

ORIGINAL ARTICLE

Compression therapy with adjustable Velcro compression devices (AVCD): Results of retrospective analysis of 48 patients with chronic leg ulcers and oedema

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ABSTRACT

Background: In most patients with leg ulcers and oedema, compression therapy is an indispensable part of successful treatment. Since 2016, a medical adjustable compression system (AVCD) has been available in Germany for this purpose. Therefore, the aim of this study was to investigate the safety of this compression system in everyday clinical practice.

Methods: Retrospective analysis of data from two certified dermatology wound centres.

Results: A total of 48 patients with chronic leg ulcers (venous leg ulcers [n = 26], pyoderma gangrenosum [n = 5], mixed leg ulcers [n = 5], post-traumatic wound healing disorder [n = 5], livedoid vasculopathy [n = 2], necrobiosis lipoidica [n = 2], ecthyma [n = 2], vasculitis [n = 1]) and oedema of the lower extremities were analysed. In addition, there were the following comorbidities: diabetes mellitus (n = 11), peripheral arterial occlusive disease (n = 5) and polyneuropathy (n = 3). During the observation period of an average of 181 days, the mean wound size decreased by 72%, in 52% of patients the wounds healed completely. Overall, 71% of patients were able to realize self-management; four patients were unable to routinely wear the system due to pre-existing pain. Two patients experienced temporary tension blisters or pressure marks due to improper use.

Conclusion: These data show that the medical adjustable compression system is a safe, effective, and easy-to-use treatment option in the management of patients with chronic leg ulcers and oedema, even with comorbidities such as diabetes mellitus, polyneuropathy and peripheral arterial occlusive disease.

KEYWORDS

Compression therapy, oedema, leg ulcer, medical adjustable compression systems, comorbidities.

Background

In Germany approximately 1–2 million people suffer from chronic wounds. Based on the current definition by the Initiative Chronische Wunden (ICW, German Wound Healing Society), wounds are deemed chronic if they have not healed within eight weeks. Apart from this time-based definition, there are wounds deemed chronic from the outset since their management calls for treatment of the persistent aetiology. These include, for example, diabetic foot ulcer, wounds associated with peripheral arterial occlusive disease (PAOD), pressure ulcers or venous leg ulcers [1].

Wounds of different aetiologies in the lower leg region are known as leg ulcers (Table 1) [2]. After appropriate diagnosis, the underlying causes must be treated for effective management [3, 4]. The cornerstone of conservative treatment in the majority of patients with leg ulcers is modern moist wound therapy and for oedema it entails compression therapy [5]. In this regard, compression therapy focuses on two key aspects. The first aim is to improve haemodynamics which requires narrowing of the venous diameter through high contact pressure values of at least 40 mmHg [6]. For the second aspect, oedema reduction, lower contact pressure values of around 20 mmHg are generally enough [7, 8].

This thus demonstrates that compression therapy can be indicated not just for patients with chronic venous insufficiency (CVI) but for all patients with leg ulcers and oedema [9]. When properly used, compression therapy quickly results in peripheral decongestion and

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pain reduction. In the long term it results in a decrease in inflammation with prevention of tissue remodelling and promotion of wound healing [10]. However, any relevant contraindications must always be ruled out before starting compression therapy (Table 2) [9]. In the past the term “relative contraindications” was also used for underlying conditions such as diabetes mellitus, minor/moderate PAOD or polyneuropathy [11]. There is virtually no scientific evidence lending credence to that belief, hence in the corresponding centres patients with such “relative contraindications” are routinely and successfully treated by means of compression therapy [10].

There is a range of materials available for administering compression therapy to patients with leg ulcers and oedema. In addition to the commonly used compression dressings with short stretch bandages, multi-component systems and ulcer stockings can be used. Since 2016, a medical adjustable compression system (AVCD) has also been available in Germany for compression therapy for patients with leg ulcers [12, 13]. The aim of our retrospective analysis was to investigate the safety of this AVCD in everyday clinical practice, in particular also in patients with, in addition leg ulcers and oedema, comorbidities such as diabetes mellitus, polyneuropathy and PAOD.

