Reducing variation in care: Implementation of a leg ulcer pathway including treatment with UrgoStart Plus and UrgoKTwo compression system

KEY WORDS
- Compression
- Evidence-based practice
- UrgoKTwo compression bandage system
- UrgoStart Plus treatment range
- Venous leg ulcer

A simplified evidenced-based treatment pathway was introduced within North Locality Central London Community Healthcare (CLCH) NHS Trust to improve patient outcomes and experience and reduce unwarranted variation (National Wound Care Strategy Programme, 2019). The pathway is based on evidence that supports the use of the UrgoStart Plus treatment range, as recommended by NICE (2019), and compression therapy using the UrgoKTwo range. This local pathway is an example used in the NICE medical technology guidance (MTG42) adoption support resources for UrgoStart for treating diabetic foot ulcers and leg ulcers. Results of following the pathway for 13 patients are described; 12 patients experienced healing within 12 weeks of commencement of the pathway.

SUE MURRAY
Clinical Lead for Tissue Viability, North Division Central London Community Healthcare NHS Trust

LORRAINE NORRIE
Tissue Viability Nurse, North Division Central London Community Healthcare NHS Trust

Individuals with venous leg ulceration experience considerable physical, social, and psychological morbidity (Platsidaki et al, 2017). Non-healing or inadequately managed venous leg ulcers (VLUs) can have serious consequences for patients' quality of life and can potentially severely limit an individual's capacity to undertake work, social activities and complete personal hygiene.

Many leg ulcers persist for a variety of reasons over months or years, and a majority fail to heal properly (Schmutz et al, 2008). They also substantially increase staff time and costs for NHS services. The annual cost of VLU management by the NHS has been estimated at £1.94 billion (Guest et al, 2017). Non-healing VLUs are 4.5 times more costly to treat than healed VLUs (Guest et al, 2017).

Timely evidence-based practice is therefore critical to reducing the impact of VLU morbidity, achieving optimal outcomes for patients, and making the best use of NHS resources and staff time.

STANDARDISING BEST PRACTICE

Evidence points to marked unwarranted variation in UK wound care services, underuse of evidence-based practices and overuse of ineffective practices (Guest et al, 2015; Gray et al, 2018). Compression therapy is recommended for the management of VLUs (Widener, 2015; NICE, 2017), but compression is not universally used in practice. Additionally, VLUs are predominantly managed by nurses in the community, mostly by non-specialist generalists, with minimal involvement of specialist clinicians (Guest et al, 2017).

A retrospective cohort analysis of the records of 505 patients in The Health Improvement Network (THIN) Database in the UK found that only a fifth of patients (22%) had an ankle–brachial pressure index recorded in their records and 13% of patients were not prescribed any recognised compression therapy – despite this being best practice. In this cohort, only 53% of VLUs healed within a year, with a mean time to healing of 3 months (Guest et al, 2017).

The improvement of patient outcomes requires a strategic approach to clinician education to standardise evidence-based practice. As such, in England, the National Wound Care Strategy Programme (NWCSP; 2019) is working to address the issues leading to suboptimal care with the ultimate aim of reducing variation by standardising evidence-based care.

DEVELOPMENT OF A VLU TREATMENT PATHWAY

In support of the NWCSP agenda, the tissue viability nurse (TVN) team at Central London Community Healthcare (CLCH) NHS Trust North Division developed an evidence-based clinical pathway for the assessment and treatment of VLUs (CLCH, 2018; *Figure 1*).

The pathway prioritises the implementation of evidence-based practices and as such, is an example used in the NICE medical technology guidance (MTG42) adoption support resource for UrgoStart for treating diabetic foot ulcers (DFUs) and leg ulcers. The benefits of using UrgoStart, as reported by the NHS staff involved in producing the NICE resource, included improved patient outcomes in terms of wound healing and quality of life; ease of use and long-term cost savings (NICE, 2019).

Evidence to support UrgoStart Plus

UrgoStart Plus treatment range contains Technology Lipido-Colloid–Nano-Oligo Saccharide Factor (TLC-NOSF), which inhibits matrix metalloproteinases (MMPs) (White et al, 2015; Lazaro et al, 2016) and promotes angiogenesis through migration and proliferation of endothelial cells (White et al, 2015, Edmonds et al, 2018). The actions of TLC-NOSF restore balance within the wound bed, supporting development of robust granulation tissue.

