mechanochemical ablation of the superficial venous trunks was performed using Phlebograph catheter. As a hardener, 3% sodium tetradecyl sulfate solution (fibro-vein) was used in the volume not more than 10 ml per procedure.

**Results.** According to the CEAP classification, 15 patients had C2 and 4 patients had C3 class. Recurrence of VVD in one lower extremity was diagnosed in 17 (89.5%) patients, and bilateral – in 2 (10.5%). In 6 (31.6%) cases, recurrence occurred in 5 or more years after the first operation, in 8 (42.1%) patients – after 3-5 years, in 5 (26.3%) – after 1-3 years. The diameter of varicose veins before treatment according to color duplex scanning (CDR) was  $7.9 \pm 0.8$  mm. The duration of the detected saphenofemoral reflux ( $n=10$ ) with the trunk of the great saphenous vein (GSV) left on the hip was  $5.7 \pm 1.4$  s, with the length  $31.2 \pm 31.4$  mm. With the preserved trunk of the GSV, crossectomy was performed in combination with mechanochemical scleroobliteration. Crossectomy was also performed in two patients with repeated dilation of the trunk of the small saphenous vein (SSV) followed by mechanochemical scleroobliteration. In two cases, insufficient shin perforants were ligated from mini-incisions, and in two more cases, foam scleroobliteration of them was performed. Within 3 weeks after the procedure, a good result was recorded in 94.7% of cases in the form of complete occlusion of sclerotized veins with the absence of reflux in them. Only in one observation incomplete occlusion of the sclerotized vein on the hip was noted, which required a repeated procedure. Long-term results were studied in 19 patients, in 94.7% of who complete obliteration of sclerotized veins and improvement of the clinical course of chronic venous disease were recorded.

**Conclusion.** Mechanochemical scleroobliteration has proven to be an effective method of treatment for lower extremity VVD being a minimally invasive procedure.

**Keywords:** chronic venous insufficiency; varicose disease; recurrence; mechanochemical sclerotherapy; results.

Lower extremity varicose vein disease (VVD) is the most common vascular pathology which, according to some epidemiological studies, is present in 30-50% of adult population, and in some populations this parameter exceeds this level [1-3]. In treatment for lower extremity VVD both open surgical operations and minimally invasive methods are

used, such as laser ablation, microphlebectomy, sclerotherapy. Despite improvements in the treatment of VVD, the problem of treatment of patients with recurrence of the disease remains unsolved [2,4,5]. According to different authors, the rate of recurrence of lower extremity VVD remains high – from 12.1 to 70% [4,5].

It should be noted that a considerable amount of patients with lower extremity VVD seek first medical advice in non-specialized medical institutions which, as a rule, leads to inappropriate selection of a method and volume of treatment [4,6]. Repeated surgical operations in recurrent VVD (RVVD) are conducted in conditions of altered tissues when any manipulations may lead to excessive trauma of superficial nerves, lymphatic vessels leading to certain complications [5,7]. Besides, recurrence of the disease occurs in the presence of rather complicated hemodynamic alterations in the venous system.

The term 'recurrence of VVD', according to Russian clinical recommendations on diagnosis and treatment of chronic diseases of veins [8], implies appearance of varicosity on the lower extremity at any time after completed invasive treatment.

In recent two decades one of variants of treatment for VVD is scleroobliteration

[8,9,10], with the advantages being low frequency of different complications, relative simplicity of the procedure, possibility for its repetition and relatively low cost. With this, effectiveness of use of scleroobliteration, especially of mechanochemical one, in recurrence of the disease is not completely studied.

*Aim* – to evaluate effectiveness of mechanochemical scleroobliteration in treatment for recurrence of varicose disease.

### Materials and Methods

A retrospective analysis was conducted of the results of examination and treatment of 19 patients with recurrences of lower extremity VVD in the department of vascular surgery of the Republican Scientific Center of Cardiovascular Surgery in the period from 2013 to 2018 with use of mechanochemical obliteration as the main method of treatment. Demographic parameters and severity of chronic diseases of veins (CDV) in the analyzed cohort of patients are given in Table 1.

