

## Scientific Summary – Latest news from science

# Safety in medical compression therapy in patients suffering from venous edema and peripheral arterial disease or diabetes mellitus

Rother U et al. Safety of medical compression stockings in patients with diabetes mellitus or peripheral arterial disease. *BMJ Open Diab Res Care* 2020;8:e001316.

#16

# Safety of medical compression stockings in patients with chronic venous disease and PAD / diabetes mellitus

## 1 Uncertainty of supply versus supply needs

The efficacy of medical compression stockings (MCS) in edema therapy is scientifically proven. Furthermore, there is the consensus that severe peripheral arterial disease is a contraindication and that severe polyneuropathy (PNP), e.g. in the context of diabetes mellitus, is a risk to be specially considered.<sup>1,2</sup>

**However, uncertainties persist regarding the supply of patients with chronic venous diseases (CVD) who are additionally suffering from a mild to moderate PAD or diabetes mellitus that is often accompanied by a diabetic peripheral polyneuropathy.**

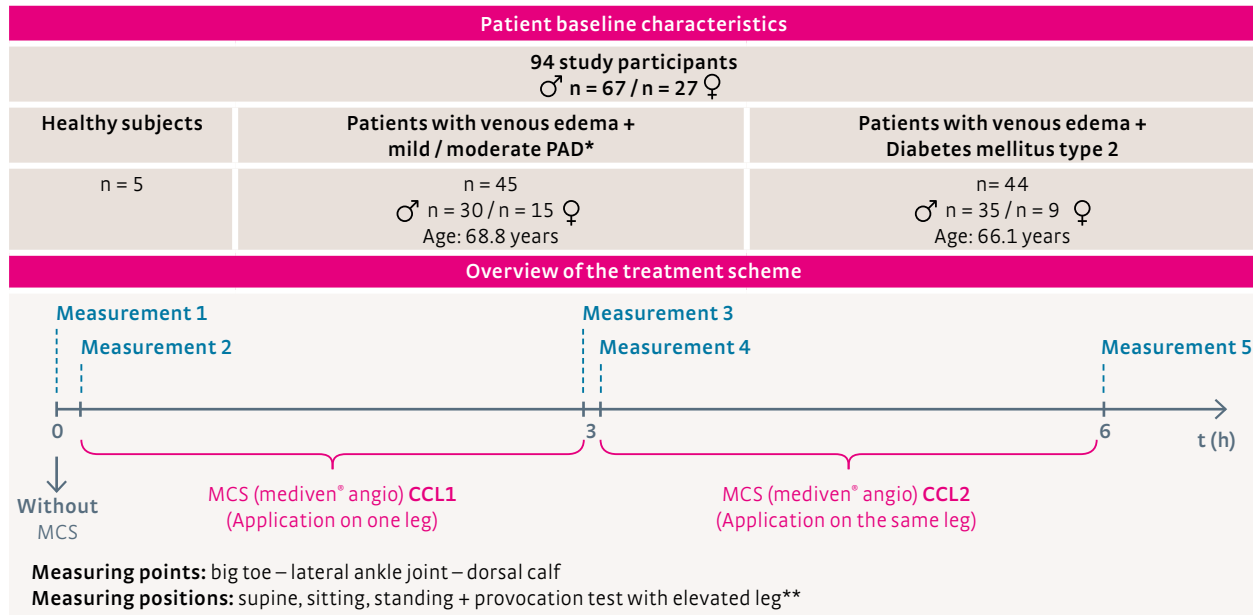
Not least because of the demographic development and the age-dependent prevalences of PAD, diabetes mellitus type 2 (respectively PNP) as well as CVD **a growing number of patients is to be expected who requires the highest degree of safety in the context of medical compression therapy.**

Tab. 1: Global prevalences of PAD, diabetes mellitus and CVD

Prevalence <sup>3-5</sup>		
PAD	Diabetes mellitus	CVD
> 200 million people in the world	422 million people in the world	About 70 %

## 2 Overview of the clinical trial<sup>6</sup>

In this context a clinical study was performed that addressed the question how wearing of a medical compression stocking influences the microcirculation in patients with venous edema and co-existing PAD or diabetes mellitus type 2 and how **the safety of medical compression therapy should be assessed in this patient population.**



\* PAD: Fontaine stadium II, Rutherford grade 1/ category 1-3; ankle brachial pressure index < 0.9 and > 0.6; systolic ankle pressure > 60 mmHg

\*\* provocation test in 65 cm elevated position of the leg

### 3 Results of the study<sup>6</sup>

#### Primary endpoint – safety in general

- **No adverse events** occurred **during the whole study**.
- No study participant showed a MCS related skin lesion, abrasion or pressure related skin damage; no study participant had to terminate the study prematurely.

