Outpatient treatment of venous diseases with medical compression stockings in Germany

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Abstract

The aim of this study was to assess the provision of medical compression stockings (MCS) to venous outpatients in daily practice, the tolerability of mediven-MCS, and the compliance and subjective and objective symptoms of patients. During the 18-month observational study in Germany, 531 venous outpatients were evaluated regarding MCS-prescriptions and demographic, physical, and clinical findings. We found that MCS were mostly of compression class 2 and light textile characteristics, irrespective of the patients' CEAP and Body Mass Index (BMI). During the study, fewer prescriptions for MCS and donning aids were dispensed than would have been possible according to patient's needs and health insurance regulations. Findings suggesting impaired MCS-tolerability rarely occurred. Prevention of constrictions, compliance of patients, and CEAP-class (C3-patients) could be improved when MCS and donning aids were individually prescribed according to the patient's individual CEAP, BMI, and age. In conclusion, patient- and disease-specific characteristics of venous patients require a more individual consideration regarding number and type of MCS-prescriptions.

Introduction

Worldwide, treatment with medical compression stockings (MCS) is a central element of the therapy and prevention of venous diseases and impairment of venous function, respectively.[1-3] Several studies have demonstrated MCS effectiveness in the treatment[4-6] and prevention[7,8] of venous disorders, in postoperative care,[9,10] and in prevention of recurrence.[11,12]

To be successful, MCS therapy requires careful consideration of disease- and patient-specific factors including CEAP class, leg circumference, edema, age, and body mass index (BMI).[13] Appropriate MCS parameters such as compression class (CCL), knitting variety (round-/flat-knitted), stocking length, and MCS characteristics (*characteristics* comprises textile MCS features affecting elasticity and other MCS characteristics) need to be set individually for every patient. In addition, outcome of MCS treatment is affected by the patient's compliance, which in turn is potentially influenced by some of the above-mentioned factors.[14,15] Guidelines such as the German MCS guideline of 2006[3] might give suggestions as to how to use MCS in different indications, but they usually do not assign definite MCS parameters to specific venous diseases, symptoms, and patient characteristics. Moreover, little is known on the provision of MCS to venous outpatients in daily practice in Germany,[16] *i.e.* if MCS prescriptions adequately differentiate between CCL, knitting variety, length, and characteristics, if MCS are well tolerated, and how tolerability is affected by both MCS and patient characteristics. Here, we report the results of a large multicenter observational study[17,18] on the outpatient medical care situation in Germany. The data evaluated included provision of MCS and donning aids to 531 venous outpatients, safety and tolerability of mediven round-knitted MCS, as well as the compliance and the subjective and objective symptoms of venous outpatients.

Materials and Methods

Study design

This study was a prospective, non-interventional/non-invasive observational study conducted between November 2011 (start of recruiting) and February 2015 (end of observational phase) in 47 participating practices in Germany. Decisions regarding diagnosis, treatment, and prescription of mediven MCS were made exclusively by the treating physician, independently of study participation. Mediven MCS (medi GmbH & Co. KG) comprise light (mediven elegance, mediven comfort, mediven for men), medium (mediven plus), and firm (mediven forte) MCS characteristics, as well as the mediven ulcer kit, in all variations (standard and made to measure), CCL, and sizes. The term, characteristics' refers to the textile MCS characteristics defining strength, rigidity, and elasticity. All diagnostic measures were performed as recommended[3] and in accordance with clinical routine practice.

The primary outcomes comprised data

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Conflict of interests: the authors on the scientific advisory board and Ms. Hahn declare that a financial association exists with medi GmbH & Co. KG due to an advisory contract. Ms. Doppel is an employee of medi GmbH & Co. KG.

Ethical approval: the study was approved by local Ethics Committees and the leading Ethics Committee (State Medical Council of Thuringia, Germany). The study was registered under DRKS00006124 (German Clinical Trials Register).