Table 1

### Demographic Parameters, Severity of CDV ( $M \pm m$ )

Total number of patients, of them	19
men	2
women	17
Age, years	36.3±4.5
Severity of CDV:	
C 2	15
C 3	4
Period of time before diagnosis of recurrence, years, average, months	1-7 34.2±5.4 months
Body mass index, kg/m <sup>2</sup>	30.2±2.4

Recurrence on one lower extremity was diagnosed in 17 (89.5%) patients, bilateral recurrence – in 2 (10.5%) cases. The period of appearance of recurrence was from 1 year to 7 years. In 5 and more years after the operation, recurrence was found in 6 (31.6%) patients, in 3 years – in 8 (42.1%) patients, in a year – in 5 (26,3%) patients.

The absolute majority of patients (17) were operated on in the conditions of general surgery departments of regional and municipal

medical institutions with use of traditional open methods. In 2 (10.5%) cases a recurrence occurred after endovenous laser coagulation of the trunks of the great saphenous vein (GSV).

Venous hemodynamics was studied with use of ultrasound apparatus Mindray DC-3 (China) equipped with linear sensor 7.5-10 MHz, in B-mode and in the mode of color flow mapping of the blood flow. The venous system of lower extremities was studied with attention to the trunks of saphenous vein left

after the primary operation, the condition of deep and perforating venous system, existence of refluxes, their duration and length.

In all cases mechanochemical obliteration of the trunks of GSV and the small saphenous vein (SSV) was performed using Flebogrif catheter which mechanically injures the internal wall of the vein with simultaneous controlled injection of a foam sclerosant. In 6 cases chemical obliteration of large branches of GSV and SSV was additionally conducted.

As a sclerosant, 3% sodium tetradecyl sulfate solution (fibro-vein) was used in the foam form prepared by Tessari method. The volume of foam used per procedure was not more than 10 ml. After a procedure of mechanochemical scleroobliteration, compression stockings were used on the extremity day-and-night followed by walking of the patient for 30-60 minutes.

The immediate results were evaluated in control examinations of patients on the next day after the procedure, in two and three weeks, during which, besides clinical examination, duplex scanning of sclerosed veins was performed. Long-term results were studied in 3, 6, 12 and 24 months after the procedure, where the existence of occlusion or recanalization of sclerosed veins, presence or absence of pathological reflux and its length, and also the diameter of recanalized veins and their length were evaluated.

The data obtained in the study, were analyzed in statistical processing using Statistica 6.0 program, with determination of mean values (M) and mean deviation (m) using variation statistics method. Differences between the groups (Student's t-test) were considered statistically significant at  $p < 0.05$ .

### Results and Discussion

Characteristics of patients with RVVD, according to anatomico-physiological and pathological positions of REVAS (Recurrent Varices after Surgery) classification [11], are given in Table 2.

Diameter of varicose veins before treatment according to the data of color du-

plex ultrasonography (CDU) varied from 5.5 to 13 mm, and was on average  $7.9 \pm 0.8$  mm (Table 3).

Duration of saphenofemoral reflux ( $n=10$ ) with the trunk of GSV left on the hip was from 3 to 9 sec. ( $5.7 \pm 1.4$ ), length – from 15 to 56 mm ( $31.2 \pm 31.4$  mm).

In all cases with the trunk of GSV left, crosssectomy was conducted because of a large diameter of ostial segment of GSV and of branches opening into it. Crosssectomy was also performed in two patients with dilated trunk of SSV. In 2 cases, due to large diameter of insufficient perforating veins of shin, they were ligated by Cockett's method from mini-incisions. In the rest 2 cases with insufficiency of perforating veins scleroobliteration was used.

Technical success of sclerotherapy procedure was 100%, that is, in all cases we managed to introduce the preparation into the lumen of the sclerosed vein. No local allergic reaction to sclerosant was noted after the procedure.

Results of duplex ultrasound of sclerosed veins 3 weeks after are given in Table 4.

