IMPROVING COST EFFICACY FOR VENOUS LEG ULCER PATIENT TREATMENT

R. Polignano, A. Andriessen ##, M. Abel #

Dpt. Cardiology & Angiology, Instituto Ortopedico Toscano (IOT) Firenze, Italy, polignan@dada.it
##Andriessen consultants, NL, anneke.a@tiscali.nl, #Lohmann & Rauscher GmbH, Rengsdorf, Germany

INTRODUCTION

The most important factor in treating Venous Leg Ulcers (VU) is the application of sustained compression.[1,2] Time to heal is the critical factor in the cost-effectiveness analysis.[3,4] For the application of short stretch bandages a commonly used technique[5,6] is the use of 2 bandages of 8- and 10 cm width, starting at the foot. The bandages may be washed and reused.

MATERIAL AND METHODS

A Clinical Pathway (CP) was developed, validated and implemented, to improve cost efficacy of treatment for patients with venous leg ulcers. The CP and selected products* were tested by using case ascertainment, looking at clinical efficacy, time to ulcer closure, wound evolution, quality of life aspects, and costs efficacy. Clinical examination was performed, depending on wound type, upon initial and at 2 week intervals for a period of 12 weeks. The patients were then followed until ulcer closure. The study group (SG) received treatment with a short stretch compression system and a dressing, depending on wound condition, as defined in the clinical pathway. The patients in the control group (CG) received conventional treatment (compression and wound dressing) as before implementing the clinical pathway.

Statistic evaluation was performed using StatXact 5.0 – double sided – α = 0,05 – paired sample with Wilcoxon-Test – unpaired with Mann-Whitney for N = 20 (10/10).

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 VU patients was used as a baseline. The number of patients that were withdrawn from the study, of which the ulcer had not closed, was listed in full, as well as adverse incidents.

Inclusion criteria:

Age: at least 18 years old; Sex: Males, Females – provided they are not pregnant; Diagnosis: VU; Ability to understand the terms of the trial and willing to give consent.

Exclusion criteria:

Significant arterial disease (APBI < 0.8); Other causes: Rheumatoid vasculitis; DFU; Malignant ulceration; Oral and/or topical corticoid-steroids; Participated in this trial previously, ulcer closed or withdrawn; Unable to understand the aims and objectives of the trial and/or poor concordance; Clinically infected ulcers, where frequent dressing changes are required. Inclusion may be considered after the infection is resolved; Ulcers < 4cm² and circumferential ulcers; Known allergy for latex or other contents of the trial products

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.

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

SUPRASORB® C, a collagen dressing with absorbent properties.- As a secondary dressing Suprasorb® P is used for light to moderate exuding wounds.

ANALYSIS PLAN

Ulcer areas[7]:
Ulcer area (tracing of ulcers margins) on each leg is measured at week 0, at the time of withdrawal and at weeks 2, 4, 8 and 12 if the ulcer is not closed. Ulcer closure rate at 12 weeks is 50% („estimate“)

Stage of the wound:
For assessment of local wound conditions (DWCS classification) the percentage of colour present is monitored and indicated on the ulcer tracings at weeks 0, 2, 4, 8 and 12.

Patient comfort assessment:
In addition to ulcer closure, 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 ulcer is closed 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, looking at: Ease of use; Ease of removal; Patient comfort, pain on removal; Durability of the regime, incidence of leakage.

Handling properties of the bandage system is recorded at the application and before the removal:
Following application of the bandages: Ease of application; appearance of the bandages after application. Assessment before removing the bandages: Perfectly in place; partly slipping, bandages still functional; extensive slipping, bandages not functional