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on the outpatient medical care situation (number and frequency of prescriptions of MCS and donning aids; MCS characteristics), mediven MCS safety and tolerability, and adverse reactions. Secondary outcomes were treatment compliance (frequency and duration of MCS wear) and the subjective and objective venous symptoms of venous outpatients receiving routine care. The study was approved by local Ethics Committees and the leading Ethics Committee (State Medical Council of Thuringia). The study was registered under DRKS00006124[19] and performed in compliance with the principles of the Declaration of Helsinki and the mandatory guidelines and regulations.

Inclusion and exclusion criteria

Male and female patients (CEAP categories C1S - C6) aged between 18 and 79 years with an indication for long-term MCS treatment (18 months) of venous disease (ICD 10) were eligible, if the patient's written informed consent was provided and if patients had not undergone compression treatment during the previous six weeks (including postoperative care with MCS). Patients with a contraindication to MCS, a short life expectancy (< 2 years), or a probable need for saphenous vein surgery or flat-knit MCS provision during the observational phase were excluded. Other exclusion criteria were non-venous lymphedema, lipedema, and the absence of physical or mental preconditions required for study participation.

Procedures

At the beginning of the study, proper fit of the MCS provided was controlled (visit 1). Visit 2 took then place after 1 month, followed by visits 3 to 5, each in 6-months-intervals. During the visits, data related to the prescription and provision of MCS and donning aids as well as demographic, physical, and clinical findings were assessed. In addition, frequency and duration of MCS wear, patient-reported MCS tolerability, and the patient's subjective and objective venous symptoms were documented.

Statistics

Data were collected on a standardized data collection form and documented by the investigator or authorized staff using a web-based system. The authorized clinical research institute (CYCLOMED GmbH) checked all data for consistency, completeness, and plausibility. Statistical analyses were descriptive. For nominal and ordinal-level data, distributions of absolute and relative frequencies are reported. Numerical data are presented as mean ± standard deviation (SD).

Results

Patient characteristics

Out of 841 patients, 784 patients were enrolled. After discontinuation of 253 patients, the population analyzed comprised 531 patients. Patients' characteristics are depicted in Table 1. In brief, 77.6% of patients were female, and 60.5% were older than 51 years (Ø 54.2 ± 14.2 years). Approximately one third of patients each was of normal weight, overweight, and obese. Most frequent diagnosis was varicose veins of the lower extremities (84.6%), and most frequent CEAP categories were C2 (34.5%) and C3 (43.3%). Frequencies of concomitant diseases and medications were as expected (Table 1).

Representativeness of the population analyzed was confirmed by the association of disease severity, age, and BMI. Elderly patients > 61 years were more often overweight or obese (71.2%; n=141) than younger patients < 41 years (44.9%; n=40), and CEAP class increased with age and BMI. CEAP classes C4 to C6 (n=53) occurred more frequently in patients who were older than 61 years (67.9%) and overweight or obese (83%).

Outpatient medical care situation

MCS were of CCL2 (23 - 32 mmHg) in almost all prescriptions (98%; CCL1 [18 - 21 mmHg] 1.8%; CCL3 [34 - 46 mmHg] 0.1%; mediven ulcer kit [2 x 20 mmHg] 0.1%). The MCS length was mostly AD (60.2%), AG (34.1%) or AT (5.7%), mainly with a closed toe (60.4%; open: 39.6%). During the study period, MCS prescriptions

Table 1. Patient characteristics.

	Population analyzed N = 531
Sex, N (%) male / female	119 (22.4) / 412 (77.6)
Age, mean (± SD)	54.2 (± 14.2)
Age distribution, N (%)	
18 – 20	4 (0.8)
21 – 30	39 (7.3)
31 – 40	46 (8.7)
41 – 50	120 (22.6)
51 – 60	123 (23.2)
61 – 70	123 (23.2)
71 – 79	75 (14.1)
BMI distribution, N (%)	
< 18.5	9 (1.7)
18.5 – 24.9	190 (35.8)
25 – 29.9	180 (33.9)
> 30	147 (27.7)
Frequent diagnoses, N (%) [c]	
Varicose veins of lower extremities [a]	449 (84.6)
Other venous disorders [b]	228 (42.9)
Clinical classification according to CEAP, N (%)	
C1S	56 (10.6)
C2	182 (34.5)
C3	228 (43.3)
C4a	38 (7.2)
C4b	6 (1.1)
C5	6 (1.1)
C6	3 (0.6)
Frequent concomitant diseases, N (%) [c]	
Spinal problems	202 (38)
Hypertension	175 (33)
Osteoarthritis	102 (19.2)
Impaired thyroid function	78 (14.7)
Diabetes mellitus	38 (7.2)
Frequent concomitant medication, N (%) [c]	
Anticoagulants	94 (17.7)
Thyroid hormones	73 (13.7)
Antidepressants	73 (13.7)
β -Blockers	67 (12.6)

