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COMPRESSION THERAPY AFTER OPEN SURGERY OF VARICOSE VEINS OF THE LOWER EXTREMITIES

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Summary

Introduction. Currently, the duration of compression therapy after open phlebectomy for varicose veins of the lower extremities has not yet been finally determined. There is no data on the need for prolonged use of compression hosiery for more than 1 week after open stripping or miniflebectomy to increase the treatment effect, as there is none on the uselessness of prolonged compression.

Purpose of the study. To conduct a study to determine the optimal duration of compression therapy after open phlebectomy.

Research Methods. To conduct the study, a scientific hypothesis was formed - wearing compression hosiery before resorption of hematomas and normalizing the color of the skin after an open phlebectomy is sufficient in terms for the frequency of local complications, swelling of the legs and disability. Two groups of patients were randomized. The first group of patients, or comparison group, consisted of patients whose compression therapy after open phlebectomy was 2 months. The second group of patients, or the study group, consisted of patients with a term of compression therapy before resorption of hematomas and normalization of skin color after open phlebectomy of the lower extremities. Criteria for inclusion in the study: C2 - C3 class according to CEAP chronic venous insufficiency (CVI) of the lower extremities; severe, multiple varicose veins of the great saphenous vein (GSV) or small saphenous vein (SSV) and their branches; previously transferred thrombophlebitis of GSV / SSV; crossectomy and stripping of GSV / SSV.

Results. The term of compression therapy in the 1st group of patients was 62.486 days (95% CI 62.099-62.873), in the 2nd group of patients 31.790 days (95% CI 31.559-32.021) (Log Rank = 5.005; p = 0.025). The period of disability in the 1st group of patients was 16.528 days (95% CI 16.169-16.888), in the 2nd group of patients 16.760 days (95% CI 16.508-17.012) (Log Rank = 1.083; p = 0.298).

Conclusions. Compression therapy after an open phlebectomy is enough to carry out during the resorption of subcutaneous hematomas, the visual disappearance of bruises and the normalization of the color of the skin for a period of, on average, up to 1 month.

Key words: compression therapy, phlebectomy, hematoma, edema.

Резюме

КОМПРЕССИОННАЯ ТЕРАПИЯ ПОСЛЕ ОТКРЫТОЙ ХИРУРГИИ ВАРИКОЗА НИЖНИХ КОНЕЧНОСТЕЙ

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Введение. В настоящее время до сих пор не определены окончательно сроки компрессионной терапии после открытой флебэктомии при варикозной болезни нижних конечностей. Данных о необходимости пролонгированного использования компрессионного трикотажа более 1 недели после открытого стриппинга или минифлебэктомии для повышения эффекта лечения нет, как нет их и о бесполезности пролонгированной компрессии.

Цель исследования. Провести исследование на определение оптимальных сроков компрессионной терапии после открытой флебэктомии.

Методы исследования. Для проведения исследования сформирована научная гипотеза – ношение компрессионного трикотажа до рассасывания гематом и нормализации цвета кожных покровов после открытой флебэктомии достаточно по срокам в отношении частоты местных осложнений, отека ног и нетрудоспособности. Рандомизированы две группы больных. Первую группу больных, или группу сравнения, составили пациенты, срок компрессионной терапии которых после открытой флебэктомии составил 2 месяца. Вторую группу больных, или группу исследования, составили пациенты со сроком компрессионной терапии до рассасывания гематом и нормализации цвета кожных покровов после открытой флебэктомии нижних конечностей. Критерии включения в исследование: хроническая венозная недостаточность (ХВН) нижних конечностей С₂ – С₃ класса по CEAP; выраженный, множественный варикоз большой подкожной вены (БПВ) или малой подкожной вены (МПВ) и их ветвей; ранее перенесенный тромбофлебит БПВ/МПВ; кроссэктомия и стриппинг БПВ/МПВ.