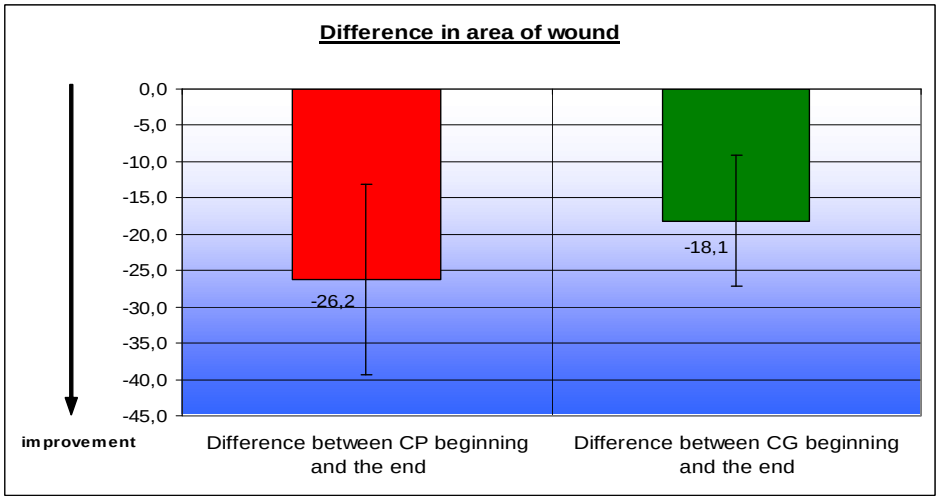
RESULTS

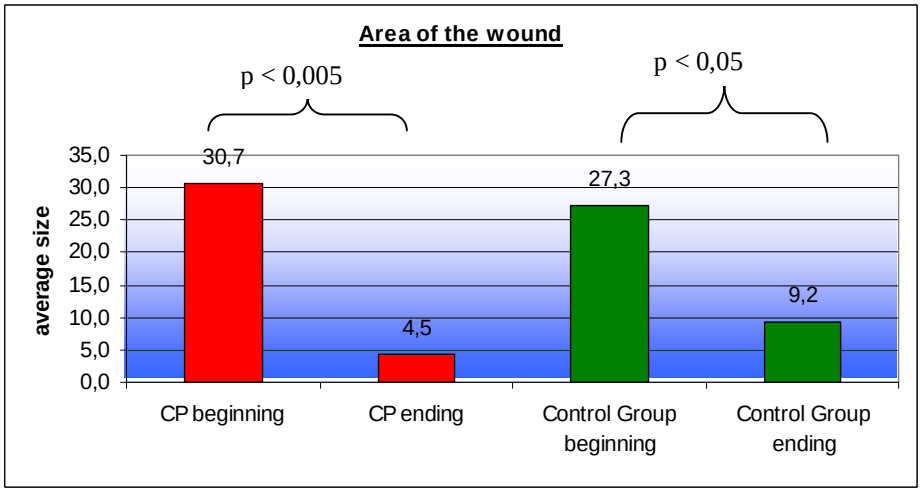
After implementation of the clinical pathway and the selected products, a statistically significant ($p < 0,005$) shorter period for ulcer closure was demonstrated for the SG when compared to previous treatment given to the CG.
5/10 of the ulcers were closed within 12 weeks of treatment in the SG vs. 3/10 in the CG. An improvement of quality of life was noted for SG ($p < 0,05$ for the combined parameters and $p < 0,005$ for pain), as well as cost savings ($p < 0,05$).
Treatment costs per patient for 12 weeks treatment for the SG was € 280,87 vs
CG € 630,02. Total cost per healed patient within the 12 weeks study period was for the SG € 262,40 vs. € 400,40 for the CG. For details see tables.

Number of dressings used

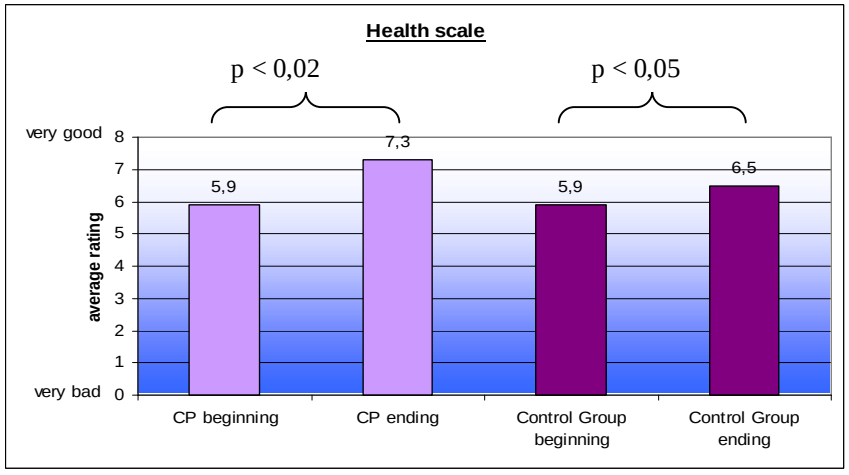
Study Group (CP- System): 14 (Min.: 9 Max.: 25), Control Group: 23 (Min.: 13 Max.: 37)
$p < 0,02$ (Difference of the mean)

