Original communication

Efficacy of medical compression stockings class I on the reduction of symptoms in patients with uncomplicated varicose veins

Results of a randomized, controlled, clinical trial

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Summary: *Background:* Aim of this study was to analyze the effect of medical compression stockings (MCS) class I (according to the German classification "RAL-GZ 387"; 18–21 mmHg) on symptoms in patients with uncomplicated varicose veins (C2s–C4a). *Patients and methods:* We conducted a randomized (1:1), controlled, clinical trial enrolling patients with uncomplicated varicose veins (CEAP: C2s–C4a). The study consisted of a one-week baseline period and a four-week follow-up period with MCS treatment (compression class I, 18–21 mmHg) in the intervention group and non-treatment in the control group. The frequency and severity of symptoms on the leg including heaviness, pain, swelling, throbbing and itching were measured every evening using an app-based measuring tool. The primary endpoint was the reduction of symptoms during compression therapy, measured by a symptom sum score over a period of 5 weeks ranging from 0 (no symptoms during the day) to 25 (symptoms all day). *Results:* Patients treated with MCS (n = 25) showed a significant improvement in the overall symptom sum score from 8.90 ± 4.26 at baseline to 6.37 ± 3.55 at follow-up (p = 0.004) whereas for patients in the control group without MCS (n = 25) the overall score remained unchanged (baseline: 7.46 ± 3.71; follow-up: 7.67 ± 4.74; p = 0.293). The intervention group reported significant improvements in symptom frequency scores for pain, leg swelling and feeling of leg heaviness ($p \leq 0.002$). In the control group the score for pain significantly increased during the follow-up period. Leg itching was numerically more frequent in patients with MCS. *Conclusion:* This study indicates that medical compression stockings class I (according to the German classification "RAL-GZ 387"; 18–21 mmHg) significantly improve the frequency and severity of symptoms in patients with uncomplicated varicose veins (CEAP: C2s–C4a).

Keywords: Compression therapy, quality of life, chronic venous disease, varicose veins

Introduction

Varicose veins are a chronic, progressive degenerative disease of the vein walls in the superficial vein system of the legs [1] and has a negative impact on patients' quality of life [1, 2, 3]. Based on the CEAP classification varicose veins are typically classified as class C2. More mild disease stages of varicose veins would be no visible/palpable signs of venous incompetence (C0) or spider veins (C1). As mentioned above varicose veins is a progressive disease and thus signs of more severe stages are oedema (C3), skin alterations (C4) and chronic venous insufficiency with leg ulcers (C5 [cured ulcer] & C6 [active ulcer]) [1, 4]. Nevertheless, in any of these stages the disease can present with or without symptoms such as pain, feeling of leg heaviness, leg tension, and leg swelling [1]. Most patients (60-70%) with chronic venous diseases are in CEAP classes C0 and C1, but already 25% are presenting with varicose veins without (C2) or with oedema (C3) [5]. The overall prevalence of varicose veins is estimated with 25.1% [6] and thus represents a highly frequent disease.

A main treatment option of chronic venous disease is compression therapy which can be performed by use of medical compression stockings (MCS), compression bandages or adjustable compression wraps. MCS are considered an indispensable treatment for varicose veins to

https://doi.org/10.1024/0301-1526/a001163

improve venous hemodynamics [1]. In Germany they are classified by RAL-GZ 387 in different compression classes (CCL) with interface pressures ranging from 18-21 mmHg (CCL 1), 23–32 mmHg (CCL 2), 34–46 mmHg (CCL III) and $\geq$ 49 mmHg (CCL IV) [7].

A recently published randomized clinical trial investigating the efficacy of MCS in patients with varicose veins showed a significant reduction in pain or aching compared to placebo stockings [8]. A second, older study indicates that compression therapy reduces the risk of leg ulcer recurrence [9]. Even though several meta-analyses report on the improved healing rates of leg ulcers using compression therapy in patients with chronic venous disease [10, 11], current data, especially randomized clinical trials on the efficacy of MCS on symptom improvement in patients with varicose veins are sparse.

Methods

Aim of our study

Due to the small amount of available data on the effects of MCS CCL I on varicose vein related symptoms we aimed to analyze the efficacy of MCS CCL I on symptom reduction, including the criteria leg pain, leg swelling, leg throbbing and feeling of heaviness in patients with uncomplicated varicose veins. For reasons of readability, we will only refer to CCL I in the following text: this refers consecutively to the German classification of compression classes according to "RAL-GZ 387" which classifies CCL I as an interface pressure of 18–21 mmHg.