Результаты. Срок компрессионной терапии в 1-й группе больных составил 62,486 дней (95 % ДИ 62,099-62,873), во 2-й группе больных 31,790 дней (95 % ДИ 31,559-32,021) (Log Rank = 5,005; p = 0,025). Срок нетрудоспособности в 1-й группе больных составил 16,528 дней (95 % ДИ 16,169-16,888), во 2-й группе больных 16,760 дней (95 % ДИ 16,508-17,012) (Log Rank = 1,083; p = 0,298).

Выводы. Компрессионную терапию после открытой флебэктомии достаточно проводить в течении рассасывания подкожных гематом, визуального исчезновения синяков и нормализации цвета кожных покровов сроком, в среднем, до 1 месяца.

Ключевые слова: компрессионная терапия, флебэктомия, гематома, отек.

Түйіндемe

ВАРИКОЗҒА БАЙЛАНЫСТЫ АШЫҚ ХИРУРГИЯДАН КЕЙІНГІ КОМПРЕССИОНДЫ ТЕРАПИЯ

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Кіріспе. Қазіргі уақытта варикозды тамырларға арналған ашық флебэктомиядан кейінгі компрессионды терапияның ұзақтығы әлі анықталмаған. Ашық стриппинг немесе минифлебэктомия жүргізілгеннен кейін емнің тиімділігін арттыру мақсатында 1 аптадан артық қолдану қажеттілігі туралы мәліметтер жоқ, әйтседе, ұзақ қысудың пайдасыздығы туралы мәліметтерде табылмады.

Зерттеу мақсаты. Ашық флебэктомиядан кейін қысу терапиясының оңтайлы уақытын анықтау үшін зерттеу жүргізу.

Зерттеу әдістері. Зерттеу жүргізу үшін ғылыми гипотеза жасалды - ашық флебэктомиядан кейінгі кезеңде тері түсі қалыпына келу және гематомалар резорбциялану уақытыда компрессионды шұлықты кию, жергілікті асқынулар, аяқтың ісінуі және еңбекке жарамсыз уақытқа сәйкес. Науқастар екі топқа рандомизацияланды. Пациенттердің бірінші тобы немесе салыстыру тобы ашық флебэктомиядан кейінгі компрессионды терапия 2 ай болған пациенттерден тұрды. Екінші топты немесе зерттеу тобын флебэктомиядан кейінгі кезеңде тері түсі қалыпына келгенше және гематомалар резорбцияланғанша компрессионды шұлықты киген науқастар құрады. Енгізу критериялары: созылмалы веналық жеткіліксіздік С₂ – С₃ класс, CEAP бойынша; үлкен тері асты немесе кіші тері асты венасының айқын, көптеген варикозы; ертеректе үлкен және кіші тері асты венасының тромбофлебитін бастан өтізу; кроссэктомия және үлкен және кіші тері асты венасының стриппингі.

Нәтижелер. Науқастардың 1-ші тобында компрессионды терапия мерзімі 62.486 күнді құрады (95% ДИ 62.099-62.873), науқастардың 2-ші тобында 31,790 күн (95% ДИ 31.559-32.021) (Log Rank = 5.005; p = 0.025). Еңбекке жарамсыздық уақыты 1-ші топта 16,528 күнді құрады (95 % ДИ 16,169-16,888), 2-ші топта 16,760 күнді құрады (95 % ДИ 16,508-17,012) (Log Rank = 1,083; p = 0,298)

Қорытындылар. Ашық флебэктомиядан кейінгі компрессионды терапияның ұзақтығы тері астындағы гематомалардың резорбциясы, көгерулердің көзбен жоғалып кетуі және терінің түсінің қалыпқа келуіне дейін жеткілікті, орта есеппен 1 айға дейін жеткілікті.

Түйін сөздер: компрессионды терапиясы, флебэктомия, гематома, ісіну.

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Introduction

Compression therapy remains an important component in the management of patients with chronic venous insufficiency of the lower extremities due to venous valve reflux [11, 2]. Chronic venous insufficiency (CVI) is stratified using the CEAP classification: Clinical, Etiology, Anatomy, Pathophysiology. In practice, the clinical part - Clinical - of this classification, which evaluates venous disease based on the presence of dilated veins, edema, skin changes or ulceration, is most widely used [3, 6].