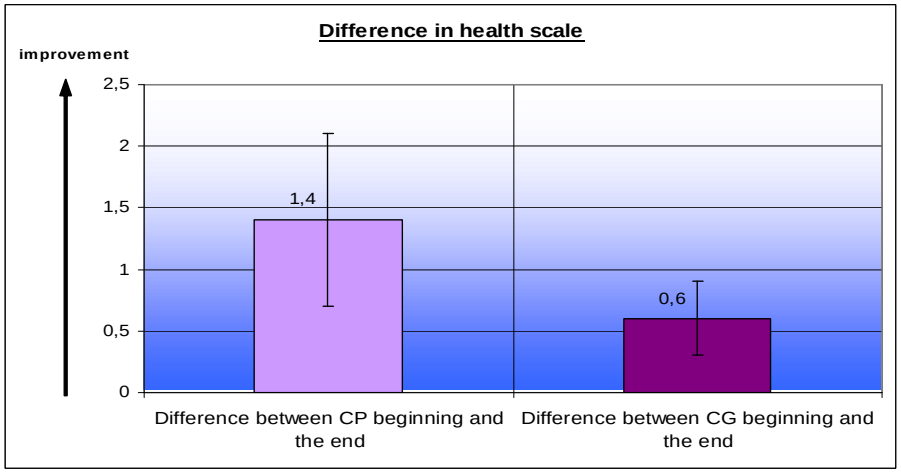
Area of the wound



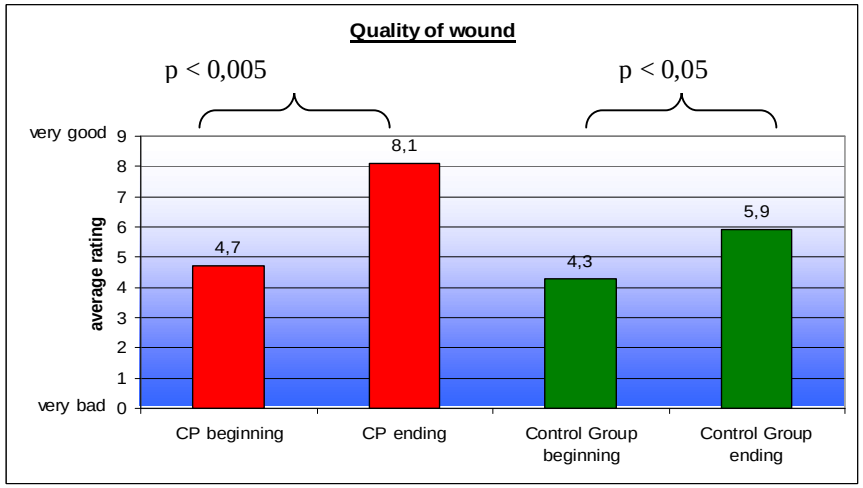


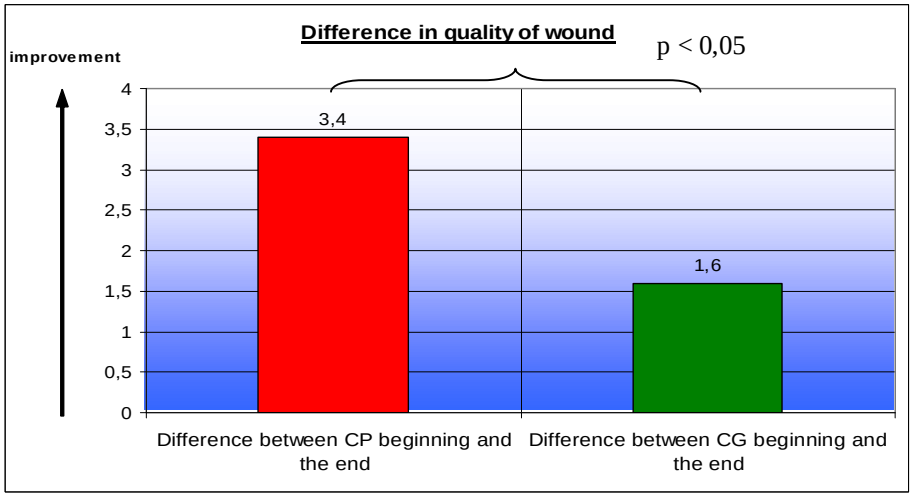