BMI: body mass index; a) I83.0., I83.1., I83.2., I83.9 (ICD-10-GM-2015); b) I87.0., I87.1., I87.2. I87.9 (ICD-10-GM-2015); c) multiple answers possible; datasets contained missing values (age distribution 0.2%; BMI distribution 0.9%; CEAP class 1.5%).

were predominantly for light characteristics (light 73.8%; medium: 23.5%; firm: 2.1%). Importantly, prescriptions of light MCS characteristics dominated irrespective of the patients' CEAP (Figure 1A) and BMI (Figure 1B), and, equally important, this predominance of light characteristics was observed throughout the whole study period.

During the 18-month observational study, patients received an average of 4.1±1.8 MCS prescriptions per patient. Approximately one third of patients each received three or less prescriptions during the study (35.4%; n=188), no prescription of a second pair at the beginning of the study (31.6%), and no repeated prescription at visit 3 (31.3%), 4 (27.3%), and 5 (34.8%).

Prescriptions of donning aids were generally rare and only slightly increased during the study, from 8.1% at the beginning (n=43) to 13.8% (n=73) at visit 5. Surprisingly, prescriptions of donning aids were not more frequent in cases of obese (11.3%) and overweight patients (7.1%) as well as in cases of patients with concomitant diseases such as spinal problems (9.9%) and osteoarthritis (11.1%). Only a higher age resulted in slightly increased prescriptions of donning aids (61-70 years: 12.2%; 71-79 years: 17.3%).

Safety and tolerability

There were no major tolerability issues in this study. Leg examinations potentially indicative of impaired MCS tolerability rarely occurred and tended to decrease during the study (Table 2). At the end of the study, constriction furrows at the top band of the MCS, at the popliteal cavity, and at the ankle were found in 17, 17, and 7 patients who wore light (15, 15, 6) and medium MCS characteristics (2, 2, 1). No constriction furrows occurred in patients wearing MCS of firm characteristics. Obese or overweight patients who wore MCS of light characteristics had constriction furrows more frequently than those who were underweight or of normal weight.

During the study, between 21.6% and 29.6% of patients had dry skin on the leg wearing MCS. At the beginning of the study period, only 36.5% of participants stated to use skin care products on their legs. Other skin examinations suggesting reduced tolerability were rare, and no relevant skin findings were observed in the majority of patients (Table 2).

Compliance

At the different study visits, most patients reported to wear the MCS daily (65.3 - 75.6%) and from morning until evening (48.4-68.4%). During the study, however, the proportion of patients exhibiting this high level of compliance decreased by 10.3% (daily) and 20.0% (morning until evening; Table 3). Compliance to MCS treatment appeared to depend on a number of factors such as the absolute number of MCS prescriptions and the prescription of donning aids. Patients who wore their MCS daily had received more (repeated) prescriptions than patients who wore their MCS occasionally (at study end, the prescriptions per patient ratio was 0.8 for daily users and 0.5 for less frequent users).

