

Commitment of patients with varicose veins to compression therapy

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Abstract

Objective: To determine adherence to the implementation of medical recommendations regarding compression therapy within 1 year after receiving them by patients with varicose veins of the lower extremities.

Material and methods: A prospective comparative study Patients cOMmitment to coMpression theraPy (POMP) was conducted with the participation of phlebologist surgeons, each of whom included patients with varicose veins of the lower extremities in the study for 5 weeks, who sought consultation and needed compression therapy. Twelve months after the consultation, an outsourced call center conducted a telephone survey of patients in order to obtain information on the specifics of their compliance with the recommendations received.

Results: The general registration database of the study contained individual data on 394 patients. 12 months after receiving recommendations on the use of compression hosiery, 246 patients aged 44, 35-55 (Me, IQR) were available for a telephone survey and agreed to complete it. There were 42 men (17.1%), 204 women (82.9%). Among them, class C1 was noted in 32 (13.1%), C2 in 83 (33.7%), C3 in 109 (44.3%), C4 in 20 (8.1%), C6 in 2 (0.8%) patients. 189 patients (76.8%) were compliant with medical recommendations: 110 using compression hosiery and 79 who stopped taking it based on medical recommendations. The number of respondents who noted an improvement in the manifestations of varicose disease was significantly higher in the group of patients who used compression hosiery ($p < 0.001$). Patients who already had experience with compression therapy ($p < 0.001$) and patients whose professional activities are associated with heavy physical labor and long-term orthostasis ($p=0.031$) were more committed to compression therapy. There were no reliable differences in patient compliance with differences in gender and education level.

Conclusion: High patient adherence to medical recommendations regarding compression therapy was established 12 months after receiving them.

Introduction

Currently, compression therapy remains an important part of the treatment of lower limb varicose veins (LLVV), complementing a variety of invasive treatments for this pathology. The mechanism of action of compression therapy is associated with a decrease in the diameter of the saphenous and deep veins, optimization of the work of the muscle pump of the lower leg. The effects of its use as a result lead to a decrease in residual venous pressure and a decrease in edema of the lower limb [1]. The use of compression products with graduated compression has the 1st level of evidence [2-4]. The use of compression stockings after invasive treatment of LLVV effectively relieves postoperative pain, leads to regression of lower limb edema, promotes an early return to a normal lifestyle, and improves the patient's quality of life. At the same time, the duration of the use of compression therapy after invasive treatment of varicose veins of the lower extremities does not yet have a strict scientific justification, and therefore it is recommended to adhere to the best clinical practice adopted in a particular medical institution [5,6]. Compression hosiery with graduated compression in LLVV is significantly superior to placebo hosiery in terms of the effectiveness of relief of pain and discomfort in the legs [7].

However, the compliance of patients with compression therapy and their compliance with medical recommendations regarding the

use of certain compression products is very variable, depends on many factors and is often unpredictable. Understanding the extent to which patients comply with the recommendations received (and for what reasons they are not followed) is extremely important for the effective work of a phlebologist. The aim to study the implementation of recommendations on the use of compression therapy by patients with varicose veins of the lower extremities within 12 months after receiving these recommendations.

Materials and methods

A prospective multicenter study POMP (Patients cOMmitment to coMpression theraPy, ID: NCT04096729) was conducted by phlebologists who treat patients with chronic venous diseases in Minsk, Vitebsk, Gomel (Republic of Belarus). The study was approved by the ethical committee of the Belarusian State Medical University

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(No. 1 dated August 30, 2019). Patients with varicose veins C1-C6 according to the clinical part of the CEAP classification were included in a prospective comparative study if they met the criteria presented in Table 1. All patients gave written consent to participate in the study.

Each of the phlebologists within 5 weeks included in the study patients with LLVV who applied for a consultation and needed compression therapy using compression stockings. All patients provided written consent to the registration of personal data, participation in the study and telephone survey. In the patient's individual card, the demographic, professional, social, and anamnestic data were recorded, as well as, additionally, for women, data on the number of births. To characterize class C according to the CEAP classification in patients with bilateral lesions, data on the lower limb with more pronounced manifestations of chronic venous insufficiency were used.

Recommendations for the use of compression stockings were determined by the phlebologist surgeon individually for each patient. The design of this study did not provide for standardization of recommendations on the methods and timing of application. In addition to compression therapy, it was possible to prescribe any other type of medical and / or invasive treatment.

12 months after the consultation of the phlebologist surgeon, a telephone survey of patients was conducted in order to obtain information about the features of their implementation of the received recommendations (Table 2). A specialized outsourcing call center was involved in the telephone survey. Patients' answers to questions were recorded in the form of an electronic document and an audio file.

Statistical analysis: Descriptive statistics were used to describe the main characteristics of the groups before and after treatment. When the data distribution was not normal, the median (Me) and interquartile range (IQR) were calculated. The Mann-Whitney test was used to analyze the data of two independent samples by quantitative trait.

