

## CLINICAL REPORT

# Leg Ulcer Point Prevalence can be Decreased by Broad-scale Intervention: a Follow-up Cross-sectional Study of a Defined Geographical Population\*

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In 1988 a cross-sectional epidemiological study was performed in Skaraborg County, Sweden, establishing leg ulcer point prevalence. Based on the results of that study a complete change in the care of leg ulcer patients was brought into practice. The objective of this postal cross-sectional follow-up study was to evaluate the success of the new management strategy. Responding healthcare providers were asked to report all patients with an open wound below the knee that did not heal within a 6-week period after onset of ulceration. Validity of results was ensured by examining 203 randomly selected patients. Based on clinical examination, an assessment of the underlying causes of ulceration was made. The study setting was inpatient and outpatient care in hospitals, primary care and community care within Skaraborg, with a population of 254,111. The response rate was 100% from district nurses, hospital wards and outpatient clinics. Reports were collected from healthcare providers, mainly nurses, in all 15 communities. A total of 621 individual patients with active leg ulcers were identified. Age-adjusted sex ratio of ulcer patients was 1:1.1 (M:F). The median age was 79 years. A total of 507 patients (82%) were older than 64 years. District and community nurses provided care for the majority (88.5%) of patients. The study verified a point prevalence of 2.4/1000 population in 2002 compared with 3.1/1000 in 1988, a 23% decrease in leg ulcer prevalence. Venous insufficiency was still the dominating causative factor, although the number of patients with venous leg ulcers was reduced by 46%. Arterial ulcers had decreased by 23%, while patients with ulcers of diabetic and multifactorial causes were increased. In conclusion, it is likely that this reduction in point prevalence reflects the introduction of the change in management strategy undertaken in the area. *Key words: leg ulcer; prevalence study; epidemiology; cross-sectional study; aetiology.*

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Leg ulcers cause much suffering for affected patients (1) and consume substantial healthcare resources (2, 3). Approximately 1–2% of the total healthcare budget in western countries is spent on patients with leg ulcers (3). To evaluate the size of the problem various epidemiological studies have been undertaken (2, 4–9). Based on previous studies in Skaraborg County, Sweden (4, 9, 10) the size of the problem in this geographical area has been well defined and resources have been diverted to areas of need. Among the previously identified problems were lack of education and too great a focus on the ulcer itself rather than on its underlying causes.

The strategy undertaken in Skaraborg for improving the outcome for patients with leg ulcer includes education for all healthcare providers and the development of guidelines and organized care pathways, and establishing a leg ulcer network. Special emphasis has been focused on using early Doppler-aided diagnosis and increased use of vascular surgical intervention. There has been an improved use of compression therapy, including prescription of compression hosiery by specialist nurses. In 1999 the Skaraborg Leg Ulcer centre opened with a hospital ward and outpatient clinic. In addition, several nurse-led leg ulcer clinics in different communities have been set up. The aim has been to develop a network around the individual patient, offering tailor-made care based on the aetiology of the leg ulcer, the key phrase being multidisciplinary co-operation. The approach is shared care of leg ulcer patients between both community and primary care nurses, together with specialist care. In addition the approach involves co-operation between different specialists, mainly within dermatology, vascular surgery and infectious diseases. Through providing each patient with an early diagnosis of the ulcer the specialists can be consulted at the appropriate time and not only as the last resource. The outcome goal is not only healed ulcers, but also sustained ulcer healing and thus freedom from recurrence.

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Several studies have shown improved healing rates of leg ulcers for selected cohorts of patients (2, 11), but it is unknown if the improved healing rates also resulted in an actual reduction in leg ulcer prevalence in the total population. The present study is therefore unique in its character by analysing the prevalence in the total population.

The main aim of this study was to evaluate the point prevalence of leg ulcers in Skaraborg and to compare the result with that of a similar study in the same geographical area performed in 1988 (4) in order to investigate the effect of the new management strategy. Furthermore, a secondary aim was to examine possible changes in the aetiological spectrum.