TLC-NOSF appears to have robust evidence, both qualitative and quantitative, as a local treatment in the standard of care on various wound aetiologies. For neuroischaemic DFUs, the EXPLORER, a double-blind, randomised controlled trial (RCT) demonstrated the TLC-NOSF dressing significantly increases complete wound closure rate compared to the control dressing (UrgoTul) and reduced healing time (Edmonds et al, 2018). Post-hoc analysis indicates that if TLC-NOSF treatment is initiated earlier, better outcomes may be achievable (Làzaro-Martinez et al, 2019).

The Challenge Study, a double-blind RCT, compared the treatment of non-infected VLUs and mixed aetiology leg ulcers with TLC-NOSF versus the control dressing (UrgoTul). The primary study outcome found that relative wound area reduction was 58.3% in the TLC-NOSF treatment group compared with 31.6% in the control group (95% CI; p=0.002) (Meaume et al, 2012). TLC-NOSF treatment also promoted faster healing of VLUs and mixed leg ulcers compared with the control, and significantly reduced patients' pain and discomfort and anxiety and depression) (Meaume et al, 2017).

Evidence to support Compression therapy

Compression bandaging is the most effective treatment for venous leg ulceration (O'Meara et al, 2012) by reversing venous hypertension and increasing venous return for the purpose of promoting wound healing (Widener, 2015). Timely and appropriate selection of compression bandages and dressings informed by evidence-based guidance, such as the SIGN guidelines (2010), is critical to optimising patient outcomes.

A variety of bandages are available, including elastic, inelastic, and combined systems, offering alternatives for the clinician to seek the most suitable solution for the individual patient. Multi-component systems are more effective than single-component systems, and those that contain an elastic bandage appear to be more effective than those composed mainly of inelastic constituents (O'Meara et al, 2012). Two-component bandages may also offer benefits over four-component systems in terms of patient comfort and health-related quality of life (Lazareth et al, 2012).

UrgoKTwo is a two-layer compression bandage system combining a short-stretch bandage (KTech) with a long-stretch bandage (KPress) that provides continuous compression for the patient, whether they are active or at rest. The pressure indicators are designed to help clinicians achieve greater consistency in application (Young et al, 2013) and can be used when training nurses. This aids accurate, safe compression and allows consistency of care.

LOCAL IMPLEMENTATION OF THE TREATMENT PATHWAY

In the North Locality CLCH NHS Trust, leg ulcer clinics are led by specialist nurses and managed with by the TVN team. The team consists of five