Health scale



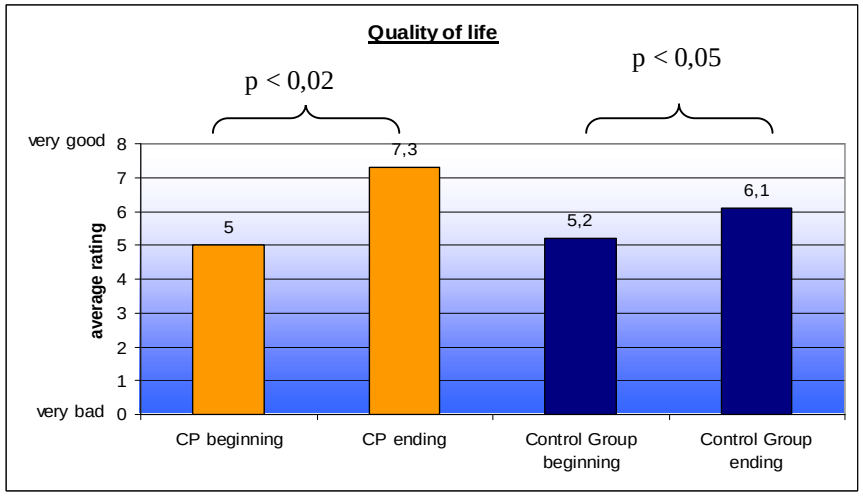


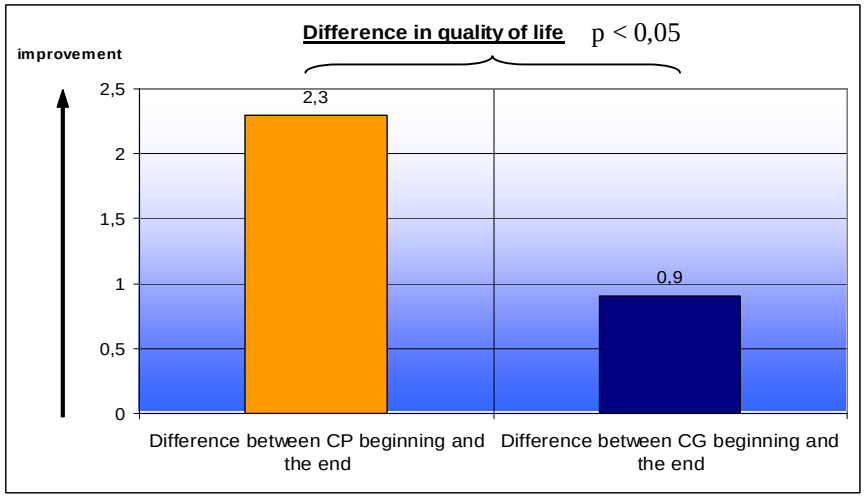
Quality of wound – evolution of the wound bed condition



