CLINICAL PATHWAY AS A TOOL FOR WOUND MANAGEMENT OF PATIENTS WITH VENOUS LEG ULCERS

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INTRODUCTION

Complex wounds may cause a dependence of patients on professional care for a longer period than necessary. Healthcare reflects an interest in linear continuity.

Leg ulceration is tissue breakdown that occurs in already damaged skin, it is a common condition with a prevalence between 1.5 and 3 per 1000[1,2,3,8]. Various studies on leg ulceration show that approximately 90% of causes for ulceration of the lower limb are of venous -, i.e. venous-lymphatic origin[4,5,8,9,13-16].
As age progresses mixed venous-arterial forms become more frequent, especially in connection with diabetes mellitus[23-26]. About 6% of the causes for leg ulcerations are of arterial origin, the remaining circa 4% are divided over the other groups[4,5,8,26,28]. Leg ulcers are considered chronic, when it takes more than six weeks to close them[4,5,8,25-28]. Most patients are managed in primary - care, community nurses spend a considerable amount of their time managing leg ulcers patients[6,12].
It is recognised that the most important factor in treating venous leg ulcers is the application of effective sustained compression[23-29]. A venous ulcer will fail or be slow to heal without the application of sustained graduated compression[1-20, 23-29]. Studies have shown a strong correlation between the duration of the ulcer and the time it takes to healing the ulcer[3-6,12-16,25-29]. Large size ulcers (circumferential ulcers) were reported to take longer to heal than small ulcers($< 4cm^2$)[27].
Many of the bandages traditionally used to treat patients with venous leg ulceration, are ineffective due to lack of technique and practice by persons applying the bandage[12,17,23-25,27].

For the application of short stretch bandages different application techniques are in use. A commonly used technique[21,26,27] is the application of 2 bandages of 8- and 10 cm width, starting at the foot. The system is reapplied when clinically required at the discretion of the care giver, by the patient/family or nurse[27]. The bandages are washed and reused up to 6 times.

MATERIAL AND METHODS

This paper gives a report of the development and validation of a clinical pathway for patients with venous leg ulcers. The evidence based clinical pathway (box I) and applicable products* (box II and III), were tested by using case ascertainment.

The purpose of this study is to evaluate a clinical pathway, applied for patients with venous leg ulceration, looking at the performance of the compression system used and the dressings applied.

Before recruitment to the study patients were assessed using a standard procedure which includes the measurement of ankle brachial pressure indices (ABPI) and Doppler, to determine whether the patient is suffering from significant peripheral arterial disease. If applicable, further diagnostics, using Duplex Sonography, phlebography and DPPG were performed.
In-patients and/or out-patients at the trial centre are recruited to the study. The number of patients in this study (N = 10) was not based on a statistical consideration.
Patients are treated applying the clinical pathway on an intention to treat basis, with the short stretch bandage system (Rosidal® Sys) and a wound dressing from the Suprasorb® range. The clinical Investigator sought permission of the relevant consultant for their patients and of the patient to be included in the study.

A standardized questionnaire is used for this clinical evaluation. Identified patients were clinically examined to determine general condition, associated factors, wound type, stage, wound evolution, quality of life aspects, efficacy of treatment, costs efficacy (focussing costs of treatment as well as time investment of staff) etc. Clinical examination was performed, depending on wound type, upon initial assessment and at 2 week intervals. The evaluation included structured interviews on how wound management was carried out, before implementing the clinical pathway.
Available outcome of the centre on the treatment of patients with venous leg ulcers was used as a baseline.
For each individual patient, the clinical evaluation observation period was 12 weeks.
The patient record form booklet was completed for one wound only. The number of patients that were withdrawn from the study, of which the ulcer had not healed were listed in full, as well as adverse incidents, whether bandage related or otherwise.

INCLUSION CRITERIA

1. Age: at least 18 years of age.
2. Sex: Males, Females - provided they are not pregnant.
3. Diagnosis: Venous leg ulceration.
4. Administrative: The patient is able to understand the clinical evaluation and is willing to consent to the study.