The Vein Consult program, which included 91,545 people from 20 countries, identified CVI in 83.6% of those included in the study. Among patients with CVI, women accounted for 68.4% and prevailed over men. The average age of those examined with CVI was 53.3 years, and the distribution by disease classes was as follows: C0 - 19.7%, C1 - 21.7%, C2 - 17.9%, C3 - 14.7%, C4 - 7.5%, C5 - 1.4%, C6 - 0.7% [7].

The most accepted compression therapy options for CVI are compression hosiery and elastic bandaging of the lower extremities. At the same time, compression hosiery has several advantages compared to elastic bandaging of the lower extremities: the physiological distribution of pressure does not depend on the skills of the patient or doctor, there is no need for medical participation, there is no need to model the cylindrical profile of the limb of the compression product, it meets the aesthetic requirements of patients, creates favorable conditions for maintaining the water and temperature balance of the skin of the limb, it is possible to choose the optimal pressure due to the choice of compression grade, high product strength and long-term preservation of the original compression degree [1, 8].

Currently, the timing of compression therapy after open phlebectomy for varicose veins of the lower extremities has not yet been finally determined. There is no evidence of the need for prolonged use of compression hosiery for more than 1 week after open stripping, miniflebectomy, or endovenous thermoligation to increase the treatment effect, nor is there any uselessness of prolonged compression [1, 10].

A systematic review revealed four studies evaluating the use of compression stockings after surgery for varicose veins. No benefits were found between short-term (3 to 10 days) and longer (3 to 6 weeks) compression in relation to

postoperative pain, leg swelling, frequency of complications and disability [1, 4].

In connection with the foregoing, we conducted a study to determine the optimal duration of compression therapy after open phlebectomy.

Research Methods

To conduct the study, we formed a scientific hypothesis - wearing of compression hosiery before resorption of hematomas and normalizing the color of the skin after an open phlebectomy is sufficient in terms for the frequency of local complications, swelling of the legs and disability.

End points of the study: primary - the term of compression therapy, bruises and large hematomas, edema of the lower limb, local pain and paresthesia, thrombophlebitis of venous tributaries, wound infection, deep vein thrombosis; secondary - the period of disability, relapse of varicose veins in the long term.

Sample size was calculated for regression analysis using the PASS 2000 program, version 12.0.4 [12]. The required total sample was 162 patients, at least 81 patients in the compared groups.

Study design - a randomized clinical trial, "blind" randomization using sealed envelopes. The first group of patients, or comparison group, consisted of patients whose compression therapy after open phlebectomy was 2 months. The second group of patients, or the study group, consisted of patients with a term of compression therapy before resorption of hematomas and normalization of skin color after open phlebectomy of the lower extremities.

Criteria for inclusion in the study: chronic venous insufficiency (CVI) of the lower extremities C2 - C3 class according to CEAP; severe, multiple varicose veins of the great saphenous vein (GSV) or small saphenous vein (SSV) and their branches; previously transferred thrombophlebitis of GSV / SSV; crosssection and stripping of GSV / SSV. Exclusion criteria: CVI of the lower extremities C1, C4 - C6 class according to CEAP, stem form of varicose veins with single varicose branches of GSV / SSV, acute thrombophlebitis of GSV / SSV, post-thrombotic disease of the lower extremities, concomitant pathology from vital organs in the stage of decompensation, endovenous thermoligation, sclerotherapy of GSV / SSV.

Follow-up time: 30 days after surgery, followed by a follow-up interval every 6 months to 3 years.

The results of surgical treatment of 170 patients with open phlebectomy for varicose veins of the lower extremities, 85 patients in each group, from January 2018 to January 2020 according to the Department of Cardiovascular Surgery of the University Hospital of the Non-Profit Joint-Stock Company «Semey Medical University», were analyzed.

The average age of patients at the time of surgery in the 1st group was 51.2 years (Me = 52.0; Q1 = 48.5; Q3 = 56.4), in the 2nd group - 52.4 years (Me = 53, 0; Q1 = 46.2; Q3 = 58.6). Women made up the bulk in both groups of patients - 58 (68.2%) people in the 1st group and 54 (63.5%) people in the 2nd group; men - 27 (31.8%) and 31 (36.5%), respectively.