#### Primary endpoint – safety regarding microcirculation\*

- In patients with venous edema and PAD as well as in patients with venous edema and diabetes mellitus, **the microcirculation / -perfusion** – measured by the parameters  $sO_2$  and flow – **is stable under both compressions classes CCL1 and CLL2** as well as **comparable to** the values of the **healthy subjects**.
- Depending on the measuring points and patient positions an improvement of perfusion can be observed for both compression classes.
  - Especially in the standing position an **improved perfusion** can be observed at the measuring point “lateral ankle”, obviously by promoting the venous backflow through the externally applied medical compression stocking.

#### Secondary endpoint – MCS wearing comfort

- The **wearing comfort** was rated by the patients as **very good to good** using the Likert-type scale (from 1 - 10)\*\*: CCL1 achieved a mean value of 1.84 (standard deviation 0.84), CCL2 achieved a mean value of 2.10 (standard deviation 0.92).

\* The microcirculation was determined by  $sO_2$  (oxygen saturation of hemoglobin) and flow (blood flow)

\*\* Likert-type scale from 1 - 10: 1 = optimal wearing comfort, 10 = massive impairment

**Additional recommendations for the everyday care from the German S2k guideline “Medical compression therapy“ and the international consensus paper „Risks and contraindications of medical compression treatment”<sup>1,2</sup>**

- **It is recommended that every patient receiving medical compression therapy should be screened for conditions that increase the risk of complications.** These conditions include, amongst other things, severe peripheral arterial disease and severe microangiopathy which are common in patients with diabetes. (consensus paper, recommendation 1, highest recommendation grade “recommended”)
- **In patients with polyneuropathy and sensory loss as a result of a diabetic neuropathy, specific precautions are suggested.** These measures include padding of bony prominent structures, special care of fit, low pressure and close monitoring and controls. (consensus paper, recommendation 10, high recommendation grade “suggested”)
- **In every patient with impaired perfusion of the lower limb (ankle brachial pressure index [ABPI] <0.9), the clinical effect of the medical compression stocking on leg blood supply should be carefully monitored.** (consensus paper, recommendation 14, highest recommendation grade “should”)
- **Severe PAD should be considered as contraindication** if one of these parameters applies: ABPI <0.5, systolic ankle pressure <60 mmHg, toe pressure <30 mmHg or TcPO<sub>2</sub> <20 mmHg on the dorsum of the foot. (consensus paper, recommendation 12&13 and German S2k guideline recommendation 31, highest recommendation grade “should”)
- **Severe sensitivity disorders of the extremities and severe peripheral neuropathy (e.g. in diabetes mellitus) should be considered as risks.** (German S2k guideline, recommendation 32, highest recommendation grade “should”)

## Author's conclusion:<sup>6</sup>

In patients with venous edema and co-existing mild to moderate PAD or diabetes mellitus

- **the use of the medical compression stocking mediven® angio is safe and feasible with compression class I as well as compression class II.** Both compression classes are well tolerated.
- **the microcirculation is stable under both compression classes as well as in all physiological body positions and is comparable to the values of healthy subjects.**
- **a close monitoring** is indicated in order to provide the patients the **best possible benefit of compression therapy.**

<sup>1</sup> Rabe E et al. German S2k guideline: Medical compression therapy. Status 12/2018. Online available at: <https://www.awmf.org/leitlinien/detail/II/037-005.html> (Last access 2020, Jul 13th)

<sup>2</sup> Rabe E et al. Risks and contraindications of medical compression treatment – A critical reappraisal. An international consensus statement. *Phlebology* 2020 Mar 2;268355520909066. doi: 10.1177/0268355520909066. [Epub ahead of print]

<sup>3</sup> Shu J, Santulli G et al. Update on peripheral artery disease: Epidemiology and evidence-based facts. *Atherosclerosis* 2018;275: 379–381.

<sup>4</sup> Key facts Diabetes – WHO. Online available at: <https://www.who.int/news-room/fact-sheets/detail/diabetes> (Last access 2020, Jul 27th).

<sup>5</sup> Vuylsteke ME et al. An Epidemiological Survey of Venous Disease Among General Practitioner Attendees in Different Geographical Regions on the Globe: The Final Results of the Vein Consult Program. *Angiology* 2018;69(9):779-785.

<sup>6</sup> Rother U et al. Safety of medical compression stockings in patients with diabetes mellitus or peripheral arterial disease. *BMJ Open Diab Res Care* 2020;8:e001316.