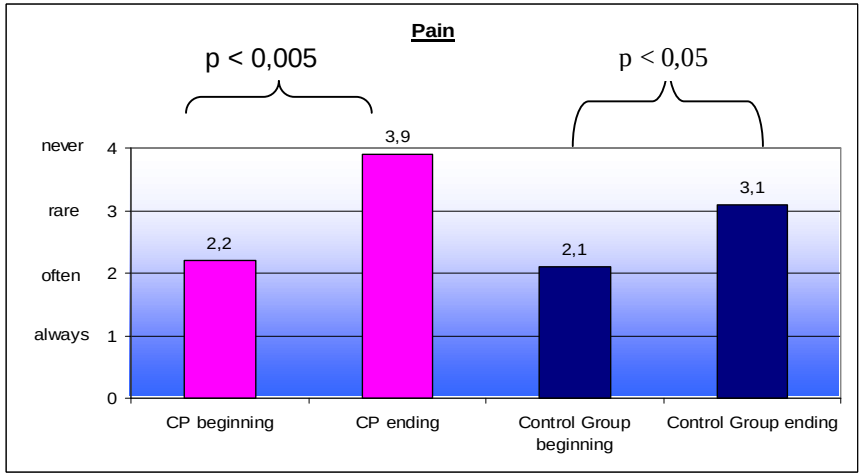


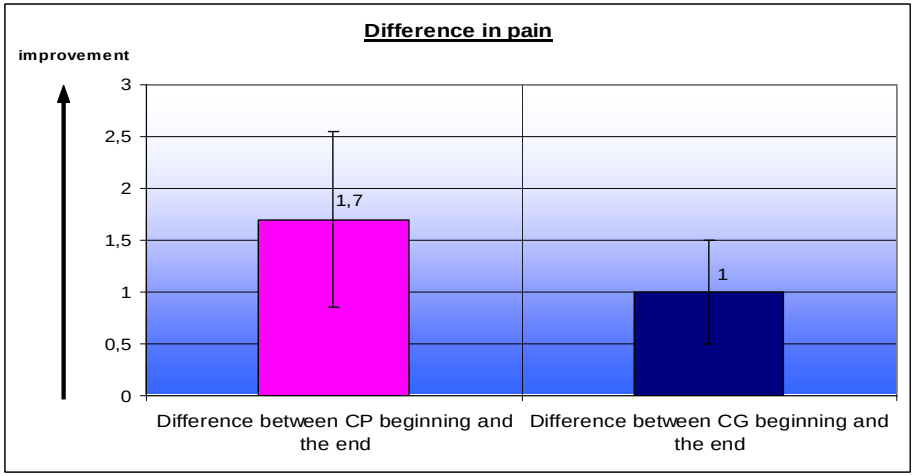
Quality of life



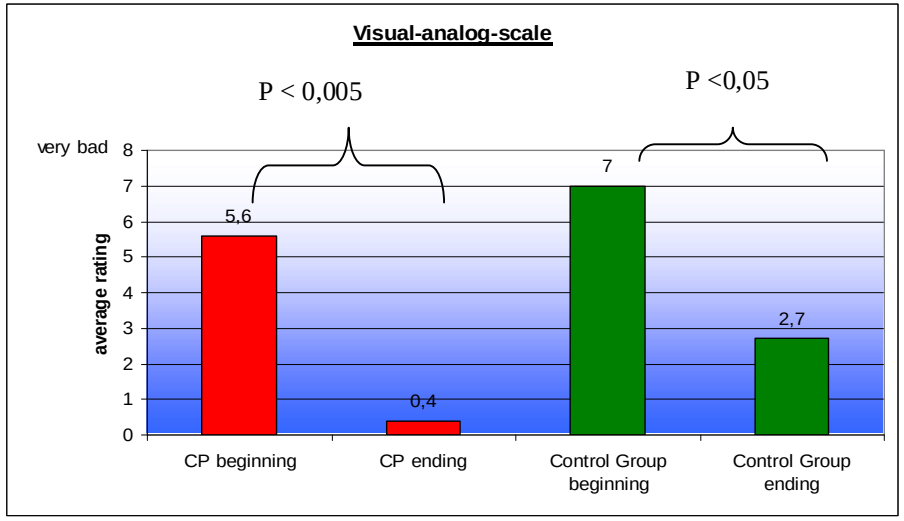


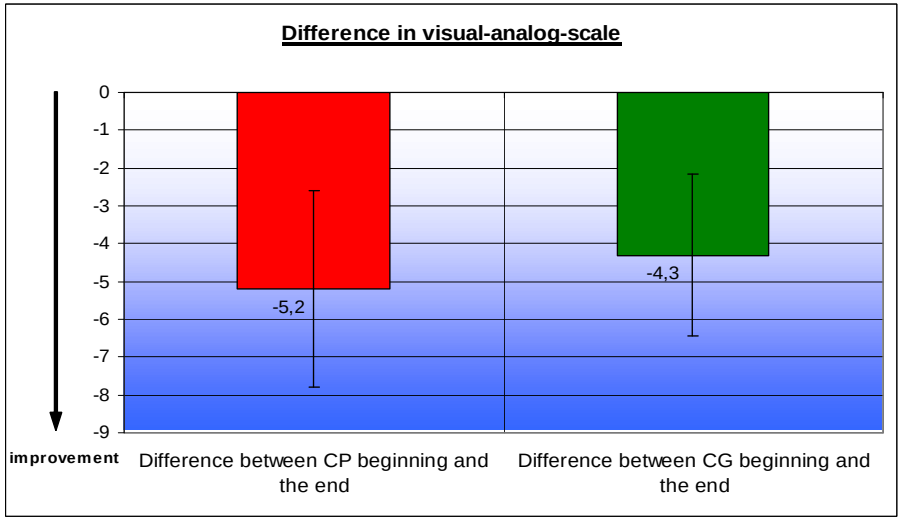
Pain



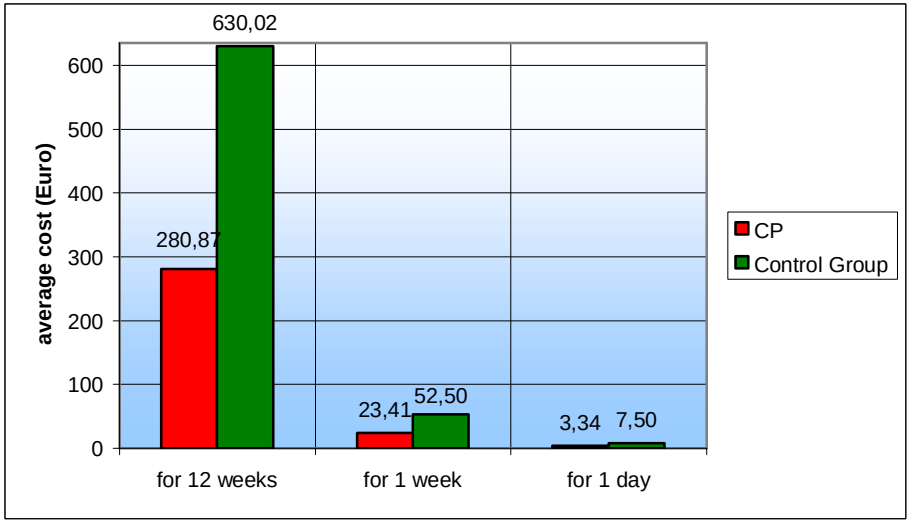