Statistical data processing was carried out using the statistical software package SPSS, version 20. Quantitative data with a normal distribution are presented as mean (M) and standard deviation (SD). If there is no subordination to the law of the normal distribution of quantitative data, the latter are presented in the form M - sample mean, Me - median, Q1 and Q3 - lower and upper quartiles as scattering measures. Qualitative data are presented as absolute numbers and percentages. Before starting the analysis of quantitative data, they were checked for normal distribution (Q-Q diagram, asymmetry, Shapiro-Wilk test for samples of up to 50 observations and Kolmogorov-Smirnov

for samples of more than 50 observations). In the normal distribution, parametric criteria were used to compare quantitative data (Student t-test, one-way analysis of variance), otherwise, nonparametric criteria (Mann-Whitney, Kraskell-Wallis test) were used. To compare qualitative characteristics, χ^2 Pearson, Fisher's exact test, were used. The analysis of predictors of complications in the 30-day period was performed using logistic regression, determining the odds ratio (OR) and 95% confidence interval (CI), and in the long-term postoperative period using Cox regression with determining the risk ratio (RR) and 95% CI, respectively. Survival analysis was performed using the Kaplan-Meier method and the Log-Rank statistical criterion. For the criterion of statistically significant differences the $p < 0.05$ was taken.

In the preoperative period, in addition to clarifying the patient's complaints and medical history, a local examination and physical examination of the lower extremities were performed. The final diagnosis of CVI was made on the basis of ultrasound dopplerography of the lower extremities, with the help of which the patency and compressibility of the veins, their diameter, the state of the valvular apparatus of the superficial, deep and perforating veins were determined. Data on the failure of the valve apparatus GSV / SSV and venous reflux are presented in table 1.

Table 1. The failure of the GSV / SSV valves and venous reflux.

Venous reflux	1-st group, n = 85, abs. (%)	2-nd group, n = 85, abs. (%)	p
Failure of safeno-femoral anastomosis, GSV valves, upper reflux	79 (92,9)	81 (95,3)	0,884
Failure of popliteal-femoral anastomosis, SSV valves, upper reflux	8 (9,4)	7 (8,2)	0,808
Perforating vein valve failure, lower reflux	59 (69,4)	62 (72,9)	0,737

Indications for open phlebectomy in patients of both groups were CVI of the lower extremities C2 - C3 class according to CEAP; pronounced, multiple varicose veins of GSV or SSV and their branches; previously transferred thrombophlebitis of GSV or SSV. All patients underwent classical safenectomy or parvectomy with ligation of the safeno-femoral or parvo-popliteal anastomosis, Babcock saphenous trunk stripping, followed by removal of varicose dilated venous inflows according to Narat; insolvent perforating veins were tied subcutaneously according to Kokket.

The results of the study

The results of treatment of patients were studied in a 30-day and long-term 3-year postoperative period. The evaluation criteria in the 30-day postoperative period were the presence of bruises and large subcutaneous hematomas, edema of the lower extremity, local pain and paresthesia, venous thrombophlebitis, wound infection, lymphorrhea, deep vein thrombosis (table 2).

Table 2. Complications in the 30-day postoperative period.

Type of complication	1-st group, n = 85, abs. (%)	2-nd group, n = 85, abs. (%)	p
Large subcutaneous hematoma	10 (11,8)	9 (10,6)	0,835
Local pain and paresthesia	17 (20,0)	22 (25,9)	0,376
Swelling of the lower limb	23 (27,1)	26 (30,6)	0,599
Thrombophlebitis of the venous tributaries	4 (4,7)	3 (3,5)	0,739
Suppuration of the wound	1 (1,2)	2 (2,4)	0,564
Lymphorrhea	8 (9,4)	6 (7,1)	0,617
Contact dermatitis	2 (2,4)	1 (1,2)	0,564
Skin necrosis	1 (1,2)	2 (2,4)	0,564
Deep Vein Thrombosis	-	-	-

As can be seen from the data presented, in patients of both groups there were only local complications. Moreover, various complications varied on average from 1.2% to 30.6% of cases. Analysis of complications in the 30-day postoperative period did not reveal their relationship and effect on the duration of compression therapy (table 3).