Table 1. Inclusion/ exclusion criteria

Inclusion criteria	Exclusion criteria
Age from 18 years; compression therapy prescribed by a phlebologist.	Hearing impairments that may interfere with the telephone survey.

Table 2. Questions included in the telephone survey

1.	How do you apply compression stockings?	1) More than 4 hours daily 2) Less than 4 hours daily 3) Constantly in the presence of factors unfavorable for the veins of the legs 4) Sometimes in the presence of factors unfavorable for the veins of the legs 5) I don't use it at all
2.	If you do not use compression stockings, then why?	1) The doctor canceled 2) The doctor initially prescribed to wear less than a year 3) Too hard put on / take off 4) Uncomfortable to wear 5) Hot 6) Itching 7) Ugly 8) Doesn't help 9) It gets worse when I start wearing 10) Can't wash every day 11) Other (with explanation) 12) Didn't buy at all
3.	How do you assess the changes in the manifestations of varicose veins in your legs?	1) Improvement 2) No change 3) Deterioration
4.	What product do you use?	1) Golfs 2) Stockings 3) Stocking on one leg with a fastener at the waist (monostocking) 4) Pantyhose
5.	What class of compression do you use?	1) 1st 2) 2nd 3) 3rd

When evaluating the data in two dependent groups on a quantitative basis, the Wilcoxon test was used. When studying the qualitative trait of two independent samples, Pearson's test was used. The McNemar test was used to analyze the qualitative trait of two dependent samples. Changes were considered significant at $p < 0.05$.

Results

Based on the inclusion criteria, the overall study registration base contained individual data on 394 patients. 12 months after receiving recommendations on the use of compression stockings, 246 patients were available for a telephone survey and agreed to undergo it. The main characteristics of patients included in the general registration database and those who completed the telephone survey are presented in Table 3.

Thus, the characteristics of the group of patients who underwent telephone surveys did not have statistically significant differences from the characteristics of patients in the general registration base in terms of age, sex, clinical and social criteria.

Survey results: The statistics of responses to the 1st question of the telephone survey questionnaire (How do you use compression stockings?) presented in Table 4.

Thus, 110 respondents (44.3%) with certain characteristics used compression stockings during the year. Noteworthy is the information on 79 patients who stopped the use of compression therapy within 1 year on doctor's recommendation. According to the CEAP classification, they are presented as C1-7 (8.9%), C2 - 27 (34.2%), C3 - 39 (49.4%), C4 - 6 (7.6%). Of these patients, invasive treatment (surgery, sclerotherapy) was performed in 29 (36.7%) respondents, improvement in the clinical manifestations of varicose veins was noted in 54 (68.4%) respondents.

Analyzing the answers to the 1st and 2nd questions, we can conclude that 110 respondents who use compression stockings and

Table 3. Baseline characteristics of patients included in the study

Index	Characteristic		p
	General registration base data	Phone survey data	
Age (Me, IQR)	43,5 (34-55)	44,0 (35-55)	0,831
Female (n, %)	303 (76,9)	204 (82,9)	0,096
Male (n, %)	91 (23,1)	42 (17,1)	
C1 (n, %)	55 (13,8)	32 (13,1)	
C2 (n, %)	153 (39,1)	83 (33,7)	
C3 (n, %)	149 (37,6)	109 (44,3)	
C4 (n, %)	29 (7,5)	20 (8,1)	0,370*
C5 (n, %)	4 (1,0)		
C6 (n, %)	4 (1,0)	2 (0,8)	
Higher education			
Yes (n, %)	231 (58,6)	149 (60,6)	0,660
No (n, %)	163 (41,4)	97 (39,4)	
Professional activity, associated with hard physical labor			
Yes (n, %)	109 (27,7)	57 (23,2)	0,258
No (n, %)	285 (72,3)	189 (76,8)	
Professional activity, associated with hard physical labor and long-term orthostasis			
Yes (n, %)	143 (36,3)	87 (35,4)	0,869
No (n, %)	251 (63,7)	159 (64,6)	
Professional activity, associated with long sitting work			
Yes (n, %)	214 (54,3)	136 (55,3)	0,828
No (n, %)	180 (45,7)	110 (44,7)	
Family history of chronic venous disease			
Yes (n, %)	283 (71,8)	182 (74,0)	0,638
No (n, %)	111 (28,2)	64 (26,0)	
History of venous thromboembolism			
Yes (n, %)	55 (13,9)	30 (12,2)	0,709
No (n, %)	339 (86,1)	216 (87,8)	
Smoking			
Yes (n, %)	72 (18,3)	43 (17,5)	0,965
No (n, %)	322 (81,7)	203 (82,5)	
Number of childbirths			
No (n, %)	36 (11,7)	27 (13,2)	
One (n, %)	92 (30,3)	54 (26,5)	
Two (n, %)	156 (51,7)	108 (52,9)	0,764**
Three (n, %)*	18 (6,0)	15 (7,4)	
Four (n, %)	1 (0,3)		