Within 3 weeks from the procedure only in one case incomplete occlusion of sclerosed vein was noted on hip which required a repeated procedure.

Long-term results were studied in all patients in the periods up to 6 months, in 18 (94.7%) patients in the period up to 12 months and also in 18 (94.7%) patients in the period up to 24 months by clinical assessment of severity of VVD and by their duplex scanning. One patient left the experiment due to change of the place of residence. In 94.7% of observations reduction of the severity of clinical manifestations and of the degree of chronic disease of veins (CDV) was recorded. No recurrences were noted in a single patient within the first year of observation.

Repeated CDU showed that all sclerosed veins were obliterated with no blood flow in their lumen. In the period from 13 to 24 months 18 patients were examined,

Table 2

*Distribution of Patients with Recurrence According to REVAS Classification*

<b>T – Localization of Recurrent Varicose Veins</b>		<b>n</b>	<b>%</b>
G	Inguinal region	0	0
T	Hip	20	80
P	Popliteal fossa	1	4
I	Shin including ankle and foot	4	16
<b>S – Source of Reflux</b>			
0	No reflux	0	0
1	Veins of small pelvis and abdominal cavity	0	0
2	Saphenofemoral junction	10	52.6
3	Perforating veins of hip	3	15.8
4	Saphenopopliteal anastomosis	2	10.5
5	Perforating veins of popliteal fossa	0	0
6	Sural veins	0	0
7	Perforating veins of shin	4	21.1
<b>R – Reflux</b>			
Clinically significant – clinical presentation of chronic venous insufficiency (CVI) (R+)		4	21.1
Non-clinically significant – no clinical presentation of CVI (R+)		15	78.9
Clinical significance unclear (R?)		0	0
<b>N – Cause of Reflux</b>			
NSs – cause of reflux in the zone of previous operation		0	0
Technical mistakes		8	42.1
Tactic mistakes		5	26.3
Neovascularization		0	0
Cause unclear		0	0
Several causes		6*	31.6
<b>Lesions of Saphenous Veins Trunks</b>			
AK – great saphenous vein above knee joint		13	68.4
BK – great saphenous vein below knee joint		4	21.1
SSV – small saphenous vein		2	10.5
0 – none/another		0	0
<b>Probable Provoking Factors</b>			
GF – general factors		3	15.8
Heredity		4	21.1
Obesity		2	10.5
Deliveries after the previous operation		7	36.8
Hypodynamia, long stay in the vertical position		3	15.8

Table 3

*Diameter of Varicose Veins by Data of CDU*

<b>Localization</b>	<b>n</b>	<b>Average Dimeter of Vein, mm</b>
GSV (the trunk left on hip)	10	10.2±1.1
GSV (an additional trunk on hip)	3	8.4±0.8
GSV (the trunk left on shin)	4	7.9±0.6
SSV (the trunk left)	2	7.5±0.6
GSV branches on hip	2	6.7±0.5
GSV branches on shin	4	7.1±0.6

Table 4

***Immediate Results of Mechanochemical Sclerotherapy of Saphenous Veins  
by CDU Data (n=25)***

Localization	n	Average Vein Diameter (mm)		p
		before procedure	after procedure	
GSV (the trunk left)	10	10.2±1.1	2.1±0.6	<0.05
GSV (an additional trunk on hip)	3	8.4±0.8	2.3±0.5	<0.05
GSV (the trunk left on shin)	4	7.9±0.6	1.9±0.3	<0.05
Small saphenous vein (the trunk left)	2	7.5±0.6	1.4±0.4	<0.05
Branches of GSV on hip	2	6.7±0.5	1.4±0.3	<0.05
Branches of GSV on shin	4	7.1±0.6	1.2±0.5	<0.05

and only in one of them repeated varicosity of aberrant veins of shin was noted that resulted from continuation of the main disease with the underlying next pregnancy.

Thus, in the long-term period after mechanochemical scleroobliteration good results were obtained in 94.7% of patients, with recurrence in one case.

