Tubulcus®-Kompressionstherapie des venösen Ulcus cruris
Ergebnisse einer prospektiven Anwendungsbeobachtung

W. Vanscheidt¹, R. Kohnen², I. Achhammer³
¹Freiburg, ²Imerem GmbH, Nürnberg, ³Innothera GmbH, Sulzburg

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Zusammenfassung

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V enous leg ulcers affect at least 0.2% of the population in the developed world which is considered as a significant socio-economic disorder (1, 13, 15, 18, 19). The aim of the treatment of venous ulcers is to ensure healing of the wound and prevention of recurrence. Independently of the local wound treatment, either alone or combined with surgery, compressive therapy is the recognized as gold standard in the treatment of venous ulcers, usually performed with bandages (2, 3, 8). The correct application of those bandages must be learned and continuously trained (12). Its quality depends of the skill of the fitter and is - when patients do it themselves - negatively influenced by individual physical conditions like obesity, arthritis, and general immobility. In general practice bandages are often poorly positioned, they may be too loose and slip or too tight causing constriction. Therefore, patients not only experience their disease as negative but also the treatment. This causes poor compliance with compressive therapy and consequently delayed healing (11).

To overcome those problems, different tubular compression devices and stockings were developed. One of these is Tubulcus®, a ready-made tubular compression device (Fig. 1), with no heel and open-toed exerting a well-defined constant pressure over time (4-6). It can be applied without the need for a qualified fitter, and putting on is facilitated by a special positioner.

Post-Marketing Observational Studies (PMOS) allow the observation of a disease process and its treatment under naturalistic conditions. The aim of this study was the doc-
umentation of efficacy and tolerability of the Tubulcus® therapy of the venous leg ulcer as well as the patients’ subjective well-being during a 3-month period in daily practice.

Patients, material, methods

Design

This study was performed as prospective, open-label, naturalistic post-marketing observance study (PMOS). A total of 40 physicians in Germany (general practitioners and specialists in dermatology and/or phlebology) participated in the study and documented data for 116 patients. The observation period was supposed to cover 3 months and started with the first application of Tubulcus®. Any other compression treatment was discontinued at the beginning of the study.

According to the principles of PMOS no selection criteria for including patients were established. However, the physicians documented treatments of patients with venous leg ulcer and the need of a compressive therapy with Tubulcus®. The treating physician made sure that the indication and contraindications (arterial occlusive disease stage II-IV or arterial blood pressure index <0.9, decompensated heart failure) for the treatment with Tubulcus® were respected and the correct size for each individual patient determined.

The data collection was conducted between September 2000 and October 2001. At inclusion, patient characteristics, diagnosis of the venous insufficiency, prior compressive therapy, leg circumferences, concomitant treatment of the ulcer other than compressive therapy, appearance of the ulcer (determination of size) and the surrounding skin and concomitant diseases were documented. After about 12 weeks of treatment (or earlier in case of complete healing) documentation of ulcer size, leg circumferences, appearance of the ulcer and the surrounding skin, global assessment of efficacy and tolerability by physicians and patients, complete duration of wearing Tubulcus® and frequency of changes was performed. Additionally a questionnaire was used to measure patients convenience with Tubulcus® treatment.

Statistics

Statistical analysis was performed descriptively, presenting frequency distributions and descriptive statistics for quantitative data (mean, standard deviation, median, minimal and maximal values). If applicable, changes in ordinal or metric data between baseline and final assessments were compared by paired tests (signed rank U-test), in case of qualitative data, by chi²-symmetry test (McNemar test for 2 × 2, Bowker test for n × n tables) were used. Values p <0.05 for these comparisons indicate that there was a non-random change between both assessments in the variable affected; such findings are explorative in nature and limited to the description of the data of this PMOS.

Results

Patients

Altogether 116 patients with venous leg ulcer were observed. About one third were men (35.5%) and two thirds were women (63.8%); mean age was 65.6 years (range 36-90 years). Post thrombotic venous ulcer was diagnosed in 38% of the patients. The most frequent concomitant diseases other than CVI were diabetes mellitus (11.2%), hypertension (9.5%), coronary heart disease (6.0%) and obesity (6.9%).

The majority of patients (82%) had previous treatment with compressive therapy and almost all had additional local treatment (93.1%) of the ulcer. The ulcer treated was located at the left leg in 52.4% and at the right leg in 44.0%. It was situated lateral malleolar in 22.4% and medial malleolar in 67.2% of the patients’ legs.

Treatment

The mean duration of the treatment with Tubulcus® was 67.7 ± 28 days (median: 76 days, maximum: 120 days).