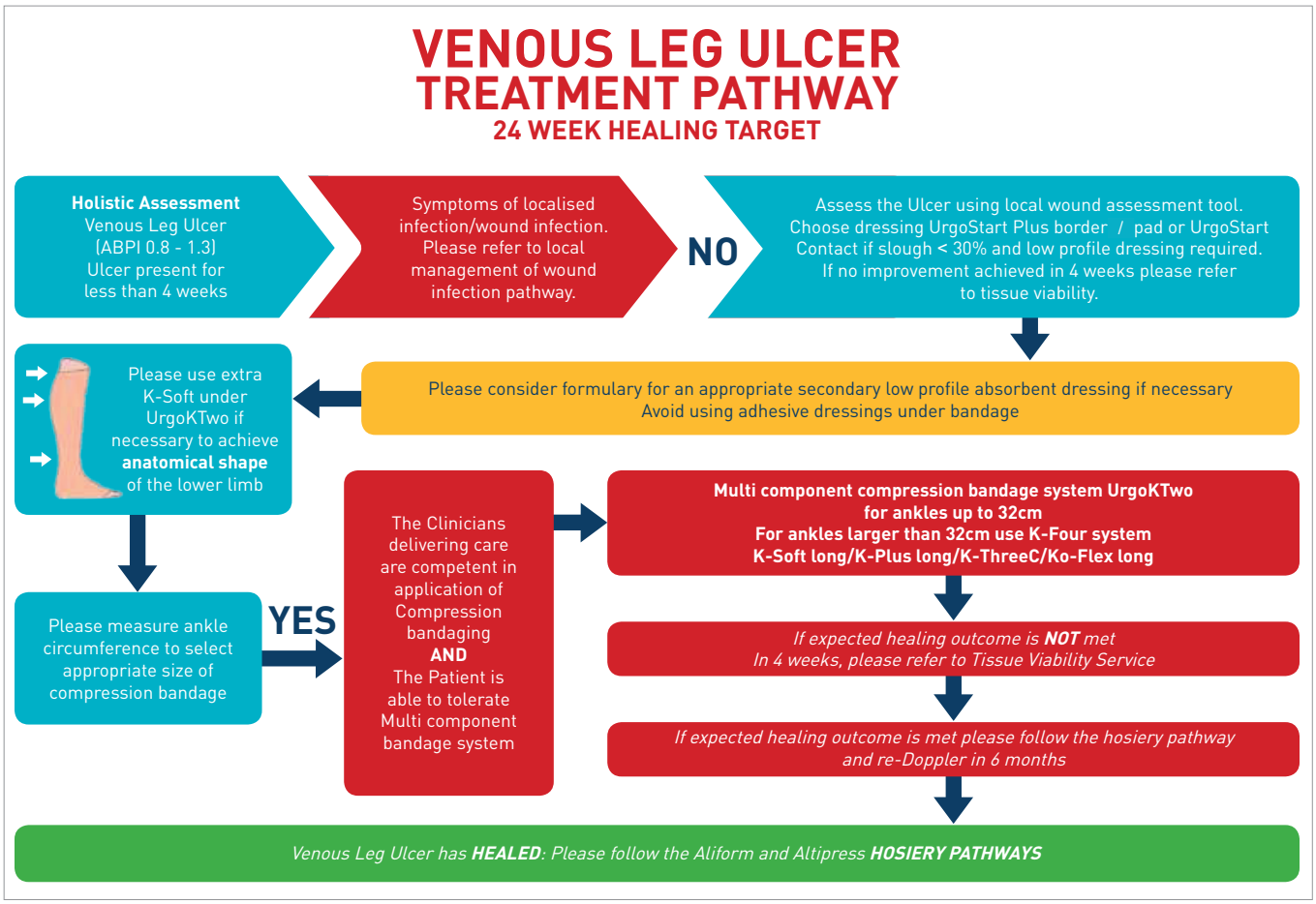

Figure 1. Central London Community Healthcare NHS Trust VLU Treatment Pathway recognised by NICE (2019) Medical Technology Guidance 42

trained members of staff and a support practitioner who has achieved robust competencies in wound management. Due to a backlog of patients who required leg ulcer care, supplementary clinical sessions were held on alternate Saturdays and Sundays. The supplementary clinics were managed by an experienced team member (band 6) and Clinical Lead to ensure continuity of care throughout.

The evidence-based treatment pathway has been in existence for over a year, but there has been slow buy-in from staff. The challenges community nurses have in implementing evidence-based wound care practice can include time pressures to learn a new pathway, lack of awareness, lack of confidence or knowledge (Grothier, 2018). By implementing the pathway as part of the weekend clinic, it was hoped it would illustrate that following an evidence-based pathway would improve consistency in care and patient outcomes with the overall aim to promote local implementation and uptake among staff.

Following holistic assessment, including an ankle–brachial pressure index (ABPI), all suitable patients were treated with the UrgoStart Plus treatment range and the UrgoKTwo compression bandage therapy system. Patients were informed about UrgoStart Plus, its mode of action and application to the wound bed. The patients attended the leg ulcer weekend clinic each week until healing.

A bespoke electronic tracker, which was developed with Urgo Medical, was used to monitor and assess relevant patient and wound data. The evaluation period was over 12 weeks as best practice states that if a VLU has not healed after a maximum of 12 weeks of treatment, the patient should be referred to an appropriate specialist (Wounds UK, 2016).

RESULTS

Thirteen patients were referred to the supplementary weekend clinic and were tracked for 12 weeks. The patient sample comprised four women and nine men aged 34–89 years (mean of 73.3 years, median 77 years). Seven patients had comorbidities, including cardiac arrhythmia and diverticulitis, atrial fibrillation and hypertension, type 2 diabetes with chronic kidney disease, diabetes, and thalassaemia trait. One person injected drugs intravenously.

All thirteen patients were referred to the supplementary weekend clinic with sub-optimally managed VLUs, which had been treated previously with a variety of regimens. Eleven patients had previously been managed in a walk-in centre, one in general practice, and one by self-care.

