



A Novel Device for the Management of Venous Ulcers with Chronic Venous Insufficiency

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Introduction

Venous stasis ulcers or venous leg ulcers (VLU) are chronic wound that takes long time to heal and presents a clinical challenge for healthcare professionals. VLU is mostly derived from dysfunction of macro and micro circulation.^{1,2}

Cleveland Clinic define the cause of VLU derives from "a failure of the valves in the veins of the leg that causes congestion and slowing of blood circulation in the veins".³ Its symptom include swelling, pain, itching and is prone to recurrence^{4,5} rate as high as 70%.^{6,7,8}

Guidelines and consensus varies throughout the world⁹ in assessment, referral, investigation and treatment modalities¹⁰⁻¹⁶. Ankle brachial pressure index (ABPI) is widely recognize as assessment tool but there is no consensus as to when to commence compression. Compression is recommended in all VLU cases along with wound bed preparation during various stages of wound healing¹⁷. A meta-analysis in VLU compression used find that compression increases ulcer healing rates compared with no compression, and multi-layer systems were more effective than single-component systems¹⁸. However, patient's compliance remain the major determining factor in effective treatment. Advance surgical endovascular procedures are done by surgeons in many cases but the waiting time in hospital is long and often unattainable and costly in private.

Of late, Intermittent Compression Device (ICD) were also used in the treatment of chronic ulcerations of the lower limb¹⁹ but it still has issue with compliance and it is not without complications^{20,21}. A new device Flowaid FA-100 Sequential Contraction Compression device (SCCD) has a similar function as the ICD's but a different mode of action. SCCD works by sending a specific sequential pattern, timed electric pulse into the muscles of the leg. It cause a peristaltic series of contractions of the leg muscles, compress the veins in the leg to increase in venous outflow. When the pulse release muscle relaxes result in arterial inflow.

Methodology

A study was conducted in Hospital Kuala Lumpur. 5 Patients with VLU on the same leg and/or bilateral VLU were selected. Inclusion criteria includes patients with VLU for at least 30 days with ABPI score of 0.9 – 1.2 and CEAP score 3 - 6 . Five VLU patients were recruited to receive SCCD treatment on one or both legs (i.e., if unilateral or bilateral VLUs) for 1 ½ hour ± 15 minutes

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twice per day on top of standard wound care per local protocol. Weekly wound visit were planned, where wound size were measured, picture taken, and ABPI monitored. Subjects were followed up for 4 weeks.

Result

• A pilot study was conducted on 5 different patients with chronic venous insufficiency with venous leg ulcer in various sites of the lower limbs. Patients were assessed, cleanse, debrided and standard dressing protocols were used. Flowaid was used as adjunctive therapy on affected limbs and it helped because the main pathology is pooling of blood that caused a reduction in venous return.

• Flowaid is a Sequential Contraction Compression device that helps to send blood back to the heart thus reducing pooling of blood, reduce edema and leg circumference 22, raises foot temperature 23 and improves popliteal blood flow 24 thereby helps in healing of wounds. Wound size improved in all five patients and the wound bed preparation showed clear improvement. This is a preliminary study preceding a bigger study of 30 patients to be conducted after this study.

Conclusion

There are some Flowaid FA-100 studies done with evidence showing multiple subjects experience reduce edema and leg circumference²², raises foot temperature²³ and improves popliteal blood flow²⁴. Other studies also suggest Flowaid works well to reintroduce blood flow in venous insufficiencies and relieve symptoms of diabetic peripheral neuropathy²⁵, lower pain and increase walk distance due to peripheral arteries disease²⁶.

The current case series reflected benefit over patient with chronic insufficiencies that developed ulcers. It is important for patient with venous insufficiency or venous ulcer actually gets standard of care. Compression have always been a standard of care for all these cases and with adjunctive therapy like Flowaid Sequential Contraction Compression device it can help in time to healing, better healing and proper wound management. The main factor here is to ensure wound is healed with minimum or no complication and to reduce healing time.

Flowaid Sequential Contraction Compression device may help patient who are unable to secure surgical intervention, and those who could not comply to compression successfully.

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