## METHODS

Skaraborg is situated in the south-western part of Sweden. The population of 254,111 consists of a mixed rural and urban population. The proportion of the population older than 64 years was estimated to be 18.4% in 1988 and 19.2% in 2002 (Statistiska Centralbyråns official statistics 31 December 1987 and 1 November 2002). This compares with a mean of 17.7% in 1988 and 17.2% in 2002 in the total Swedish population. The study was approved by the local research ethics committee of Gothenburg University, Sweden.

In order to identify all patients receiving treatment for leg ulcers within the healthcare system in Skaraborg a postal questionnaire study was performed. All healthcare providers within the area were asked to register all leg ulcer patients under treatment during a 6-week period (28 October – 8 December 2002). A chronic leg ulcer was defined as an ulcer below the knee that had been open for 6 weeks or longer. All reported patients were cross-checked to avoid double registration. Healthcare providers were asked to register patients by social security number, which contains information on exact birth date and gender. Taking into account the patients' right to integrity, an option was given to be registered only by year of birth and sex (due to requirements from the research ethics committee).

In 1990 a large reform was made in primary care, which shifted the responsibility for patients from primary care to community care, resulting in more caretakers than in 1988. In order to ascertain that the entire population of leg ulcer patients in Skaraborg was included, it was of utmost importance that all the different groups of caretakers were involved in the study. Prior to the postal questionnaire personal telephone calls were made to all district nurses in primary care, all responsible nurses in the community, all head nurses in hospital wards and outpatient clinics at all 4 hospitals in Skaraborg, informing them how and when the registration was to be conducted. In addition, all chiropodists, diabetic nurses, private nursing homes and private primary care units were contacted. Written information concerning the study defining leg ulcers and how to register the patients was sent together with the registration forms. After the registration period, all responsible community nurses were reminded by e-mail to collect the information from their personnel. All non-responding units were contacted by telephone.

In order to be able to compare the results with those of the 1988 study, special attention was focused on achieving the same high response rate. Thus, all units that had stated that they did not have any leg ulcer patients and all non-responders were contacted by telephone and interviewed thoroughly regarding

whether they had any patients with open ulcers below the knee. In addition, for each patient who had been registered only in a hospital ward or from an outpatient clinic, efforts were made to identify the regular caretaker in primary or community care in the patients' home community.

Validation of the results was ensured by clinical assessment of a random sample of the patients. The patients were randomly selected and stratified according to community (half of the patients reported in each community was selected). The examination included clinical examination of one physician (the first author=AF) including measurement of ankle-brachial pressure index (ABPI) and assessment of venous insufficiency by handheld Doppler. The patients were also interviewed regarding medical and ulcer history. The method of primary examination was the same as in the study of 1988 (10). In the event of indications of venous insufficiency (clinical signs and/or results from the handheld Doppler assessment) further investigation with colour Doppler ultrasound was offered to the patient. The ulcers were classified in the same manner as in 1988 (10) and then grouped into larger groups representing major causes of ulceration: venous, arterial, diabetes, multifactorial and other. The examination results of the patients were reviewed by Dr Olle Nelzén (examining physician in 1988) to ensure that classification was performed in the same manner. Based on the outcome of aetiological assessment an estimate of the aetiological distribution within the total ulcer population was made by assuming an equal distribution, as in the examined random sample.

## RESULTS

The response rate was 100% from district nurses, hospital wards and outpatient clinics. As the small care units within each community had some overlapping areas it was difficult to define the precise number of units that comprised each community. There were, however, replies from responsible nurses in all 15 communities, but it was not possible to define the exact response rate at the community nurse level.

Initially 361 patients were reported by 79 units (16 December 2002). After reminders the total count rose to 802 patients reported by 250 units (20 January 2003). These 802 individuals were cross-checked using social security numbers, resulting in 633 individual patients. Seventy patients chose to be registered by birth year and sex. After corrections, 621 individual patients with active leg ulcers remained (367 women, 254 men (Fig. 1); median age 79 years). The median age for women was 81 (range 37–99) years and for men 75 (range 16–94) years. Eighty-two percent of the patients were over 64 years of age. The sex ratio (male: female) was 1:1.4 and age adjusted 1:1.1.