EXCLUSION CRITERIA

Specific exclusions will be:

1. Patients with significant arterial disease (APBI < 0.8)
2. Patients with other causes to their ulceration, according to the clinical diagnosis:

   a) Rheumatoid vasculitis
   b) Diabetic foot ulceration
   c) Malignant ulceration

3. Patients on (oral and/or topical) medication containing cortico-steroids
4. Patients who have participated in this trial previously and who have healed or were withdrawn
5. Patients who are unable to understand the aims and objectives of the trial and/or have a history of poor compliance
6. Patients with clinically infected ulcers, where frequent dressing changes are required. These patients may be included in the study after the infection is resolved
7. Patients with ulcers < 4cm² and circumferential ulcers
8. Patients with a known allergy for Rubber Latex or other contents of the trial products.

Analyses plan

Healing rate at 12 weeks is 50% („estimate“)

Ulcer areas:
The total area of ulceration on each leg will be measured at week 0, at the time of withdrawal and at weeks 2, 4, 8 and 12 if they have not healed. The areas will be determined from tracing of ulcers margins.

Stage of the wound:
For assessment of local wound conditions the DWCS classification model is used, which is based on optical parameters of wounds. The percentage of colour present is to be monitored and indicated on the ulcer tracings at weeks 0, 2, 4, 8 and 12.

Patient comfort assessment:
In addition to time to healing, assessments are made on patients comfort and the level of pain that each patient suffers, at weeks 0, 2, 4, 8 and 12 and also the week the limb heals or the patient is withdrawn. A specifically designed QOL questionnaire is used to assess patients' quality of life aspects.

Handling properties of the dressing/bandaging regime:
Handling properties of the dressing is recorded at application and after removal of the dressing. The following aspects are assessed:

- Ease of dressing use.
- Ease of dressing removal.
- Patient comfort, pain on removal.
- Durability of the dressing regime, incidence of leakage.

Handling properties of the bandage system is recorded at the application and before the removal of the bandages. The following aspects are analysed:
Following application of the bandages: - ease of application of the bandaging system; - appearance of the bandages after application.

Assessment before removing the bandages: - perfectly in place; - partly slipping, bandages still functional; - extensive slipping, bandages not functional

RESULTS

The interim results demonstrated an improvement of quality of care, cost savings and moreover an improved level of knowledge and communication between the clinicians involved in the care of patients with venous leg ulcers.

CONCLUSIONS

Communal knowledge and effort can be tuned to the interest of patients, institutions and commercial parties. Clinical pathways applied throughout the complete care chain, supports improvement of quality of care.

*Rosidal® Sys, a short stretch compression bandage system. Suprasorb® A, Suprasorb® P or Suprasorb® C and Vliwazell® are products of Lohmann & Rauscher GmbH.

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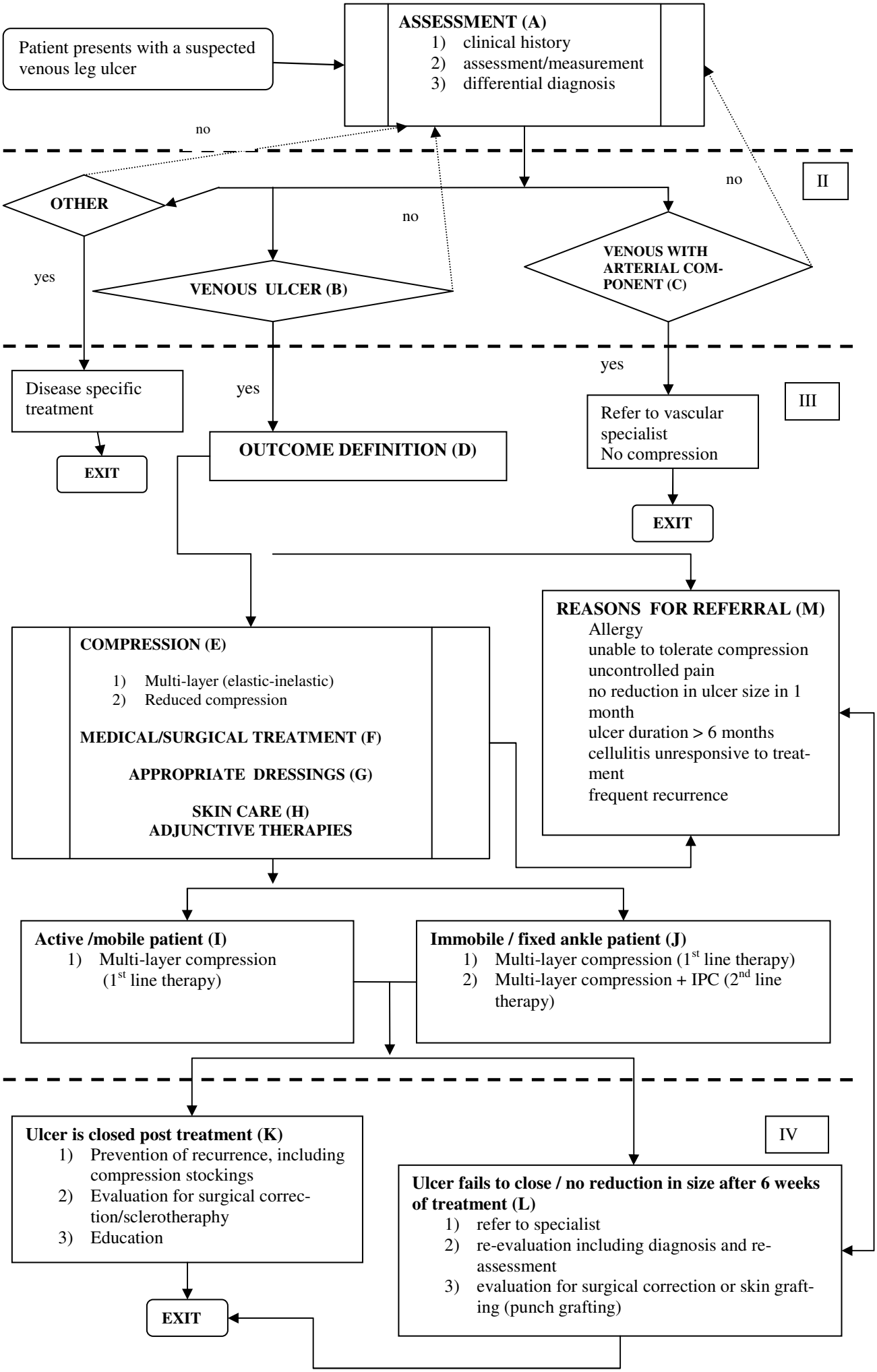
BOX I CLINICAL PATHWAY FOR VENOUS LEG ULCER PATIENTS