Materials and Methods

Wound Care Centers

This study was conducted in the certified Dermatology Wound Care Center of University Hospital Essen and University Hospital Erlangen. Both hospitals have been awarded Wound Seal Certification as per the criteria of the German Initiative Chronische Wunden (ICW) as well as of the German Society of Dermatology (DDG). Certification ensures the application of equivalent quality standards in both centres for diagnosis and management of patients with chronic wounds.

Materials

An AVCD was prescribed for all patients with chronic leg ulcers and oedema before enrolment in this study. The only system available on the German market at that time was the circaid® juxtacures® (medi, Bayreuth). When first ap-

plied, this system must be tailored to the individual leg circumference (Fig. 1). The pressure can then be selectively set within a pressure range of between 20 and 50 mmHg, using the supplied BPS card (Built-In Pressure® System) and the markings on the AVCD. Guidance and instructions on proper use are also given.

Patients

The aim was to include in this analysis all patients with a chronic leg ulcers and oedema of the lower extremities who had been treated with an AVCD for at least one month.

Statistics

All patient data were electronically processed and transferred to Excel tables. The latter were then used for statistical evaluation of the patient data.

Results

Patients

In total, data were evaluated for 48 patients. Twelve patients from Erlangen and 36 patients from Essen were enrolled. These comprised 21 men and 27 women aged between 31 and 88 years. The mean age was 65 years. In 32 patients one leg was treated with circaid juxtacures and in 16 patients both legs.

Genesis of leg ulcer

All patients enrolled in this study suffered from chronic leg ulcers and oedema. But the wounds were of very heterogeneous genesis. In total, 26 patients had a venous leg ulcers and five patients each had pyoderma gangrenosum, mixed leg ulcers or post-traumatic

Table 2: Contraindications to compression therapy [9]

- Advanced PAOD (critical ischaemia)
- Phlegmasia cerulea dolens
- Decompensated heart failure
- Septic phlebitis

wound healing disorder. Two patients each had chronic wounds secondary to livedoid vasculopathy, necrobiosis lipoidica or ecthyma. In one patient vasculitis was the underlying cause [2].

Relevant comorbidities

There are a number of comorbidities previously classified as “relative contraindications” to compression therapy but based on the current evidence that is no longer fully tenable. Therefore, some of the potentially relevant comorbidities were also evaluated in these patients. Eleven patients had diabetes mellitus (2 × type 1, 9 × type 2), five patients had PAOD and three patients polyneuropathy.

Observation periods

Observation periods of up to 539 days were documented. Since four patients discontinued treatment, a mean observation period of 181 days was recorded for 44 patients.

Ulcer reduction

During the documented treatment periods, the leg ulcers completely healed in 23 patients (52%, n/N = 23/44). The mean reduction in ulcer size during the observation periods was 72% (n = 42, because it was not possible to determine the exact wound size in two patients).

Table 1: Diseases that can lead to chronic leg ulcers [2]

- Vascular diseases, e.g. chronic venous insufficiency, peripheral arterial occlusive disease, lymphoedema
- Vasculitis/vasculopathy, e.g. leukocytoclastic angiitis, Polyarteritis nodosa, Livedoid vasculopathy
- Dermatological diseases, e.g. pyoderma gangrenosum, necrobiosis lipoidica, Epidermolysis bullosa
- Infectious diseases, e.g. ecthyma, mycobacteriosis, malignant syphilis
- Neoplasms, e.g. basal cell carcinoma, squamous cell carcinoma, lymphoma
- Metabolic diseases, e.g. calciphylaxis, oxalosis, diabetes mellitus
- Medications, e.g. hydroxyurea, anagrelide, cumarin
- Exogenous factors, e.g. dermatitis artefacta, radiation, trauma
- Haematological diseases, e.g. sickle cell anaemia, dysproteinaemia, leukaemia
- Genetic defects, e.g. Klinefelter syndrome, Progeroid syndrome, factor V Leiden mutation

Self-management

In total 34 patients were able to independently don and doff the AVCD. As such, 71% of patients ($n/N = 34/48$) were able to realize self-management. These patients comprised 19 women and 15 men with a mean age of 61.9 years.