The mean wound size on initial assessment was 9.1 cm^2. The mean pain score was 4.1 on a visual analogue scale (*Table 1*). Of the 13 VLUs, 11 had slough. The mean wound duration before treatment in the leg ulcer clinic was 8.5 weeks. The range of episode durations prior to treatment in the clinic was 2–16 weeks.

All but one of the wounds (92%) healed before 12 weeks (mean healing time 6.8 weeks) (*Table 1).* The mean pain score on final assessment was 0. Changes in the condition of the surrounding skin and exudate levels are summarised in *Figures 2 and 3.* Half of patients had macerated surrounding skin at initial assessment, and this issue was resolved in most of the patients by week 6, and in all but one by week 8. This observation closely mirrors the changes in exudate from mostly moderate or low to none. *Box 1* describes a case study of patient 7.

DISCUSSION

The observations in this patient group of effective exudate management and tolerance of the dressing support results previously demonstrated in others studies (i.e. Edmonds et al, 2018).

Six patients had a chronic VLU (longer than 6 weeks [Frykberg and Banks, 2015]) when they were referred to the weekend leg ulcer clinic. Once admitted to the leg ulcer clinic and treated according to the evidence-based CLCH VLU pathway, three of those patients healed in less than 4 weeks. One of these patients (patient 10) had an ulcer for 10 weeks before presenting to the supplementary weekend clinic. With treatment according to the CLCH VLU clinical pathway, all but one patient healed within 12 weeks. An achievable outcome where evidence-based practice is consistently implemented.

It has previously been demonstrated that if patients are referred early and treated with UrgoStart

Table 1. Summary of wound characteristics at intial and assessment (*n*=13).

n	Initial assessment				Final assessment				Healing time following referral to the clinic (weeks)	Duration of this wound episode
	Wound size (cm^2)	Pain score prior to treatment	Surrounding skin	Exudate level	Wound size (cm^2)	Pain score following treatment	Surrounding skin	Exudate level		
1	1.5	9	Maceration	Low	Healed	0	Healthy	None	9	15 weeks
2	2.0	8	Dry	Low	Healed	0	Healthy	None	8	4 weeks
3	6.0	0	Dry	Low	Healed	0	Healthy	None	8	16 weeks
4	1.0	0	Dry	None	Healed	0	Dry	None	2	8 weeks
5	9.0	0	Healthy	Low	Healed	0	Healthy	None	8	12 weeks
6	4.8	4	Maceration	Moderate	Healed	0	Maceration	Moderate	11	5 weeks
7	10.2	9	Maceration	Moderate	Healed	0	Healthy	Low	8	9 weeks
8	60.0	7	Maceration	Moderate	Healed	0	Healthy	None	11	3 weeks
9	8.4	2	Maceration	Moderate	0.55	0	Healthy	None	n/a	10 weeks
10	1.2	5	Healthy	None	Healed	0	Healthy	Low	2	12 weeks
11	6.0	0	Dry	Low	Healed	0	Healthy	Low	3	3 weeks
12	1.3	2	Dry	Low	Healed	0	Dry	Low	4	12 weeks
13	7.2	7	Maceration	Moderate	Healed	0	Healthy	None	8	2 weeks