In the long-term postoperative period, attention was drawn to the presence of edema of the lower extremity, the development of thrombosis and thrombophlebitis of the superficial and deep veins, and the relapse of varicose veins (table 4).

Table 3.

The effect of complications on the duration of compression therapy in the 30-day postoperative period.

Hospital complications	p	OR	95% confidence interval for OR	
			Lower	Upper
Large subcutaneous hematoma	0,808	1,126	0,433	2,927
Local pain and paresthesia	0,363	0,716	0,349	1,470
Swelling of the lower limb	0,612	0,842	0,433	1,636
Thrombophlebitis of the venous tributaries	0,134	1,030	0,012	1,058
Suppuration of the wound	0,715	0,991	0,944	1,041
Lymphorrhea	0,054	1,034	0,999	1,069
Contact dermatitis	0,374	1,024	0,972	1,028
Skin necrosis	0,434	0,956	0,853	1,071

Table 4.

Complications in the long-term postoperative period.

Type of complication	1-st group, n = 85, abs. (%)	2-nd group, n = 85, abs. (%)	p
Swelling of the lower limb	7 (8,2)	6 (7,1)	0,796
Thrombophlebitis of the venous tributaries	3 (3,5)	2 (2,4)	0,414
Deep Vein Thrombosis	2 (2,4)	1 (1,2)	0,564
Relapse of varicose veins	1 (1,2)	2 (2,4)	0,564

When analyzing the data obtained in the long-term postoperative period, special attention was paid to preserving edema of the lower extremity after the termination of compression therapy. Moreover, in all cases, the preservation of edema of the lower extremity after removal of the compression hosiery was associated with the presence of deep vein thrombosis in the early postoperative period, insufficiency of the valvular apparatus of deep veins, or with the presence of secondary lymphostasis after the infectious and inflammatory diseases of the lower extremities or pelvic organs. The recurrence of varicose veins in the long-term period in the operated

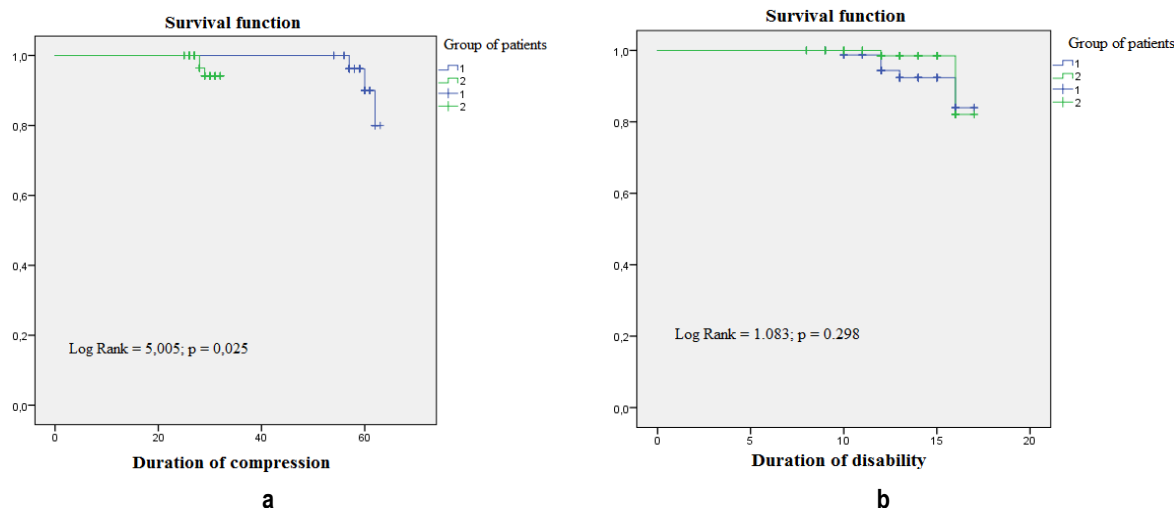
patients was due to the development of insufficiency of perforating vein valves in non-operated basins of the saphenous veins. Complications in the long term also did not affect the duration of compression therapy (table 5).