A higher number of elderly and obese patients wore their MCS daily or at least on

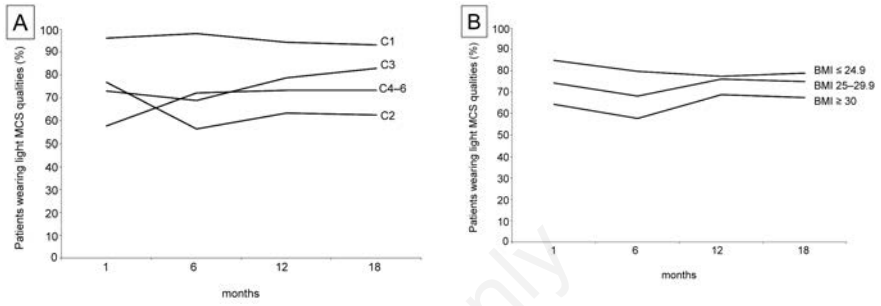

Figure 1. Light characteristics of medical compression stockings (MCS) dominated throughout the study, irrespective of the patients' CEAP (A) and BMI (B). This figure depicts the percentage of light compression stocking characteristics prescribed during the study. The first time point (1 month) includes the screening visit at the start of the study, visit 1 (after 7 days), and visit 2 (after 1 month). Visit 3, 4, and 5 took place after 6, 12, and 18 months. The term *characteristics* comprises textile MCS features affecting elasticity and other characteristics. Due to the low case numbers, classes C4a, C4b, C5 and C6 were pooled. Likewise, weight classes were pooled into BMI ≤ 24.9, BMI 25 - 29.9 and BMI ≥ 30.

Table 2. Safety and tolerability of mediven medical compression stockings.

	Number (%) of patients during visit V2 - V5			
	V2 (N=529)	V3 (N=523)	V4 (N=512)	V5 (N=528)
Incidents				
Medical devices safety plan*	0 (0)	0 (0)	0 (0)	0 (0)
Leg examination				
Cold foot	22 (4.2)	6 (1.1)	12 (2.3)	15 (2.8)
Pale foot	7 (1.3)	10 (1.9)	10 (2.0)	5 (0.9)
Constrictions (top band MCS)	37 (7.0)	28 (5.4)	18 (3.5)	17 (3.2)
Constrictions (popliteal cavity)	41 (7.8)	26 (5.0)	26 (5.1)	17 (3.2)
Constrictions (ankle)	10 (1.9)	14 (2.7)	10 (2.0)	7 (1.3)
Skin examination				
Dry skin on the leg	140 (26.5)	155 (29.6)	143 (27.9)	114 (21.6)
Probable allergic skin reaction	5 (0.9)	3 (0.6)	1 (0.2)	1 (0.2)
Transient skin irritation	13 (2.5)	9 (1.7)	14 (2.7)	7 (1.3)
Persistent skin damage	2 (0.4)	1 (0.2)	1 (0.2)	2 (0.4)
No relevant findings	285 (53.9)	294 (56.2)	299 (58.4)	358 (67.8)
Subjective tolerability				
Perceived to be comfortable	403 (76.2)	368 (70.4)	377 (73.6)	374 (70.8)
Improvement in symptoms	248 (46.9)	278 (53.2)	261 (51.0)	226 (42.8)
No symptoms (during MCS wear)	518 (97.9)	514 (98.3)	506 (98.8)	521 (98.6)
Sensation of constriction°	31 (5.9)	16 (3.1)	17 (3.3)	9 (1.7)
Increase in pre-existing pain	6 (1.1)	1 (0.2)	1 (0.2)	1 (0.2)
Subjective intolerance	2 (0.4)	7 (1.3)	2 (0.4)	1 (0.2)
Sensation of coldness in the leg	22 (4.2)	8 (1.5)	8 (1.6)	4 (0.8)
Peripheral sensory disturbances	4 (0.8)	1 (0.2)	1 (0.2)	0 (0.0)
Pruritus	37 (7.0)	32 (6.1)	21 (4.1)	19 (3.6)

MCS, medical compression stockings. *No incidents, as defined in the Medical Devices Safety Plan Ordinance, occurred; °sensation of constriction: instep, in the popliteal cavity, proximal.