For the 14 patients unable to realize self-management, the task was undertaken in 12 patients by a nursing service and in two patients by a relative acting as carer. Of these patients, eight were women and six men; the mean age was 70.1 years.

Safety-related observations

In total, while four patients had a history of trying out the system, they did not continue to use it routinely. This was always due to intense pain. These four patients had experienced very severe pain already prior to treatment and had not previously been able to successfully use any compression therapy. It was therefore attempted in this study to initiate AVCD compression with low pressure values of 20 mmHg [14]. That attempt had proved very successful for many other patients with very painful wounds and similar indications and the patients were able to routinely use compression therapy.

No safety-related events occurred during the observation period in 95% of patients ($n/N = 42/44$). The following observations were documented in two of the 44 patients: one 69-year-old male patient with venous leg ulcers and with no relevant comorbidities, who had used compression therapy over a long period of time, suddenly experienced tension blisters despite wearing an understocking. It was revealed that despite induction, the patient had incorrectly used the AVCD without fitting the BPS card.

One 59-year-old male patient with venous leg ulcers initially experienced pressure marks because the system was incorrectly donned by the patient. The patient had type 2 diabetes but no polyneuropathy. After repeat induction the system was correctly used and the wound fully healed without any problem in the later course.

Discussion

Compression therapy is a pivotal pillar of successful conservative treatment of patients with leg ulcers and oedema.

Nonetheless, recent evaluation of the datasets of a large German health insurance fund revealed that only 40.6% of patients with florid venous leg ulcers undergoing medical treatment also received compression therapy [15]. As such, in Germany there are still glaring shortcomings in the provision of this essential compression therapy to these patients.

Today, there is a range of materials available for administering compression therapy to patients with leg ulcers and oedema. These systems should not slip out of place, cause pain, they should maintain the necessary treatment pressure throughout the treatment period and, in line with the principle of self-management and independence, be easy to don and doff [11]. The AVCD is a treatment option available in Germany since 2016. This entails segment-wise application of compression pressure to the lower leg via several Velcro fasteners. In this system the compression pressure can be selectively set, via these Velcro fasteners using the BPS card, within a range of between 20 and 50 mmHg and can also be checked and

readjusted over the course of the day. The foot is then treated separately with an ankle-high sock. Hence, appropriately trained patients can achieve effective self-management tailored to their individual needs [11, 13]. These compression systems are routinely used at the two dermatology wound clinics awarded wound seal certification at University Hospitals Essen and Erlangen. The aim of the present retrospective analysis was therefore to investigate the safety this AVCD in everyday clinical practice.

The results of our analysis demonstrated that 95% of patients with chronic leg ulcers and oedema were able to use the AVCD without experiencing any safety-related event. Thanks to its readjustment functions, the AVCD helps to introduce patients to compression therapy while also starting with low pressures and, on the other hand, it can be individually readjusted following pressure loss due to oedema reduction [6, 14]. Pressure values can be selectively set using the BPS card, thus enhancing safety for everyday treatment.

There continue to be widespread misperceptions about the contraindications to compression therapy. For example, in the case of PAOD, a distinction must absolutely be made between critical ischaemia and minor to moderate PAOD. According to the S2k Guideline recently issued by the German Society of Phlebology, critical ischaemia is deemed present if at least one of the following parameter measurements has been recorded (9):

- Ankle-brachial index (ABI) < 0.5
- Ankle arterial pressure < 60 mmHg
- Toe pressure < 30 mmHg
- Transcutaneous oxygen partial pressure measurement (TcPO₂) < 20 mmHg dorsum of foot

Compression therapy is contraindicated in patients with critical ischaemia. However, the DGP (Deutsche Gesellschaft für Phlebologie) Guideline points out that compression therapy can still be used for patients with an absolute ankle arterial pressure of between 50 and 60 mmHg if they are closely monitored clinically [9]. In such cases inelastic materials, such as juxtacures, with a resting pressure up to maximum 40 mmHg, should be used [16–18].