The determination of the adequate size of Tubulcus® corresponding to the respective circumferences was no major practical problem. As expected, smaller sizes were more frequently used for women (S: 17.6%, M: 29.2%, L: 28.4%, XL: 12.2%, XXL: 0%) and larger ones for men (S: 2.4%, M: 24.4%, L: 41.5%, XL: 19.5%, XXL: 7.3%). Application of the Tubulcus® or slipping of a wound dressing during application was no problem for the physicians but for a few patients it was difficult to put it on by themselves.

Tubulcus® was worn at day and night by half of the patients (47.4%). In 31% of the patients it was changed daily, in half of the patients every second day or twice a week and in a few once a week (6%). Reasons for changes were mainly routine treatment (78.5%) or necessary due to heavy exsudation (17.2%).

Treatment with Tubulcus® was continued after the end of the observational period in 73 patients (62.9%), including 21 patients with their ulcer completely healed.
For the 19 patients (out of 29) who had their treatment stopped at the end of the study, the reasons were commented as follows:

- complete healing (8 patients),
- adverse event (3 patients),
- worsening of the ulcer (2 patients), and
- application difficulties with the Tubulcus® (5 patients).

**Efficacy**

**Ulcer size**

The largest diameter of the ulcer was measured at baseline and at final visit and was documented according to the classification into five classes of maximal diameter (≤2.5, >2.5-5, >5-7.5, >7.5-10, >10 cm). The comparison of ulcer sizes at baseline and at final assessment revealed

- complete healing in 25.9%,
- improvement by at least one category of ulcer size in 42.9%,
- stable condition in 29.5%, and
- worsening in 1.8% (2 patients).

In total, 77 patients (68.8%) experienced complete healing or reduction of size of their ulcer (p<.0001, Bowker test). Ulcer sizes of <5 cm found in the majority of patients at start of therapy (70.6%) had a better chance to heal or improve with Tubulcus® therapy than larger sized ulcers (Tab. 1).

**Oedema**

The circumference of the ankle decreased by 0.72 ± 1.7 cm (ranging from -7.5 to +11.5 cm) between baseline (24.8 ± 3.6 cm) and final assessment (24.1 ± 3.5 cm). Also the circumference of the calf was by 1.1 ± 2.0 cm (range -13.5 to +5.9 cm) smaller at the final assessment (36.2 ± 4.8 cm) than at the time of starting Tubulcus® treatment (37.2 ± 4.6 cm). Though the changes seem small in size, the p-values, which are associated with the pre-post comparison (p <.0001, Wilcoxon rank sum U-test, for both variables), indicate that these changes are not at random.

**Clinical appearance of the ulcer and the surrounding skin**

To characterise in more detail the appearance of the ulcer, it was documented whether it was granulated, fibrous, without reaction, exsudative or superinfected. The parameters of the ulcer’s appearance changed in a favourable manner: granulation increased, all other signs decreased. All these changes were associated with values p <.0001 in pre-post chi² McNemar symmetry tests.

For 17.2% of the patients a normal surrounding skin was documented at baseline. The global rate of erythemas did not change during the observational period which, however, is due to equal rates of appearance and disappearance. In contrast, the presence of oedema, eczema and inflammation decreased to very low rates at the final assessment (p <.0001, McNemar test) (Tab. 2).

**Global rating of efficacy**

The efficacy of Tubulcus® treatment was judged slightly more favourable by the treating physician than by the patients: 77.6% of the physicians and 70.7% of the patients estimated the efficacy globally as “very good” or “good”. The categories “bad” or “very bad” occurred in 7 patients (both by physician and patients).

**Tolerability, adverse events**

Three fourth of physicians and patients rated the tolerability of the compressive...
therapy as “very good” or “good”. Eight patients (6.9%) stated treatment as “bad” or “very bad” compared to 5 physicians (4.3%).

Only 3 adverse events were reported in 3 patients: One woman (age: 83 years) was hospitalised for inguinal hernia after two weeks of treatment. In a 74 year-old man treatment was stopped after 30 days for dysaesthesia associated with itching, prickling and feeling of pressure, and in the third patient (age: 59 years) the treatment with Tubulcus® was not continued after complete healing after 35 days and thereafter was reported as an adverse event, consisting in itching of the leg (an allergy could not be excluded). A relationship to Tubulcus® treatment was suspected in the latter two patients. In one further men (82 years) treatment was stopped after 35 days because his ulcer worsened.

### Subjective experiences

At the final visit, patients were asked to complete a questionnaire and to report their subjective perspective on wearing the Tubulcus®. The patients were asked about their experience concerning flexibility of the ankle region, slipping of Tubulcus®, problems with daily hygiene, appearance of Tubulcus® on the leg and comfort in general of wearing it. The results are given for all patients in the Table 3.