Treatment of patients with RVVD is a complicated part of phlebology which is associated with formation of perverse venous hemodynamics, existence of CDV of different severity, and also with altered tissues associated with formation of postoperative scars.

According to different authors, recurrence of VVD develops both after use of traditional phlebectomy, and after minimally invasive methods of treatment, at the rate from 12.3% to 80% [4,5,12,13]. There exist several factors leading to RVVD: tactic and technical mistakes in use of different surgical methods, neovascularization and progress of the disease [4,11]. In our study the main causes of development of recurrent VVD were both tactic mistakes, and a mistake in determination of the volume of surgical intervention, and also insufficient knowledge of variant anatomy of venous system which led not only to leaving of major venous trunks, but also of an additional major vein in 3 patients.

The experience of treatment of patients with recurrent VVD including our own experience, shows that many patients think about repeated surgical interventions with fear and skepticism, especially after traditional open

phlebectomies. Introduction of mini-invasive methods of treatment of VVD including treatment of recurrences, into the practice, permitted to minimize the volume of the surgical trauma, and also to reduce the time of the procedure. As M.De Maeseneer (2011) noted, nowadays traditional open operations are not operations of choice [6], however, the number of patients on whom open operations are performed, remains significant which in many aspects results from referral of patients to non-specialized clinics, and also from poor fitting of clinics with modern equipment permitting mini-invasive high-technology operations on venous system.

Variants of treatment for RVVD is scleroobliteration and laser ablation. According to the latest recommendations of European Society for Vascular Surgery, scleroobliteration and laser ablation can be used in treatment for RVVD [14]. In the European consensus on sclerotherapy it was noted that practically any caliber of veins is suitable for foam obliteration which provides a good result in treatment for RVVD [15]. In Russian clinical recommendations on diagnosis and treatment of chronic diseases of veins [5] it is also noted that in case of insufficiency of the trunk of GSV or SSV left after the previous intervention and of dilatation of their branches, endovenous laser obliteration of veins, radiofrequency obliteration of veins, or non-thermal and chemical methods of endovenous obliteration are indicated, and this recommendation is based on the level of insuffi-

ciency of IC. As a variant of sclerotherapy, mechanochemical obliteration may also be used, however, at present the results of its application are not studied which does not permit to speak about its effectiveness in treatment for RVVD in full measure. To our data, the technical success of the procedure was 100%, within 24 months a good result was noted in 94.7% of patients.

According to some authors, complete obliteration of GSV in sclerotherapy is required [16,17]. Besides, as it was shown by the work of P. Pavei et al. [18], a good result of echo-foam scleroobliteration within 5 years reached 60-80%, depending on localization of RVVD. Despite minimally invasive type of the method, possibility of its repeated use and some other positive aspects, the results of its application remain a matter of discussion [16,18]. Today there are no studies where different methods of treatment for RVVD were compared with mechanochemical scleroobliteration which does not permit to make reliable conclusion about this method as a method of the first line of treatment.

After chemical scleroobliteration there exists a probability, although a very rare one,

for development of threatening complications such as disorder of cerebral circulation, complete or partial thrombosis of superficial and/or deep veins with development of thromboembolism of the pulmonary artery [20-22].

Some surgeons also use a combined approach with application of open surgery, in particular, of crossotomy and elimination of horizontal reflux [23-25]. In our work, a combined approach was also used and contributed to the positive result obtained. However, because of a small sample of patients, a study of the effectiveness of the used method should be continued.

### Conclusion

Mechanochemical scleroobliteration being a minimally invasive method of treatment for recurrence of lower extremity varicose vein disease, in most cases permits to achieve good results. However, since there is no data of comparison of the results of this methods with the results of other methods, at the moment it is impossible to make a final conclusion in favor of this method as the first line of therapy, therefore this question remains open for further examination.

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#### Дополнительная информация [Additional Info]

**Источник финансирования.** Бюджет ГУ Республиканский научный центр сердечно-сосудистой хирургии Министерства здравоохранения и социальной защиты населения Республики Таджикистан. [Financing of study. Budget of Republican Scientific Center of Cardiovascular Surgery.]