Visual-analog-scale

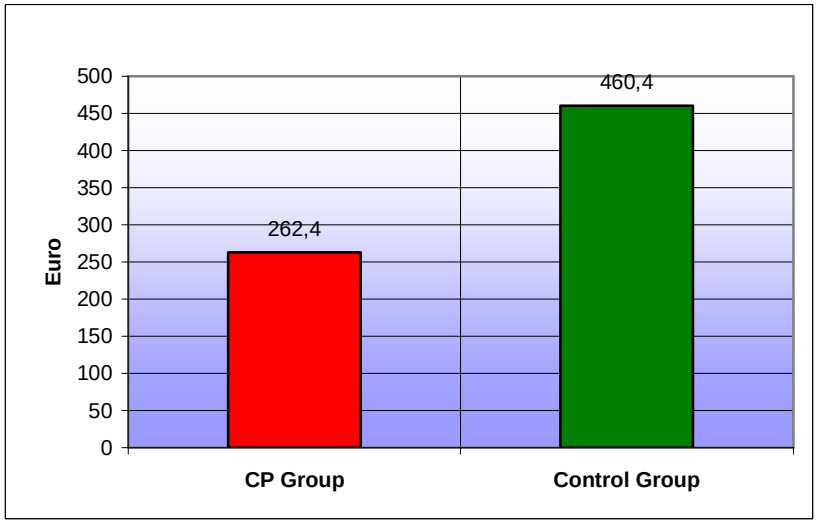




Treatment costs per patient



Costs per healed patients (after 12 weeks)



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, improves quality of care and provides cost-savings.

