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A cost-effectiveness study of leg ulcer treatment in primary care

Comparison of saline-gauze and hydrocolloid treatment in a prospective, randomized study

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Objective – The majority of leg ulcer patients in Sweden are managed by primary health care personnel. To compare, in a primary care setting, the healing results and the expenses of two commonly used wound dressings for leg ulcers.

Design – Thirty patients with leg ulcers of venous or mixed venous/arterial aetiology were randomized to treatment with saline-soaked gauze or with the hydrocolloidal dressing [HCD – DuoDERM® (ConvaTec, A Bristol-Myers Squibb Company, Princeton)]. All patients were bandaged with the same compression of low-stretch-type [Comprilan® (Beiersdorf AG, Hamburg)].

Setting – Vårdcentralen Marieberg, Primary Health Care Centre, Motala, Sweden.

Outcome measures – Healing/reduction of ulcer area, pain, costs for material, nursing time, kilometres driven were registered during a six-week period.

Results – Two patients dropped out of the study, one in the gauze-group due to erysipelas, and one in the HCD-group for social reasons. A total of 1234 dressing changes were analysed. Costs for material were similar in the two groups. When the total care including nursing- and travelling time and kilometres driven were analysed, the mean cost for treatment with gauze dressings was 4126 Swedish Kronor (SEK), and with HCD, 1565 SEK.

Seven patients in the HCD-group and two in the gauze-group healed during the study. The reduction of the ulcer area was 19% in the gauze-group and 51% in the HCD-group ($p < 0.16$).

Conclusion – The total care, analysed in an authentic clinical setting, must be considered when different wound-care methods are discussed. In this study the use of HCD showed lower costs than use of gauze-dressings. As regards healing there was a tendency to improved healing with HCD, but no significant difference. Patients in the HCD-group reported significantly less pain at dressing changes ($p < 0.003$) than patients in the gauze-group.

Key words: ulcer treatment, saline-gauze, hydrocolloid treatment.

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A large proportion of patients with leg ulcers are treated in community health care (1,2). Many different methods/local wound dressings are used. One study in Malmö (3) demonstrated that 24 different wound dressings were used randomly in primary health care, whereas the leg ulcer clinic at the Department of Dermatology was limiting the type of dressings to three or four. Using few, well-documented dressings gives security to the nursing staff, facilitates observation of the healing process, and may substantially reduce costs.

To evaluate cost-effectiveness in the care of chronic ulcers, many variables must be considered. The distance from the patient to the caregiver, the dressing materials, cleansing agents, absorptive dressings, and nursing time must be paired with the results of the treatment.

The purpose of the present study was to compare the total cost, including material costs, nursing time spent on dressing changes, and travelling costs, as well as healing progress, in randomized groups of leg-ulcer patients in a community setting.

The study was designed and run in close cooperation between the Department of Research and Development in Primary Health Care, Mjölby, and the primary health care centre, Marieberg, Motala. In this centre six physicians and 14 nurses are serving a population of 12 000 inhabitants. The group is responsible for the care of a population living, both urban and rural, in an area of 50 kilometres diameter.

Material and methods

Thirty consecutive patients with leg ulcers of venous or mixed arterio/venous aetiology were included. They were informed about the study and their rights to withdraw at any time, in accordance with the Helsinki II Declaration. The protocol comprised examination by a physician and registration of coexisting diseases, present medication, Body Mass Index (BMI), smoking habits, blood pressure, circulatory status (Laser Doppler), overall activity, and mobility in the foot-joint. Serum-Iron, haemoglobin, albumin and serum-Zinc were determined. All ulcers were photographed using a standardized method (Kodak Instattech close-up lens with fixed frame). The patients were randomly allocated to one of two

treatment groups, saline-soaked gauze dressings, changed twice a day, and hydrocolloidal dressing (HCD), changed once a week or more frequently if needed (heavy leakage). Identical low-stretch compression bandages were used in the two groups. The bandages were re-used and changed only when dirty. All ulcers were cleaned with soap and tapwater. The study period was six weeks.