Box II: The following materials were tested in the study:

SUPRASORB® A is a calcium alginate dressing, available as a wound sheet, for superficial wounds and as wound filler for deep wounds.

Based on its expansion property alginates are suitable for wound cleansing and hemostasis (Ca-ion release)[30-32]. Alginate dressings are derived from brown seaweed. The alginate dressings in use may contain a high co-polymer derivative, calcium alginate. Alkali-ions and magnesium salts of alginic acids, together with water, respectively exudate, form a gel of high viscosity[30-32].

SUPRASORB® P, a hydrocellular foam dressing with absorbent properties.*

The dual-layer polyurethane wound dressing has a foam core which has a high absorbent capacity and maintains a moist wound healing environment. The polyurethane membrane cover protects against bacteria- and is water repellent, allowing the patient to shower. The dressing is easy to apply and to remove and does not cause any trauma upon dressing removal. Dressing changes should take place when the dressing is saturated or leakage occurs. Depending on exudate production the dressing can be left in place for up to 5-7 days.
The non-adhesive dressing is used for the study in size 10 x 10 cm.

SUPRASORB® C, a collagen dressing with absorbent properties.

The dressing is constructed of pure, non-cross-linked bovine collagen, in a porous structure. The dressing absorbs exudate, supports coagulation and stimulates the process of wound healing. The dressing is used in all the different phases of wound healing, it is especially effective in the treatment of stagnant wounds to support wound closure. For the study the 6 x 8 cm and 8 x 12 cm dressing is used, depending on the wound size.

a) As a secondary dressing Suprasorb® P is used for light to moderate exuding wounds.

b) For wounds that produce copious amounts of exudate Vliwazell® absorbent wound dressing 10 x 10 cm. is used. Vliwazell® is a conformable non-woven wound dressing, with a cellulose core. A moisture inhibiting layer of non-woven material on the back of the dressing protects clothing, preventing exudate strike through.

Box III: ROSIDAL® SYS, Short stretch bandage ulcer system:

The bandage system is used in both the study and the control groups. The system has the following components:

TG, Tubular bandage, non elastic:

The non-elastic tubular bandage is applied on the skin for protection and fixation of the wound contact dressing. A length of 2,5 times the size of the lower limb is used, one half to cover the dressing, the second half to cover the compression bandage, to support it from slipping.

