

Editorial Focus

A long-awaited small step forward in the management of the post-thrombotic syndrome

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Post-thrombotic syndrome (PTS) is a simultaneously easy and difficult clinical entity for practicing physicians. The easy part is the clinical presentation and diagnosis. When a patient presents with unilateral complaints of pain and swelling of the leg, has a history of deep vein thrombosis (DVT) of that same leg, and the presence of a new or recurrent thrombosis is excluded, a diagnosis of post-thrombotic venous insufficiency can be made on the spot, with or without confirmation of venous valve insufficiency by Doppler ultrasound (1). In severe cases venous ulceration of skin and underlying tissue may develop. Other symptoms may include itching or tingling of the leg, and typically the symptoms are worse by standing for a long time or at the end of the day and they resolve with recumbency.

Then the difficult part begins. Management of venous insufficiency is a challenge, as there is a paucity of effective strategies and most of the interventions are cumbersome and not very well tolerated by patients. The standard treatment of PTS encompasses the use of custom-fit elastic graduated compression stockings, which were shown to be effective in reducing the signs and symptoms of post-thrombotic venous insufficiency in several studies (2–4). Also, prescription of elastic stockings shortly after the diagnosis of DVT seems to prevent the subsequent development of PTS. In the landmark randomized controlled trial by Brandjes et al. (3) application of elastic compression stockings in patients with acute DVT reduced the incidence of mild to moderate PTS by about 50%, whereas the occurrence of severe post-thrombotic complaints was reduced from 28% in the control group to 15% in the stockings group. Systematic reviews on measures against venous insufficiency advocate the use of elastic compression stockings to prevent the development of PTS (5).

However, there are several limitations associated with the use of elastic compression stockings for the treatment and prevention of post-thrombotic venous insufficiency. First, the therapy may be effective in the majority of patients but many patients keep complaints or have little, if any, relief of their symptoms from this treatment. Secondly, there are many practical questions surrounding this management strategy that cannot be answered on the basis of the available evidence from clinical studies, in-

cluding the duration of treatment, whether proximal stockings (which are much less comfortable for the patient) are more effective than below-the-knee stockings, and the ideal pressure that should be exerted by the compression stocking. Lastly, and importantly, compression stockings are badly tolerated by many patients, because they are often not comfortable, very difficult to put on (especially in elderly patients, who often need help from family or care-givers), and not very aesthetic. Hence, better management strategies with more efficacy and better tolerance by patients are required.

In this issue of *Thrombosis and Haemostasis*, O'Donnell et al. present a clinical study with a new venous return assist device for the treatment of severe PTS (6). The device (Venowave) consists of a small peristaltic pump that is attached around the calf and may be worn when ambulant. This device was shown to markedly increase venous blood flow at the femoral vein level in a previous study (7). O'Donnell et al. have studied this device in a randomized double blind cross-over study in patients with severe PTS. Strong features of this trial are the cross-over design, which allowed comparing the new technique with the control treatment in the same patient, and the use of a dummy treatment with a similar, but non-functioning device, to be able to perform a double-blind analysis. Since assessment of efficacy could only be done using subjective measures and scoring systems, this study design is essential to prevent bias by patients and investigators. Interestingly, four times more patients reported to have benefit by the Venowave pump and many of these patients were willing to continue with the use of this device after termination of the study. The use of the Venowave device resulted in a significant improvement of scoring systems for PTS in comparison to the control treatment. Importantly, apart from heat sensation, skin irritation, and increased sweating, the device appeared to be reasonably well tolerated and there were no clear treatment-related adverse effects. In conclusion, the new device tested in the present study seems to be a promising new option that may in the future be added to our arsenal to improve the management of PTS.

Besides its strengths, the present study also has a few limitations. The number of participating patients was relatively small, and more experience in larger and potentially less selected

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patient groups may be required before large-scale introduction of this device could be advocated. Also, it would be interesting to follow patients who are treated with the Venowave device for a longer period of time to establish a long-term benefit, both in terms of symptom relief as well as prevention of clinically relevant complications of venous insufficiency, such as the occurrence of venous ulcers.

The application of mechanic compression devices to treat PTS is not entirely new (8), but the earlier devices were large and therefore not very practical and could not be used in a continuous ambulant state. The present intervention does not carry these dis-

advantages, although there was some inconvenience to some of the patients. Nevertheless, although also this strategy is not expected to completely solve the burden of post-thrombotic venous insufficiency in all patients, it may add a valuable new tool and may relieve symptoms in a subset of patients with severe PTS that cannot be treated with conventional means. As PTS is estimated to occur in 20–30% of patients with a DVT (9) and is associated with considerable morbidity, reduced quality of life, and considerable health care expenditure and other costs to society (10, 11), every little step forward to improve its management may be considered as a major leap.

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