The nurse in charge of the patient was provided with registration cards to be filled in at all visits for ulcer care. The cards comprised information concerning distance, material costs as well as costs of cleansing pads, absorption bandages, and compression bandages. The treatment and travelling time spent at each dressing change was also registered. At every treatment, the reason for dressing change, the methodology of cleansing, and the number of baths/showers with the dressing in situ were registered. The pain experienced at dressing changes and between dressings was registered on a visual analogue scale (VAS).

At the end of the study, all patients were again seen by the physician for measurement and photography of the ulcer as well as summing-up of the experience. Changes in ulcer area/healing were blindly measured by two independent investigators from the standardized slides. Statistical analysis of healing, costs and pain was performed by Wilcoxon's test.

Results

26 women and four men with a median age of 76 years (range 49–89) were included. The ulcers were predominantly of venous origin, but six were of mixed venous/arterial aetiology (Table I). Two patients dropped out of the study, one from the saline-gauze group due to erysipelas, and one from the HCD-group for social reasons. There were no statistical differences between the two groups regarding age, nor any of the other laboratory data, BMI (26.4 ± 5.1), Zn/S (13.9 ± 1.6 mmol/l), smoking habits, and hypertension (DBP <90).

Five patients had values of fasting B-glucose ≥ 6.5 mmol/l (6.5 – 8.6), one in the HCD-group and four in the saline-group. Basic patient data are shown in Table II.

Table I. Aetiology of the ulcers

	Gauze	HCD
Venous	12	10
Mixed venous/arterial	2	4

Table II. Basic data

	Gauze	HCD
General health		
Good	12	12
Reduced	2	2
Pulsation (Laser doppler)		
A.dors.ped		
Normal	4	4
Reduced	10	10
Walking	11	9
Walking with help	1	
Mainly sitting	2	5
Weight KG M =	73	70
	(56–132)	(56–84)
Length cm M =	166	164
	(155–187)	(143–175)
BMI	26.8	26.4
	(21.0–37.9)	(20.1–39.1)
Diabetic	4	1
Hypertension	2	1
Odema/medication		
Diuretic	7	8
Morbidity of foot joint		
Normal	5	9
Reduced	9	5

Healing

Seven patients healed and four improved in the HCD-group, while two healed and seven improved in the saline-gauze group. No improvement or deterioration was seen in three patients in the HCD-group and five in the saline-gauze group. The ulcer area decreased in the HCD-group from $\bar{x} = 1387 \text{ mm}^2$ (25–6795) to $\bar{x} = 678 \text{ mm}^2$ (0.5640) after treatment. In the gauze group, the ulcer area decreased from $\bar{x} = 857 \text{ mm}^2$ (80–3808) to $\bar{x} = 696 \text{ mm}^2$ (0–3800). Mean percentage reduction in ulcer area was 51% in the HCD-group and 19% in the saline-gauze group ($p < 0.13$, Wilcoxon test).

Response to the different treatments is shown in Fig. 1 and Table III.

Regarding the patients with increased value of

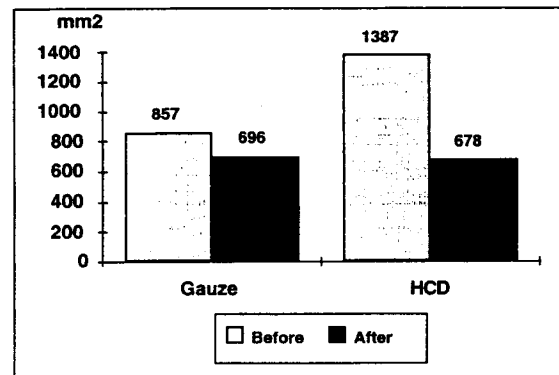


Figure 1. Mean ulcer area before and after six weeks' treatment

Table III. Response to the different treatments

	Healed	Improved	No change/ deteriorated
HCD	7	4	3
NaCl	2	7	5

fasting B-glucose, the patient in the HCD-group healed, two of the patients in the saline-group decreased, and two increased their leg ulcer area.