Study design

This study was a randomized, open label, controlled, clinical trial performed in two study centers in Germany between 18th of January 2019 and 30th of September 2022. Study participants with uncomplicated varicose veins (CEAP: C2s–C4a) were recruited in hospital outpatient departments. Patients who fulfilled the inclusion criteria were 1:1 randomized using the www.randomizer.org online tool and allocated into an intervention group or a control group. During the first study week (baseline period) both intervention and control group received no compression therapy and were asked to log their symptoms in an app-based digital logbook. During study weeks 2–5 (follow-up period) the intervention group received medical compression stockings (MCS) with CCL I (Mediven plus; CE marking; circular knit; length: AD and AG; colors: caramel and black), whereas control group was not treated with MCS or any other compression therapy (Figure 1).

Under consideration of an effect size of 0.5 (Cohen's d), an alpha error of 5% and a statistical power of 1-β = 80% the sample size for each group was calculated with 70 participants. In addition to that, a drop-out rate of 10% was considered and thus, optimal sample size was calculated with 77 per group (154 study participants in total). The study was approved by the ethics committee of the University of Bochum, Germany (approval number: 17-6274).

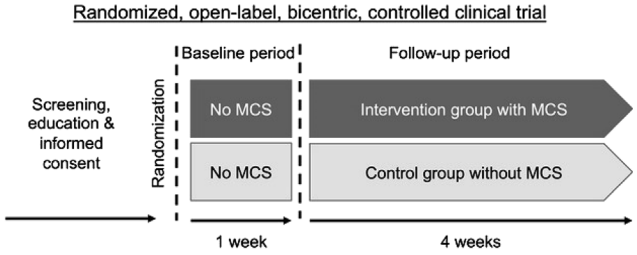

Figure 1. Study design; MCS, medical compression stockings.

Inclusion criteria

Patients were included into the study if they fulfilled the following inclusion criteria: having uncomplicated varicose veins [CEAP: C2s–4a), being aged 18–75 years, duplex sonographically confirmed incompetence of saphenous veins and/or deep conducting veins, regular symptomatic presentation of leg heaviness, pain, swelling, throbbing and itching with an initial overall symptom sum score of at least 5 points, having the ability and facility to operate the electronic diary (smartphone app) to collect the symptom score and a doppler sonographically determined ankle-brachial index (ABI) > 0.5 or systolic absolute pressure > 60 mmHg and a BMI $\leq$ 35 kg/m^2. The ankle-brachial index was determined by measuring the systolic blood pressures of the A. tibialis posterior and A. dorsalis pedis on both feet of each study participant, as well as the systolic blood pressure of the A. brachialis on both arms. It was then calculated by dividing the lower measurement for blood pressure on each foot by the mean blood pressure of both brachial arteries.

Exclusion criteria

Exclusion criteria included acute deep or superficial leg vein thrombosis, the inability or unwillingness to put on or wear compression stockings, having at least one absolute contraindication to compression therapy, a significantly limited mobility (e.g. walking on crutches, rollator, wheelchair), having had surgical or interventional measures on the veins in the last 6 weeks before study enrollment and if a serial supply with the study product was not possible (e.g. caliber jumps in the leg shape).

In addition, the following criteria were defined as termination criteria: occurrence of an acute illnesses with effects on leg symptoms such as acute bed confinement, immobilization, acute internal illness or need for inpatient treatment for other reasons. If such an event occurred, the patient was advised to immediately contact the study center.

Study endpoints and symptom data collection

The primary endpoint of this study was the overall daily symptom score over the study period of 5 weeks. Secondary endpoints were the weekly mean of the overall symptom score as well as the sub scores for feeling of leg heaviness, pain, swelling, throbbing, and itching.

The used symptom score tool was adapted from the VVSymQ instrument [12], was in German language and measured patient reported outcomes. The original VVSymQ instrument was evaluated in patients with varicose veins with great saphenous vein incompetence [12] and the used German version was adapted on the needs of patients with uncomplicated varicose veins. The symptom measuring tool used in the present study consists of sub scores for complaints of leg heaviness, pain, swellings, throbbing, and itching. The sub scores can be analyzed separately and used to calculate an overall symptom score. Study participants were asked to answer the symptom instrument via smartphone app by evaluating the abovementioned symptoms daily between 5 pm and 10 pm using a six-step rating scale based on how often the symptoms occurred since waking up in the morning (0, at no time; 1, rarely; 2, sometimes; 3, over a long period; 4, most of the time; 5, all the time).