**Конфликт интересов.** Авторы декларируют отсутствие явных и потенциальных конфликтов интересов, о которых необходимо сообщить в связи с публикацией данной статьи. [Conflict of interests. The authors declare no actual and potential conflict of interests which should be stated in connection with publication of the article.]

**Участие авторов.** Гаибов А.Д., Калмыков Е.Л. – концепция и дизайн исследования, редактирование, Нейматзода О., Буриева Ш.М. – сбор и обработка материала, статистическая обработка, написание текста. [Participation of authors. A.D. Gaibov, E.L. Kalmykov – the concept of article, design and review, O. Ne'matzoda, Sh.M. Burieva – collection and processing of material, statistical processing, writing text.]

#### Информация об авторах [Authors Info]

**Гаибов Алиджон Джураевич** – д.м.н., чл.-корр. АМН РТ, проф. кафедры хирургических болезней №2, ГОУ Таджикский государственный медицинский университет им. Абуали ибни Сино; куратор отделения хирургии сосудов, ГУ Республиканский научный центр сердечно-сосудистой хирургии МЗ и СЗН РТ, Душанбе, Таджикистан. [Alidzhon D. Gaibov – MD, PhD, Correspondent Member of the Academy of Medical Sciences of the Republic of Tajikistan, Professor of the Department of Surgical Diseases №2, Ibn Sina Tajik State Medical University; Curator of the Vascular Surgery Department, Republican Scientific Center of Cardiovascular Surgery, Dushanbe, Tajikistan.]  
SPIN: 5152-0785, ORCID ID: 0000-0002-3889-368X.

\***Неъматзода Окилджон** – к.м.н., в.н.с. отделения хирургии сосудов, ГУ Республиканский научный центр сердечно-сосудистой хирургии МЗ и СЗН РТ, Душанбе, Таджикистан. [**Okildzhon Ne'matzoda** – MD, PhD, Leading Researcher of the Department of Vascular Surgery, Republican Scientific Center of Cardiovascular Surgery, Dushanbe, Tajikistan.]  
SPIN: 2408-9107, ORCID ID: 0000-0001-7602-7611, Researcher ID: F-8729-2018. E-mail: sadriev\_o\_n@mail.ru

**Буриева Шахноза Махмадовна** – аспирант кафедры хирургических болезней №2, ГОУ Таджикский государственный медицинский университет им. Абуали ибни Сино, Душанбе, Таджикистан. [**Shakhnoza M. Burieva** – PhD-student of the Department of Surgical Diseases №2, Ibn Sina Tajik State Medical University, Dushanbe, Tajikistan.]  
SPIN: 1345-9657, ORCID ID: 0000-0002-8862-4031, Researcher ID: AAC-7511-2020.

**Калмыков Еган Леонидович** – к.м.н., н.с., ГОУ Таджикский государственный медицинский университет им. Абуали ибни Сино, Душанбе, Таджикистан. [**Egan L. Kalmykov** – MD, PhD, Researcher, Ibn Sina Tajik State Medical University, Dushanbe, Tajikistan.]  
SPIN: 8623-8897, ORCID ID: 0000-0001-6784-2243, Researcher ID: K-9827-2013.

**Цитировать:** Гаиров А.Д., Неъматзода О., Буриева Ш.М., Калмыков Е.Л. Опыт применения механохимической склерооблитерации в лечении рецидива варикозной болезни вен нижних конечностей // Российский медико-биологический вестник имени академика И.П. Павлова. 2020. Т. 28, №1. С. 57-66. doi:10.23888/PAVLOVJ202028157-66

**To cite this article:** Gaibov AD, Nematzoda O, Burieva ShM, Kalmykov EL. Experience of application of mechanochemical scleroobliteration in treatment for recurrence of lower extremity varicose vein disease. *I.P. Pavlov Russian Medical Biological Herald.* 2020;28(1):57-66. doi:10.23888/PAVLOVJ202028157-66

**Поступила/Received:** 07.10.2019  
**Принята в печать/Accepted:** 31.03.2020