The term of compression therapy in the 1st group of patients was 62.486 days (95% CI 62.099-62.873), in the 2nd group of patients 31.790 days (95% CI 31.559-32.021) (Log Rank = 5.005; $p = 0.025$). The period of disability in the 1st group of patients was 16.528 days (95% CI 16.169-16.888), in the 2nd group of patients 16.760 days (95% CI 16.508-17.012) (Log Rank = 1.083; $p = 0.298$) (Figure 1).

Table 5.

The effect of complications on the duration of compression therapy in the long-term postoperative period.

Complications	p	RR	95% confidence interval for RR	
			Lower	Upper
Swelling of the lower limb	0,147	0,002	0,0001	8,864
Thrombophlebitis of the venous tributaries	0,343	0,010	0,0001	1,942
Deep Vein Thrombosis	0,214	0,451	0,144	2,055
Relapse of varicose veins	0,456	1,246	0,899	2,155

**Figure 1. Duration of compression therapy (a) and disability (b) in a comparative aspect, Kaplan-Mayer analysis.**

The discussion of the results

Despite the recent development of minimally invasive endovenous surgical methods for treating varicose veins of the lower extremities, open phlebectomy remains the method of choice for severe varicose enlargement of the BPV / MPV trunk and its branches or violation of its patency after thrombophlebitis [5]. Currently, the long-term results of endovenous obliteration of the GSV / SSV trunk are still poorly studied, and therefore traditional open safenectomy or paravectomy remains a fairly common type of surgical intervention [9].

The term of compression therapy after open phlebectomy remains a debatable issue in modern angiology and vascular surgery and varies from 10 days to 3 weeks in some authors, and in 3-6 months in others [1, 4].

In connection with the foregoing, the analysis of the results of surgical treatment of both groups of patients was directly related to the end points of the study and, first of all, to the term of compression therapy, which was the main goal of our study. Considering that compression therapy in the postoperative period is aimed for compression the remaining superficial venous inflows, preventing the formation of subcutaneous hematomas after removal of varicose veins, stimulating blood flow through deep veins and preventing lower limb edema and deep vein thrombosis, we hypothesized that compression therapy is sufficient for the period during which the resorption of subcutaneous hematomas, the disappearance of bruises and the normalization of the color of the skin take place. We consider this time is sufficient to adapt the lower limb to the new conditions of venous circulation, when the venous outflow occurs mainly through the deep vein system, and there is no edema of the lower limb. Thus, the term of compression therapy in the 2nd group of patients, or the study group, was 31,790 days (95% CI 31,559-32,021), that is, on average, 1 month. In the 1st group of patients, or the comparison group, the duration of compression therapy was 62.486 days (95% CI 62.099-62.873) or, on average, 2 months, which, of course, is significantly longer than in the 2nd group of patients (Log Rank = 5.005; $p = 0.025$). The term of 2 months of compression therapy was determined in accordance with literature data, as well as from our own experience, when among the colleagues of vascular surgeons this term of compression therapy remains generally accepted [1,8,10,4].

In addition to subcutaneous hematomas and edema of the lower limb, in the early postoperative period, attention was paid to the development of other local complications: local pain and paresthesia, venous thrombophlebitis, suppuration of the wound, lymphorrhea, contact dermatitis, skin necrosis. In the long term, the development of recurrence of varicose veins of the lower extremities was monitored. A comparative correlation analysis of these complications did not reveal significant differences between the groups both in the hospital period and in the long term ($p > 0.05$). At the same time, one-factor logistic regression of complications in the 30-day postoperative period and Cox regression of complications in the distant period did not reveal the relationship of these complications with the duration of compression therapy ($p > 0.05$).

Thus, the results of the study allow us to conclude that compression therapy after an open phlebectomy is enough

to carry out during the resorption of subcutaneous hematomas, the visual disappearance of bruises and the normalization of skin color for a period of, on average, up to 1 month.

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