The specifically programmed smartphone app for symptom data collection represented an electronic symptom diary running on iOS and Android based smartphone systems. To prevent access to the study by unauthorized persons a login was necessary. Study participants logged in via the app and the authentication was done via OAuth 22. The connection between interface and app was done via SSL. For those analyzing the data, an admin web interface was installed, where the evaluated questionnaires could be downloaded as an anonymized Excel file. Due to security reasons access data was not sent by e-mail but handed over personally on site. For the admin it was not possible to view the participant access data. All study participants received unique IDs, generated in the clinic (on site), which consisted of the first letter of the center and a 2–3-digit number.

Statistical analysis

Characteristics of study participants were described using descriptive statistics, calculating mean, standard deviation (SD) and/or frequencies.

For the overall symptom score and sub scores mean values and standard deviation (SD) were calculated. The daily overall symptom sum score was calculated by summing up the ratings for each sub score, which means that a score of 0 corresponds to no symptoms during the day and 25 for symptoms all day. Changes in the mean of the overall symptom score as well as the sub scores between baseline period and the last six days of the follow-up period was performed using paired t-test for interventional and control group, respectively. Analysis was performed using Excel (Version Microsoft office professional plus 2016) and a p-value of ≤ 0.05 was considered statistically significant.

Results

This study was terminated early and after recruitment of 50 study participants in total as the planned sample size could not be achieved due to the ongoing corona pandemic which led to a governmentally advised closing of hospital outpatient departments. An early termination of the study was further indicated from ethical point of view, as a statistically significant improvement of symptoms could already be shown in the intervention group.

Since compression stockings are a medical device with CE marking which is accessible to the broad population, the continuation of the study would deprive eligible patients of an available therapy option. The ethics commission agreed to the early termination of the study.

Until the study was terminated no side effects, adverse events (AE) or serious adverse events (SAE) had occurred. All study participants finished the study period, no participants dropped out early.

Characteristics of study participants

A total of 50 patients (76% female, 24% male) were enrolled in the study with a mean age of 50.10 ± 11.25 years. The average body weight was 83.88 ± 15.29 kg, average body size 1.72 ± 0.09 and thus the average BMI 28.27 ± 3.98 kg/m^2. Study participants presented an ABI of 1.03 ± 0.14 and 1.04 ± 0.12 on the right leg and left leg, respectively. After 1:1 randomization the overall symptom score of the interventional group (n = 25) was 8.90±4.26 and of the control group (n = 25) 7.46 ± 3.71 during the one-week baseline period, respectively.

Efficacy of MCS on Symptoms

Study participants in the intervention group treated with MCS during the follow-up period displayed a significant decrease in mean overall symptom sum score (0 corresponds to no symptoms during the day; 25 corresponds symptoms all day) of 2.53 points from 8.90 ± 4.26 at baseline to 6.37 ± 3.55 (p=0.004) in the last six days of the four weeks follow-up period (Figure 2). In the control group without MCS the overall score remained stable (baseline: 7.46 ± 3.71; follow-up: 7.67 ± 4.74; p = 0.293).

Symptom sub scores (ranging from 0: "symptoms at no time" to 5: "all the time"), indicated significant improvements for feelings of leg heaviness ($p \leq 0.001$), pain (p = 0.002) and leg swelling ($p \leq 0.001$) in the intervention group from baseline compared to the last six days of the follow-up period (Table 1). In contrast, pain (p = 0.032) increased between baseline and the last six days of the follow-up period in the control group without MCS. Leg itching was numerically lower in the control group compared to

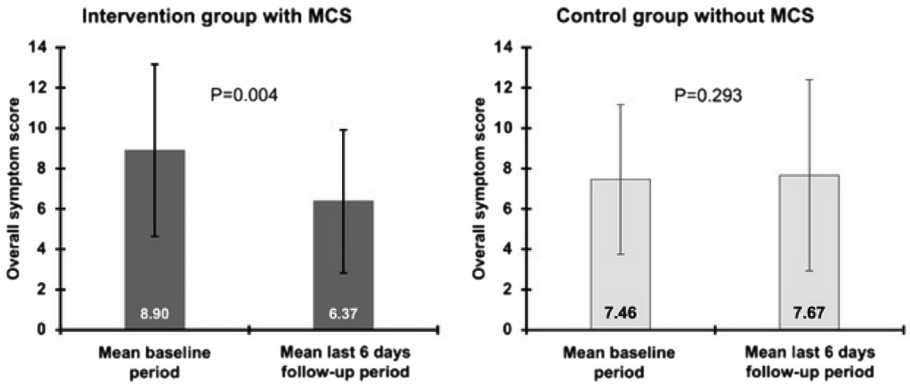

Figure 2. Overall symptoms sum score during baseline period and the last six days of the follow up period in intervention and control group; higher score corresponds to more frequent daily symptoms with 0 equal to no symptoms and 25 equal to symptoms all day.