- The results for the CP system were (SF) superior regarding evolution of the wound bed and quality of life, comparing to the control group.
- The CP system demonstrated a trend towards a superior performance comparing to the CG, regarding cost savings, wound area reduction, health scale and pain.
- Thirty patients from a second centre are to follow the next analysis.

REFERENCES

1) Nelzen O., Bergqvist D., Lindhagen A. Journal of Vascular Surgery; Vol 14: No.4: 557-567.
2) Moffatt CJ, Dorman MC, Recurrence of leg ulcers within a community ulcer service. J.Wound Care 1995; 4:(2):57-61.
3) Clark M, Compression bandages:principles and definitions. EWMA Position document. Understanding compression therapy. MEP, 2003;5-7.
4) Moffatt C.J, Franks P.J, Oldroyd M, Bosanquet N, Brown P, Greenhalgh R.M, McCollum C.N. Community leg ulcer clinics: impact on ulcer healing. BMJ 1992;305: 1389-1392.
5) Partsch H, Rabe E, Stemmer R. Compression therapy of the extremmities. Paris; Editions Phlebologiques Francaises, 1999.
6) Partsch H, Damstra RJ, Tazelaar DJ, Schuller-Petrovic S, Velders AJ, de Rooij MJM, Tjon Lim Sang RRM, Quinlan D. Multicenter, randomized controlled trial of four-layer bandaging versus short-stretch bandaging in the treatment of venous leg ulcers. VASA 2001; 30: 2108-113.
7) Gilman T. Wound outcomes: the utility of surface measures. Int J Low Extrem Wounds. 2004 Sep;3(3):125-32)

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

TG, Tubular bandage, non elastic:

The tubular bandage is applied for protection and fixation of the 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. It can be washed at a temperature of 40-60°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 approx. 50%, cohesive.

Porofix® adhesive non-elastic fixation tape:

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

Optional: *Komprex® foam rubber pads:*

The kidney-shaped pad can be applied behind the malleolus to support removal of oedema.

Application of the bandage system:

2 Bandages are used in a modified Sigg: The bandages are applied and washed on average twice weekly. For each limb, two sets of bandages (short stretch and foam under-padding bandages) are used for a period of 12 weeks (the duration of the trial.)

BOX I CLINICAL PATHWAY FOR VENOUS LEG ULCER PATIENTS

I

Patient presents with a suspected venous leg ulcer

ASSESSMENT (A) :
1**)** clinical history; 2) assessment/measurement; 3) differential diagnosis

II

OTHER

no

VENOUS ULCER (B)

no

VENOUS WITH ARTERIAL COMPONENT (C)

no

yes

III

Disease specific treatment

EXIT

yes

OUTCOME DEFINITION (D)

yes

Refer to vascular specialist
No compression

EXIT

COMPRESSION (E)

1) Multi-layer (elastic-inelastic)
2) Reduced compression

MEDICAL/SURGICAL TREATMENT (F)

APPROPRIATE DRESSINGS (G)

SKIN CARE (H)
ADJUNCTIVE THERAPIES

EDUCATION (H)

REASONS FOR REFERRAL (M)
Allergy; Unable to tolerate compression; uncontrolled pain; no reduction in ulcer size in 1 month; ulcer duration > 6 months; cellulitis unresponsive to treatment; frequent recurrence

Active /mobile patient (I)
1) Multi-layer compression (1^{st} line therapy)

Immobile / fixed ankle patient (J)
1) Multi-layer compression (1^{st} line therapy)
2) Multi-layer compression + IPC (2^{nd} line therapy)

IV

Ulcer is closed post treatment (K)
1) Prevention of recurrence, including compression stockings
2) Evaluation for surgical correction/sclerotheraphy
3) Education