Treatment costs

The cost and patient convenience were registered on 1234 occasions. There were a total of 181 (2–33) dressing changes in the HCD-group and 1053 (21–94) in the gauze-group during the observation period (six weeks). The mean number of home-visits/patient by the nurse was 59 (max 86) in the gauze-group and nine (max 26) in the HCD-group. The mean number of patient visits to the clinic was 16 (max 55) in the gauze-group and four (max 15) in the HCD-group. The mean number dressing changes per patient was 75 in the gauze-group and 13 in the HCD-group.

For the gauze-group and HCD-group, respectively, the mean material costs were SEK 608 and SEK 653, the mean cost for travel and nursing time was SEK 3518 and SEK 912, and mean total cost/patient during the six-week-period was SEK 4126 and SEK 1565 ($p < 0.009$). Differences in the treatment costs for the total six-week-period are shown in Table IV.

Table IV. Treatment costs, specified week 1–6, all patients SEK

	Gauze	HCD
Dressings, cleansing pads, absorption pads	\bar{x} = 608	\bar{x} = 653
compression bandages	(169–970)	(53–2423)
Nursing staff		
travel, time, costs	\bar{x} = 3518	\bar{x} = 912
Total cost	\bar{x} = 4126	\bar{x} = 1565
SEK	(341–13.157)	(102–6196)

Pain and social impact

Patients in the HCD-group reported significantly less pain at dressing changes ($p < 0.003$) than the patients in the gauze-group.

There were no significant differences between the groups as regards activity and ability to take care of personal hygiene.

Discussion

Nursing care of leg ulcer patients offers special challenges. Routines and rituals that have been practised for years have to be re-assessed at different intervals. The introduction of modern wound dressings that offer advantages both in practical routines and in the influence on healing have to be properly evaluated in a clinical setting. Comparative clinical trials in patient groups of high age, multi-morbidity and varying health and nutritional status always offer problems. In this randomized prospective study, we have investigated the progress of healing and the costs associated with the total care of leg ulcer patients in an authentic clinical setting in Primary Care. The two groups were largely comparable, although the median age was higher in the HCD-group (Md=77.6 yrs) than in the gauze group (Md=73.5 yrs). The two groups were not stratified regarding ulcer size. The ulcer area was bigger in the HCD-group than in the gauze-group at the study start. Even if the ulcer area reduction at completion of the study was 51% in the HCD-group and only 19% in the gauze-group, this difference did not reach statistical significance. The difference might however have been more pronounced if a longer period than six weeks had been studied, since the debriding properties of the HCD-dress-

ing is reported to enlarge the size of the ulcers in the first phase of therapy (4). More patients in the HCD-group healed during the study period ($n=7$) than in the gauze-group ($n=2$). The positive healing results in the HCD-group might be attributed to the mode of action of the hydrocolloid dressing. Fibrinolysis, stimulation of angiogenesis, and faster reepithelialization have been reported for this dressing (5–11).

The material costs were equal in the two groups, but the time spent on travelling and dressing changes, and the costs associated with the total care were almost four times as high in the gauze-group than in the HCD-group. The "year-cost" for the care of a leg ulcer patient has been calculated in several studies. This has been estimated in Sweden at 25 000 SEK (12).

In the present clinical study we have attempted to standardize as many parameters as possible. Thus all patients were bandaged by a nurse on all occasions for optimal, standardized dressing technique and compression. In an authentic clinical situation, it is likely that some patients would be able to perform some dressing changes by themselves. This would of course have altered the costs. In times when health care budgets are limited, routines of such huge impact on the total care must be considered. Patient comfort, reflected in significantly less pain reported at dressing changes in the HCD-group, is also important.

Daily dressing changes, even if appreciated by some patients for psycho-social reasons, are not recommended in modern wound care, unless medical reasons such as erysipelas, etc., are present.

Cost savings, less painful dressing changes, and possibly improved healing can be achieved if the HCD-dressing is consistently used.

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