Table I. Mean values of symptom sub scores during baseline period and the last six days of the follow-up period; MCS, medical compression stockings; p-values based on paired t-test; higher scores correspond to more frequent daily symptoms: 0, at no time; 1, rarely; 2, sometimes; 3, over a long period; 4, most of the time; 5, all the time

	Intervention group with MCS		Control group without MCS	
Symptom sub score	Mean baseline period	Mean last 6 days follow-up period	Mean baseline period	Mean last 6 days follow-up period
Feeling of leg heaviness	2.27 (± 1.09)	1.36 (± 0.89)	2.12 (± 1.05)	2.24 (± 1.36)
	P ≤ 0.001		P = 0.205	
Leg pain	1.83 (± 1.19)	1.13 (± 0.73)	1.62 (± 1.03)	1.81 (± 1.22)
	P = 0.002		P = 0.032	
Leg swelling	2.65 (± 1.42)	1.52 (± 1.14)	1.70 (± 1.03)	1.75 (± 1.36)
	P ≤ 0.001		P = 0.349	
Leg throbbing	1.23 (± 1.00)	1.00 (± 0.93)	1.12 (± 0.92)	1.30 (± 1.14)
	P = 0.141		P = 0.095	
Leg itching	1.03 (±1.01)	1.37 (±1.14)	0.91 (±0.91)	0.62 (±0.87)
	P = 0.071		P = 0.014	

the intervention group and significantly decreased in the control group from baseline to the end of the follow-up period (p = 0.014). Full details of the symptom sub score analysis is shown in Table I.

Discussion

The results of this randomized clinical trial show that MCS with CCL I for patients with uncomplicated varicose veins (CEAP: C2s–C4a) significantly reduce the daily frequency of symptoms based on the specific symptom sub scores, where 0 means no symptoms and 5 corresponds to symptoms all day, and the overall symptom sum score (ranging from 0, no symptoms, to 25, symptoms all day). The overall symptom sum score reduced from 8.90 to 6.37 points, which corresponds to a reduction in symptom frequency by 28.43%. In addition, the symptoms pain, feeling of leg heaviness and leg swelling significantly improved after 4 weeks of wearing MCS.

Comparable to the results of the present study, Kakkos et al. (2018) reported a significant reduction of pain or aching (measured by use of the Visual Analogue Scale - VAS) in patients with varicose veins wearing graduated elastic compression stockings (18–21 mmHg) for a period of one week, compared to patients wearing placebo stockings [8].

A second study by Benigni et al. (2003) including patients with early-stage chronic venous disease indicated that wearing compression stockings with a pressure of 10–15 mmHg for 15 days resulted in a significant improvement of pain and the quality-of-life criteria "mood" and "daily work activity" measured using VAS, respectively [13]. The present study was performed with four weeks of compression therapy and therefore, adds longer-term evidence data to the studies of Kakkos et al. (2018) and Benigni et al. (2003) [8, 13]. However, the study period can still be classified as short and thus does not allow to draw conclusions about the efficacy of MKS CCl I in symptom reduction of uncomplicated varicose veins over a period of many years.

The adherence to compression therapy over time could furthermore be affected by seasonal aspects, where the regular wear of compression stockings could be negatively influenced by warmer temperatures during summer

months. The recruiting period of our study was conducted from January 2019 until August 2022 during which time study participants were included during all seasons including the German summer months of June, July and August. Since study participants knew about the intervention period of 4 weeks we can, at this point, only assume that there is a long-time adherence to wearing compression stockings on the part of the patients. This assumption however is backed by a representative survey of the German population conducted by the Allensbach Institute for Public Opinion Research from 2023 in which 81% of respondents stated that they wear their stockings almost every day and have done so for an average of 6.90 years [14].

In order to maximize compliance, the individual study participants were given the choice between MCS CCl I AD or AG, independent of their presentation of varicose veins on the legs. This could be seen as a limitation to our study since a mismatch between varicose vein distribution on the leg and compression therapy may have been the case for some patients, however it mirrors real-life situations in which patients choose to wear or not wear certain types of MCS for various reasons.

Important to mention is that study participants undergoing a vein surgery six weeks before enrollment were excluded from the present study. The exclusion of patients with recent surgery was done to measure the plain effect of MCS on symptoms and to avoid interfering effects from surgical procedures which might overlay the effects of MCS. Nevertheless, the present study clearly shows the efficacy of MCS without surgery on the improvement of varicose veins symptoms.