50% of days per week (hereafter defined as *regular use*) if they had received a donning aid prescription. In elderly patients (≥ 61 years), the percentage of regular users was higher in the group with a donning aid at both visit 2 and visit 5 (68.4% and 55.7%, respectively) than in the group without a donning aid (34.9% and 34.4%, respectively). Likewise, in obese patients, the percentage of regular users was higher in the group with a donning aid at visit 2 and visit 5 (42.1% and 45.9%, respectively) than in the group without a donning aid (28.0% and 27.7%, respectively).

Subjective and objective venous symptoms

A total of 72% of patients described the MCS as comfortable. Almost all patients (98%) reported that wearing the MCS caused no symptoms, and, during the study, subjective venous symptoms improved in almost half of patients (Table 2).

In all CEAP categories, the proportion of patients reporting an improvement of symptoms during the previous 12 months increased by up to 46.1% whereas the proportion of patients reporting a deterioration decreased by up to 38.7% during the study.

In contrast to this subjective improvement, a clinically apparent improvement in CEAP class occurred in 17.7% of patients. In most patients (72.7%), the CEAP class remained stable, while deterioration was observed in 9.6% of patients. In C3 patients (n=228), treatment success can immediately be assessed by edema reduction. A total of 22.4% of these patients improved during the study (stable: 73.7%; worse 3.5%). C3 patients of both normal weight and overweight/obesity benefited more from medium and firm than from light MCS characteristics (Figure 2).

Discussion

In this observational study, we investigated the provision of MCS and donning aids to venous patients, the safety and tolerability of mediven MCS, the treatment compliance, as well as the subjective and objective symptoms of venous patients in Germany. Although MCS tolerability was very high, and venous symptoms of patients considerably improved during the study, we observed that disease- and patient-specific factors were often insufficiently addressed in MCS prescriptions, potentially affecting compliance and treatment success.

Representativeness of the study population was apparent in the patients' characteristics such as age and BMI, both known to be associated with the prevalence and severity of venous insufficiency. As expected, CEAP class increased with age and BMI, and BMI increased with age.[20,21] In view of the demographic development and the growing prevalence of overweight and obesity in both developed and developing countries,[22] our data underline the specific challenges to be considered in the treatment of venous disease in overweight and obese as well as elderly patients.

However, our study revealed that patients' characteristics such as CEAP class, BMI, and age are insufficiently considered when MCS are prescribed in daily practice. In contrast, a uniform standard care prevails. The numbers of MCS and donning aid prescriptions fell well short of what is needed and possible according to health insurance regulations in Germany. Beyond the scheduled six-monthly repeat prescription, more prescriptions would have been possible for medical, hygienic, and safety reasons.[3] The vast majority of prescribed MCS was of CCL2 and light characteristics, obviously ignoring the patients' CEAP and BMI.

A more frequent prescription of lower as well as higher CCL could have been expected, considering the distribution of patients across all CEAP classes in our study. Likewise, prescriptions of light MCS characteristics predominated throughout the study when compared to those of medium and firm MCS characteristics, even in patients of CEAP classes > C4a and BMI ≥ 30. However, more patients would presumably have required a higher working pressure produced by, for example, MCS of firmer characteristics and corresponding textile characteristics to reduce both venous volume and reflux, and, accordingly, to improve venous pump function.[23,24] The choice of the textile MCS properties can therefore be a decisive factor for treatment success.[25] Indeed, improvement in CEAP class was observed more frequently in C3 patients wearing medium or firm MCS characteristics than in C3 patients wearing light characteristics. Further studies are now required to establish clearer recommendations on the use of individual MCS characteristics and CCL.

Our study demonstrated a good tolerability of mediven MCS. Approximately half of patients reported an improvement of venous symptoms, up to two thirds of patients stated to perceive the MCS as comfortable, and almost no patient reported on symptoms having occurred during MCS wear. Considering the study duration of 18 months, this result is noteworthy as MCS are often described as comfortable by only less than one third of patients even at shorter study durations.[26] Adverse events such as constriction furrows were rare and tendentially decreased during the study. Nevertheless, regarding these side effects, we found an association between overweight or obesity and the prescription of light MCS characteristics. Constriction furrows as well as sensation of constriction

Table 3. Compliance to treatment with medical compression stockings (MCS) during the study visits 2 - 5.