The patient ratings indicate a proportion of at least two thirds who reported positive and very positive experiences after long-term treatment with the Tubulcus®. 16 patients evaluated the flexibility in the ankle joint as “bad” or “very bad”. It cannot be differentiated whether these problems were due to particular conditions of the ankle joint already present before or associated with the compressive treatment as no data at baseline are available. Only in one woman slipping of the Tubulcus® was a severe problem. Men differed from women with respect to daily hygiene: Women had more often (mainly moderate) problems than men. Also when asked for the appearance of the Tubulcus® on the leg, several women did not use the two most favorable categories but described that item more frequent than men as “acceptable”. Finally, with regard to wearing of the Tubulcus® only five patients described this quality aspect as less convenient.

### Discussion

This post-marketing observeance study (PMOS) was conducted to document the treatment of venous leg ulcers with Tubulcus® compressive therapy in a naturalistic setting in contrast to the optimised conditions of a clinical trial. Our findings indicate that Tubulcus® was efficacious, well tolerated and positively accepted by patients with venous leg ulcers.

Efficacy of compressive therapy was demonstrated in actively controlled studies. However, with the knowledge that poor patients’ compliance is one of the main problems of treating ulcers with compressive therapy in daily practice, a large-scale observeance study like the one reported here gives interesting additional information about effectiveness and tolerance of compressive therapies (16).

The efficacy of Tubulcus® was investigated before in a randomised controlled study in comparison with a short-stretch bandage, showing a complete healing rate of about 60% in both groups after a mean time scale of treatment of 42 days in a highly selected population of ulcer patients (inclusion criteria: largest diameter of the ulcer <5 cm, duration of ulcer less than 3 months, treatment only by physicians or medical staff) (7).

Within the given observation period of three months and considering so-called real life conditions in this PMOS with the treatment of any patient who required compressive therapy, its efficacy results are favourable for the Tubulcus® therapy. Though the rate of complete healings was lower, in total more than two thirds of all patients took a benefit from the compressive therapy with the Tubulcus®. The clinical condition of the ulcer of other patients was ameliorated though without decrease of the ulcer size. Only in two patients, the ulcer worsened.

Strong support is given to the favourable responder rate by a significant reduction of oedema which is a prerequisite for healing of ulcer (14, 17, 20) but also with the global ratings of efficacy by physicians and patients, which were good or very good for the great majority of treatments performed. These results are promising when taking into account that further healing can be expected at least for those patients who improved already during the observation period (10). As much as about two thirds of patients who continued Tubulcus® treatment after this period might represent candidates for complete healing after a sufficiently long treatment. This was already shown in another mono-centre observational study with Tubulcus® over six months in 53 patients with long-lasting (average: 1 year) ulcers (9). Complete healing succeeded in 69.8% of the patients, of whom 35% achieved complete healing only after three months. A longer observation period should therefore be considered in further studies.

No differences were detected in subgroup analyses (data not reported) with stratifications of the patient population according to gender or primary origin of the ulcer (post-thrombotic venous insuffi-
ciency versus varicosis, CVI and others). Therefore, the Tubulcus® treatment proved as qualified for all ulcer patients.

It was up to the physicians, depending on the clinical status of the ulcer and the need for local treatment of the wounds to decide on the frequency of changes of Tubulcus® and whether or not the Tubulcus® should also be worn at night. The findings show a broad range between daily changes, changes every second day or twice a week until ending in weekly changes. Generally, the frequency of changes decreased during the course of treatment. This indicates that Tubulcus® may very well be placed for several days and especially also over night.

The comfort for the patient is a very important factor to increase compliance. The questionnaire used in and developed for this study aimed at learning more about eventual problems of patients. We found that the patients’ experiences in this study in wearing Tubulcus® (daily hygiene, slipping, appearance, general convenience), was judged to be good or very good by most of them.

Conclusion

The application of the correct and digressive pressure, which is required to treat ulcers effectively, is hardly achieved with bandages. Their application must be trained thoroughly and probably is never achieved when the patient or a member of his family applies the bandages in daily practice. The ready-made medical compression device Tubulcus® exerts the appropriate pressure independently of the fitter. Applying Tubulcus® by the patients or family members is performed without major problems and well accepted. Treatment with Tubulcus® is efficacious and safe. The time required for treatment may exceed three months in every second patient. With a well-designed effective compression device like Tubulcus® and a better comfort, compliance problems might be reduced and healing rates increased in daily practice.

References


Correspondence to:
Prof. Dr. med. Wolfgang Vanscheidt
Paula-Modersohn-Platz 3
79100 Freiburg