Patients in the intervention group of the present study showed a decrease in the overall symptom score of 2.53 points (Figure 2) or 28.43%, which can be interpreted in a 28.43% decrease of daily symptoms. Important to mention here is that pain frequency was reduced by –38.25% in the intervention group compared to an increase of 11.73% in the control group (Tab. 1). In addition, the frequency of leg swelling was reduced by −42.64% in the MCS group compared to an increase of 2.94% without MCS. Based on the German guidelines for the diagnostic and treatment of varicose veins the aim of compression therapy in patients with chronic venous insufficiency is to reduce symptoms [1], which was achieved in the present study in terms of the overall symptom complex as well as for daily pain, leg swelling and leg heaviness frequency. Since the frequency of pain and leg swelling increased in the control group but significantly decreased in the intervention group the results provide meaningful indications on the efficacy of MCS class I in reducing symptoms in patients with varicose veins treated. This is especially important when looking at the results of a previous study which found risk factors for leg swelling including obesity, prolonged sitting, high blood pressure or urban living – factors which are all too common in our modern world [15].

In addition, the guidelines recommend compression therapy to reduce the risk of varicose veins' evolution and complications [1] since CVI is characterized by a progressive dysfunction of the venous system caused by pathological refluxes due to weakening of the vein walls and abnormal dilation [16]. Even though the present study did not analyze the effect of MCS on the disease evolution and complications, several previous publications report on benefits of MCS on these two aspects [9, 17, 18]. A study by Vandongen & Stacey (2000) indicated that MCS significantly reduce the risk of ulcer recurrence by 54% (RR 0.46 [95% CI: 0.27; 0.76]) [9, 18]. In addition, meta-analyses report that compression therapy increases the probability of ulcer healing compared to no of compression therapy [10, 11]. Patients with leg ulcers wearing compression stockings or bandages further showed significantly lower pain scores and significantly quicker healing rates for the complete closure of leg ulcers [10].

Compared to the control group without MCS patients in the intervention group with MCS reported itching numerically more frequently, which can be considered an adverse event. Nevertheless, this is a known event occurring due to significant reduction of skin hydration when wearing MCS [19]. The application of skin care or the wearing of MCS with integrated skin care might help to reduce skin irritations [20].

Limitations

This RCT has several limitations. First, the number of study participants was low, and the planned sample size was not achieved due to recruitment issues related to the corona pandemic. Second, even though the duration of the study was longer compared to similar studies [8, 13] it can still be considered short, especially since chronic venous insufficiency is a lifelong progressive disease [1]. Third, this RCT only analyzed symptoms and cannot deliver any evidence on the prevention of disease progression. Forth, study participants had to answer a self-administered questionnaire to rate their daily symptoms and therefore, we must rely on the honesty of study participants. Fifth, participants in the control group were not given placebo stockings which could have impacted reported effects due to altered expectations. Sixth, since the study was unblinded, study participants knew to which group they belonged which might also have influenced the measured effects further. Seventh, compliance of study participants in the interventional group was not measured. Eight, the length of MCS (AD or AG) was not determined by the extend of varicose veins on the legs but rather on the individual participants wishes in terms of wearing comfort and aesthetic.

Conclusions

This RCT shows that the use of MCS belonging to compression class I (18–21 mmHg; according to the German classification "RAL-GZ 387") in patients with uncomplicated

varicose veins (CEAP: C2–C4) results in an overall improvement of symptoms such as pain, leg swelling and leg heaviness. The results support previously published evidence on the positive effect of compression therapy on symptoms of chronic venous insufficiency. Based on our findings and the discussed literature MCS are an elementary part of the therapy of patients with varicose veins and should, therefore, always be considered as an indispensable treatment in this patient population.

For symptomatic treatment compression class I seems to result in the desired reduction of symptoms and can thus be advised in daily use for uncomplicated varicose veins.

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History
Submitted September 17, 2024
Accepted after revision October 20, 2024
Published online November 25, 2024

Conflicts of Interests
MS received consulting fees from Bauerfeind AG, URGO GmbH and eurocom v. V., speaker fees from Julius Zorn GmbH, URGO GmbH and Viatris and research funding from Mölmlycke Health Care AG, med GmbH & Co. KG, URGO GmbH, Huntleigh GmbH, Rheacell and eurocom e. V. LM received speaker fees and research funding from UCB Pharma GmbH and is an employee of eurocom e. V. ER is a consultant of eurocom e.V. and Sigvaris int.

Funding
This study was funded by eurocom e. V. (European manufacturers federation for compression therapy and orthopaedic devices), Berlin, Germany.

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