	Number (%) of patients during visit V2 – V5			
	V2 (N=529)	V3 (N=523)	V4 (N=514)	V5 (N=527)
Frequency				
Daily	400 (75.6)	364 (69.6)	365 (71.0)	344 (65.3)
> 50% of all days in a week	91 (17.2)	94 (18.0)	82 (16.0)	110 (20.9)
< 50% of all days in a week	25 (4.7)	34 (6.5)	30 (5.8)	26 (4.9)
Occasionally	10 (1.9)	28 (5.4)	32 (6.2)	42 (8.0)
Missing values	3 (0.6)	3 (0.6)	5 (1.0)	5 (0.9)
Daily use				
Morning to evening	362 (68.4)	304 (58.1)	291 (56.6)	255 (48.4)
Half-days or 6 – 8 hours/day	139 (26.3)	154 (29.5)	171 (33.2)	197 (37.4)
Less than half a day	10 (1.9)	9 (1.7)	4 (0.8)	4 (0.8)
At and during particular orthostatic stress	6 (1.1)	16 (3.1)	24 (4.7)	21 (4.0)
Seasonal features	5 (0.9)	38 (7.3)	16 (3.1)	42 (8.0)
Missing values	7 (1.3)	2 (0.4)	8 (1.6)	8 (1.5)

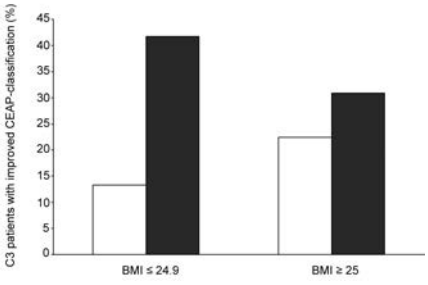

Figure 2. Percentage of C3 patients with improved CEAP class. Patients with BMI ≤ 24.9 and ≥ 25.0 had received either light MCS characteristics (white) or medium/firm characteristics (grey).

predominantly occurred with light characteristics, rarely with medium characteristics, and never with firm characteristics. The occurrence of these side effects therefore additionally emphasizes the importance of both identifying the optimal MCS characteristics for each individual patient and regularly checking the MCS fit.

A considerable number of patients reported on dry skin on the leg wearing MCS. This would have been a preventable symptom, because skin care products were only used by approximately one third of patients. This fact emphasizes the importance of patient education on several aspects of MCS therapy, including both potential side effects and the requirement of regular and long-lasting treatment.

Since chronic venous insufficiency requires a maintenance therapy with daily MCS administration, treatment compliance is essential. Our study confirmed previous publications demonstrating a positive association of the patient's compliance with the number of MCS prescriptions over time[27] and the prescription of donning aids.[28] Patients who had received a six-monthly MCS repeat prescription as recommended[3] as well as elderly and obese patients who had received a donning aid showed a better MCS-wearing frequency, which ultimately improves the prospects for long-term treatment success.[29,30] Nevertheless, the provision of donning aids did not occur to the extent we would have expected, since donning aids would have been indicated in approximately 25% of patients. However, in the study relevant relevant comorbidities i. e. spinal problems, osteoarthritis, and obesity did not constitute a relevant indication to prescribe donning aids.

Conclusions

In conclusion, venous patients are not adequately provided with MCS and donning aids, and prescriptions are generally too undifferentiated regarding CCL and MCS characteristics to meet the individual needs of patients. This unsatisfactory prescription behavior, which occurred not only at the beginning of the study but also at every visit during the 18-month study period, should be in the focus of future awareness campaigns on compression therapy. Another focus should be on the patient's compliance, especially because it can be easily improved by simple measures such as prescribing a second pair of MCS as well as donning aids. To foster the acceptance of MCS treatment, it is equally important to educate patients on their disease and corresponding treatment options as well as on potential side effects. In this context, patients should be informed on the importance of regular skin care.[26]

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