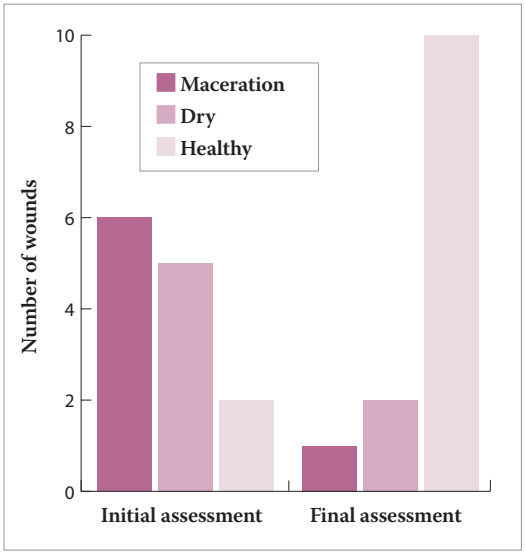

Figure 2. Condition of surrounding skin

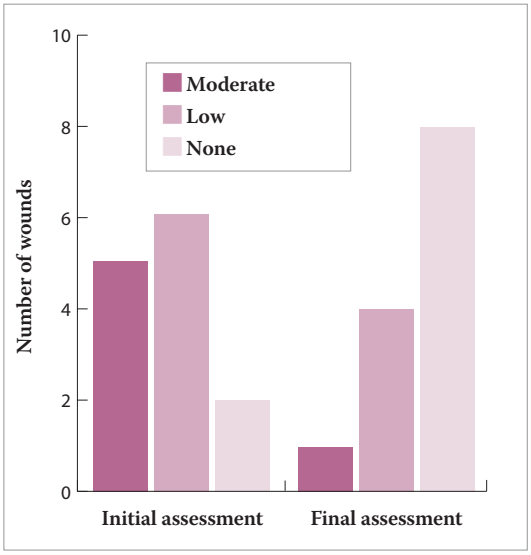

Figure 3. Level of exudate

in combination with wound aetiological treatment on first presentation, they could be ulcer free sooner (Làzaro-Martinez et al, 2019). The CHALLENGE double-blind RCT comparing the use of TLC-NOSF with a control dressing (UrgoTul) for the treatment of VLUs showed that over 8 weeks of treatment, the VLUs reduced in area by 58.3% in the UrgoStart group and by only 31.6% in the control group (Meaume et al, 2012). The REALITY pooled analysis of over 10,000 patients with a range of wound types supports these findings in the real-world, demonstrating that the sooner the TLC-NOSF treatment is implemented the better patient outcomes (Münter et al, 2017).

It is important that care delivery is evidence based, patient centred and focused on clinical outcomes, otherwise care can become task orientated and based on ritualistic and habitual behaviour (Grothier, 2018). It is regrettable that some patients still have to wait to receive optimal treatments for their wounds, especially considering the economic and social burden of wounds. All patients attending leg ulcer clinics at North Locality CLCH NHS Trust now experience care that follows the VLU treatment pathway. Following this local example, the community nurses are starting to embed the pathway into their practice. The pathway simplifies wound management and is boosting the confidence of the healthcare professionals as they are easily able to follow an evidence-based and NICE-recognised clinical pathway.

CONCLUSION

The results illustrate the effect of implementing evidence-based care in the treatment of VLUs. All but one of the patients experienced wound healing within 12 weeks. Widespread implementation of the evidence-based CLCH VLU pathway, as embedded in the NICE (2019) medical technology guidance for UrgoStart treatment range (MTG42), could have substantial benefits for patient quality of life by reducing VLU healing time.

Optimal outcomes for VLU healing require consistent care and timely use of compression and appropriate evidence-based products. This example of local implementation shows how a standardised evidence-based pathway can reduce variation in care and improve healing rates.

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Box 1. Patient 7 case study

Patient number 7 was in his late 80s and presented to the CLCH leg ulcer clinic after 3 months of self care and attending the practice nurse. The patient had underlying venous disease, no history of leg ulceration, and no other comorbidites. On a trip abroad, he returned with suspected bites to his left medial gaiter. The wound was being dressed with a soft, conformable absorbent polyurethane foam dressing.

After presenting to the walk-in centre, he was referred to the CLCH leg ulcer clinic at the start of December. The wound measured 3.2 x 3.2 cm (area=1.24cm^2) and the wound bed was 100% slough (*Figure 4*). Exudate level was moderate and the surrounding skin was macerated. Pain was documented at 9 using a visual analogue pain scale. APBI was 1.25 for both limbs with triphasic waves. The patient was initiated onto the CLCH VLU clinical pathway (*Figure 1*) and treatment with UrgoStart Plus pad and 40 mmHg UrgoKTwo compression bandage system was commenced.

At review each week, the wound bed became progressively less sloughy and, with the formation of healthy granulation tissue, the wound was on a healing trajectory. Exudate and pain had resolved, the peri-wound area was healthy. By week 8, the wound had healed (*Figure 5*). The patient is now in hosiery and has remained ulcer free for the remainder of the evaluation period.

Figure 4. First assessment CLCH leg ulcer clinic (2 Dec 2018)

Figure 5. After treatment (11 Jan 2019)

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DECLARATION

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