ROSIDAL soft®,a foam bandage:

The foam bandage is designed for padding underneath compression bandages. The padding bandage leads to an even pressure distribution and will not slip as the open pores are interlocking. The bandage can be washed at a temperature of 40-60°C, if the bandage is extremely dirty it can tolerate washing up to 95°C.

ROSIDAL K®, a short stretch bandage:

Extensibility of the bandage is approx. 90% and thin foam under padding material.

Mollelast® haft, fixation bandage:

Knitted white 70% viscose, 30% polyamide, lengthwise elastic approx. 80%, withwise extensible approx. 50%, cohesive through microfine latex coting.

Porofix® adhesive non-elastic fixation tape:

Viscose fabric, skin coloured, non-elastic tape, coated with synthetic rubber adhesive.

Optional: *Komprex® foam rubber pads:*

Synthetic latex permeable to air and water vapour. The ready for use format (kidney-shaped) can be applied behind the malleolus to support removal of oedema.

Application of the bandage system:

2 Bandages are used in a modified Sigg bandaging technique, as follows: Depending on the ankle circumference either an 8 cm. or 10 cm width bandage is applied starting on the foot. A 10 cm. bandage is used to cover the remainder of the lower leg.

Two sets of Rosidal Sys are made available at the start of the treatment.
The bandages will be applied and washed on average twice weekly. For each limb, two sets of bandages (short stretch and foam under-padding bandages) will be used for a treatment period of 12 weeks, which is the duration of the trial.

Case:

Mr. GH, an 82 year old man who presented with a venous leg ulcer (ABPI 1.01) of 16 months duration. The ulcer measured 6.2 x 3.6 cm. The wound bed was covered with 10% slough and 90% granulation tissue. After 12 weeks of treatment the ulcer was closed.

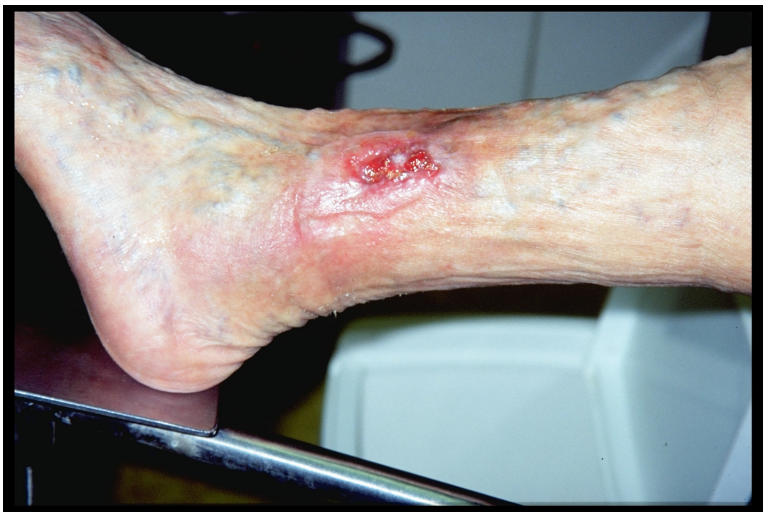


Fig 1: Upon recruitment to the study

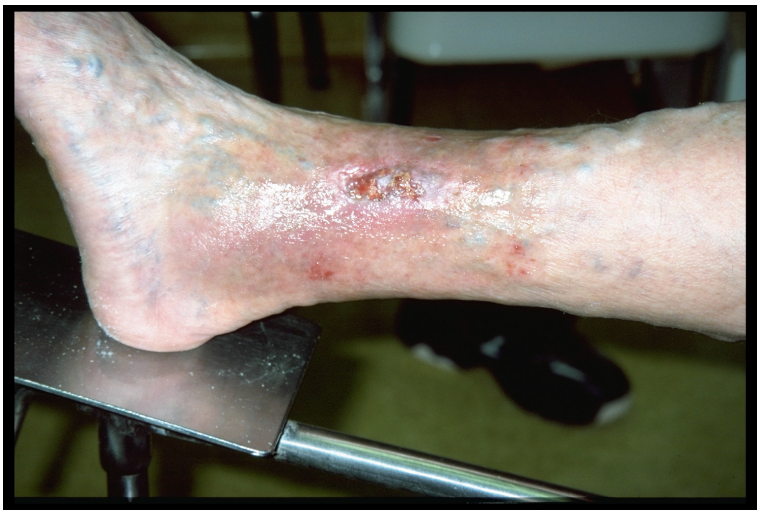


Fig 2: Status after 12 weeks of treatment