EXIT

Ulcer fails to close / no reduction in size after 6 weeks of treatment (L)
1) refer to specialist
2) re-evaluation including diagnosis and re-assessment
3) evaluation for surgical corr. or skin grafting (punch grafting)

Case report:

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. The ulcer was covered with an alginate, after which Rosidal ® Sys was applied. Dressing changes in the first 4 weeks took place twice weekly. After 4 weeks the wound was dressed with Suprasorb® C, compression with Rosidal ® Sys was continued. The patient reported the ulcer to be very painful, but in the course of the treatment the pain had gone. The compression system stayed well in place and was easy to apply and to remove. After 12 weeks of treatment the ulcer was closed.

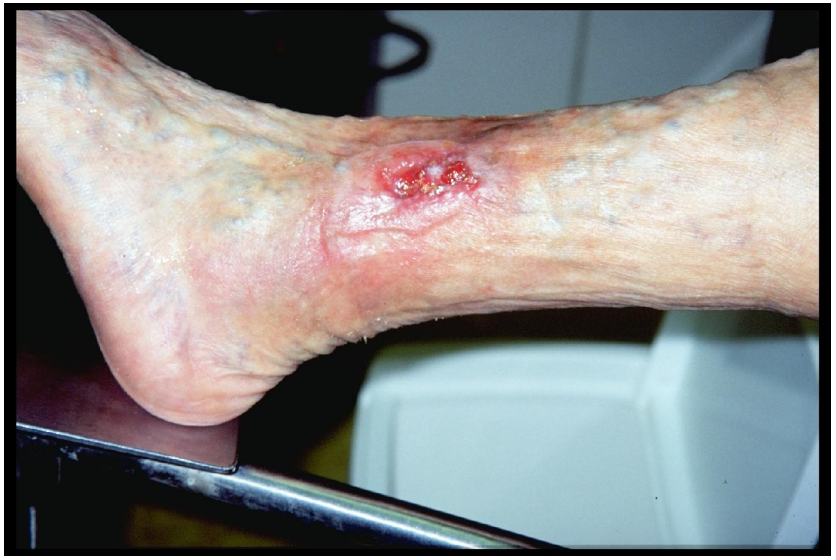


Fig 1: Upon recruitment to the study

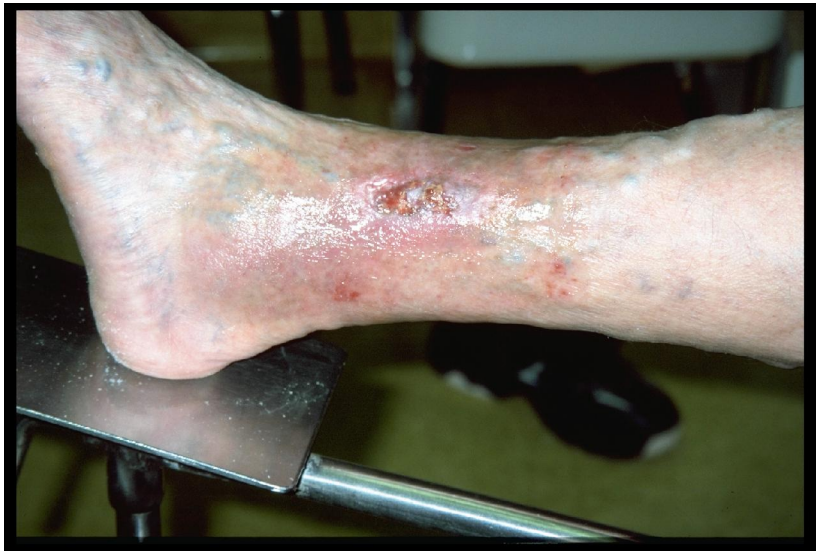


Fig 2: Status after 12 weeks of treatment

*Rosidal® Sys, a short stretch compression bandage system. Suprasorb® A, Suprasorb® P or Suprasorb® C and Vliwazell® are products of Lohmann & Rauscher GmbH. Lohmann & Rauscher GmbH supported the study with a limited educational grant.