Compression therapy is also possible in principle for patients with polyneuropathy. However, patients with poly-



Fig. 1 Using a BPS® card, the compression pressure of the adjustable compression systems can be selectively set between 20 and 50 mmHg, often by the patients themselves and readjusted if necessary over the course of the day.



Fig. 2 Once the compression bandage has been applied, a compressive sock is worn over it.

Table 3: Patient data overview

Patients			Comorbidity				Procedure			Result
Sex	Age	Diagnosis	CVI	PAOD	Diabetes	Polyneuropathy	Pre-scription	Self-management	Duranc of treatment	
Man (n = 21)	mv: 65	Venous leg ulcers (VLU) (n = 26) Pyoderma gangrenosum (n = 5)	yes (n = 35)	yes (n = 5)	yes (n = 11)	yes (n = 3)	1 leg: 32	yes (n = 34)	mv: 181 (n = 44)	mv: 72 (n = 42)
Woman (n = 27)	Range: 31-88	Mixed leg ulcers (n = 5) Posttraumatic (n = 5) Necrobiosis lipoidica (n = 2) Livedoid vasculopathy (n = 2) Ecthyma (n = 2) Vasculitis (n = 1)	no (n = 13)	no (n = 43)	no (n = 37)	no (n = 45)	2 legs: 16	no (n = 14)	Range: 0-539	100 (n = 23) 90 (n = 3) 80 (n = 1) 60 (n = 2) 50 (n = 4) 20 (n = 2) 10 (n = 2) 0 (n = 5) n.s. (n = 2) not worn (n = 4)

mv = mean value; n. s. = not specified

neuropathy are unable to sense excessive or incorrectly applied compression and may thus be prone to pressure marks or tension furrows. These patients should therefore be monitored at close intervals [9].

Diabetes mellitus does not constitute a contraindication to compression therapy. But polyneuropathy and/or PAOD is commonly seen in diabetic patients as the disease progresses, hence the aforementioned precautions need to be taken [8, 9]. The results of our retrospective analysis confirm that AVCD is a safe treatment option also for patients with these comorbidities.

The AVCD confers numerous benefits on patients with leg ulcers and oedema in everyday clinical practice. Since the scope of AVCD functions provided by the materials used here can be set via Velcro fasteners, this system can be used for decongestion as well as for maintenance therapy. As such, when properly maintained this AVCD can be used for up to six months. The application method is easy to learn and not very error-prone. In our study 71% of patients were able to don and doff the system themselves without the help of another person. For patients who are not likely to manage the system on their own because of e.g. dementia, morbid obesity or osteoarthritis, it may be possible to provide training to a relative to that effect. Self-management not only helps to cut financial resources [19], promote adherence to treatment and improve quality of life and independence [20], it also allows for control and readjustment of the therapy systems in the

course of the day [13]. Thanks to effective compression therapy, a rapid decrease in leg circumference is seen especially in the early decongestion phase and, unlike other non-AVCD alternative systems, there is no need to reapply the system while incurring additional costs [21, 22].

Conclusions for everyday practice

- Compression therapy is a very important pillar of conservative treatment for patients with leg ulcers and oedema.
- Compression therapy can be administered with different materials; medical adaptive compression systems (AVCD) are a relatively new treatment option here.
- Contraindications to compression therapy include advanced PAOD (critical ischaemia), phlegmasia cerulea dolens, septic phlebitis and decompensated heart failure.
- Our data analysis demonstrates that AVCD is an easy-to-use treatment option for patients with leg ulcers and oedema
- Most patients with comorbidities, such as polyneuropathy, diabetes mellitus or moderate PAOD, can also be safely treated with AVCD under medical supervision.

Conflicts of interest

The information below relates to fees received for lectures and/or consultation services or as sponsorship of research projects.

J. Dissemmond: Bauerfeind, BSN, Coloplast, Convatec, Hartmann, Lohmann &

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