*Calculated for patients with chronic venous insufficiency (C3-C6) and without it (C1-C2)

**Calculated for women who have given birth and who have not given birth

Table 4. Answers to the 1st question of a telephone survey questionnaire

Index	n	%
More than 4 hours daily	17	6,9
Less than 4 hours daily	1	0,4
Constantly in the presence of factors unfavorable for the veins of the legs	7	2,8
Sometimes in the presence of factors unfavorable for the veins of the legs	85	34,1
I do not use at all, although I purchased it	117	48,0
I don't use it because I didn't buy it	19	7,7
Total	246	100,0

79 respondents who stopped taking them on the basis of doctor's recommendations are in compliance with doctor's recommendations, i.e., 189 patients (76.8%).

When answering the 3rd question, 151 respondents (61.4%) reported an improvement in the course of varicose disease, 4 (1.6%) - worsened, 91 (37.0%) respondents did not notice any changes. At the

same time, among patients using compression stockings, 79 respondents (72.5%) noted an improvement in symptoms, 3 (1.8%) - worsening, 28 (25.7%) respondents noted no changes. The number of respondents who noted an improvement in the manifestations of varicose veins was significantly higher in the group of patients who used compression stockings ($p < 0.001$).

Table 5. Use of compression therapy in patients with different characteristics

Sign	p
Sex	0,237
The level of education	0,794
Professional activity is associated with hard physical work	0,879
Professional activity is associated with hard physical work and long-term orthostasis	0,031
Professional activity is associated with long sitting work	0,303
Family history of chronic venous disease	0,917
History of venous thromboembolism	0,846
Previous history of using compression stockings	<0,001
Resident of a city with a population of more than 250,000*	0,665

*The classification of cities was carried out on the basis of WHO criteria

4th question. Golfs were used by 17 respondents (15.6%), stockings - 75 (67.9%), tights - 15 (13.7%), one-leg stocking with a fastener at the waist (monostocking) - 3 (2.8%).

5th question. Compression stockings of the 1st compression class was used by 5 respondents (4.5%), 2nd - 96 (87.3%), 3rd - 9 (8.2%).

The results of assessing the reliability of differences in the sign of the use of compression stockings by patients (question 1) with their demographic, professional and other characteristics are presented in Table 5.

Discussion

The data obtained provide information about the high adherence of patients to following medical recommendations regarding compression therapy during the 1st year. The main limitation of this study is that the information used for the analysis comes from patient responses. The study of patients' adherence to compression therapy based on patient responses complicates obtaining reliable study results, and the scales created for this purpose do not have high sensitivity and specificity [8].

Previously published data from thermosensors that recorded the time of contact of a compression product with the skin demonstrated compliance in groups of patients with and without a weekly SMS reminder of 71% and 48%, respectively [9,10]. In a follow-up of 867 patients who received recommendations, it was found that only 69% of patients purchased compression stockings, and of these, 84% use them. Data on the high adherence of patients to compression therapy were obtained in a study by Ayala, et al. [11], in which it was found that 91.5% of patients in one form or another use compression stockings even in tropical climates, but only 31.8% patients strictly follow medical recommendations.

An interesting, from our point of view, result of the POMP study was a greater adherence to medical recommendations regarding compression therapy of those patients who already had experience with its use ($p<0.001$). It was also predictable that patients whose work activity is associated with heavy physical labor and long-term orthostasis are more committed to compression therapy ($p=0.031$). Unexpected for us was the result of the absence of significant differences in compliance with compression therapy for 1 year in groups of patients with different levels of education and place of residence (residents of large cities/residents of small towns).

Comparing the previously published results of our study of patient adherence to compression therapy with a follow-up period of 1 month [12] with the results of the present study, we found an interesting feature. It consists in the fact that in groups of patients who followed or did not follow medical recommendations after 1 month and 1 year there are no significant differences ($p=0.493$). This does not allow us to state that the patients who adhered to compression therapy after 1 month were also adherent to it after 1 year. Or vice versa, that patients

who did not use compression therapy after 1 month did not use it after 1 year. The reasons for these features need further study.

Conclusion

This multicenter study demonstrated high patient adherence to medical recommendations for compression therapy. 12 months after receiving the recommendations, they are followed by 76.8% of patients. To obtain more complete information about the compliance of patients and their individual assessment of the effectiveness of compression therapy, it is necessary to unify medical recommendations on this issue.

Conflict of interests

The telephone survey was carried out with the sponsorship of the network of orthopedic salons ORTOS. The authors declare that there are no other conflicts of interest.

Ethical aspects

The study was approved by the ethics committee of the Belarusian State Medical University.

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