The majority of patients were reported from a single source, as illustrated in Fig. 1. For patients reported from more than one source, preference was given to district nurses and community nurses as the primary providers of care. Two hundred and twenty-four patients (36%) were cared for by district nurses and 326 (52.5%) by community nurses (Fig. 2).

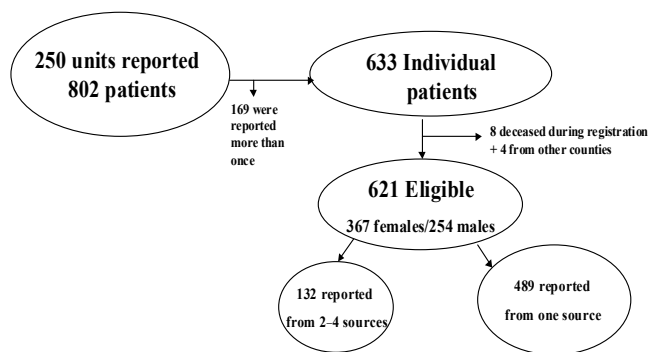


Fig. 1. Study flow-chart.

*Prevalence distribution over age and sex*

Between 1988 and 2002 there was an overall decrease in leg ulcer point prevalence for both men and women. (Fig. 3.) There was a large decrease in prevalence for all age groups over 55 years of age for both men and women, with the exception of men aged 65–74 years, who showed a relative increase. The total number of leg ulcers within this age group was unaltered and the increase in prevalence was due to fewer men in Skaraborg in this age group in 2002 compared with 1988. For the younger age groups (<54 years) the difference in prevalence between 1988 and 2002 was less than ±0.02. The decrease in prevalence increased with age and was also greater for women than for men.

*Validation*

Of the 621 patients, 281 were invited for clinical examination. Of these, 47 declined, 22 were deceased and 9 were lost to follow-up. After examination of 203 invited patients, wrong inclusions were estimated at 2%, which altered the number of leg ulcer patients from 621 to 609, by assuming an equal proportion of wrong inclusions within the total material.

*Point prevalence*

In 1988, 795 patients with ongoing leg ulcers were identified in the same catchment areas as studied here-

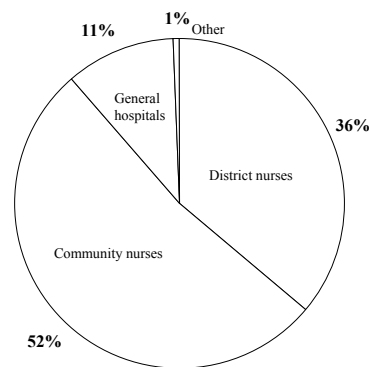


Fig. 2. Primary providers of care for leg ulcer patients in 2002 (n=621).

in (with adjustment made for the exclusion of Habo and Mullsjö communities since 1988) (4). The study verified a point prevalence of 2.4/1000 population in 2002 compared with 3.1/1000 in 1988, suggesting a 23% decrease in leg ulcer prevalence. There were geographical differences between the different communities. Seven out of 15 communities showed a 30% or more decrease in leg ulcer prevalence.

*Ulcer aetiology*

The 203 patients examined had a total of 246 ulcerated legs. The resulting ulcer aetiological pattern is depicted in Fig. 4. There was a pronounced decrease in venous ulcers (-46%) and smaller decrease in arterial ulcers (-23%). There was an increase in both diabetic (+20%) and multifactorial ulcers (+45%).

DISCUSSION

In order to obtain reliable data the present study needed to be broad and very thorough. One obstacle in performing the study was the reorganization in patient care (the ÄDEL-reformation performed in all of Sweden), which shifted the responsibility for the patients from district to community nurses, resulting in many more different caretakers. To ascertain that this did not have an effect great emphasis was placed on reaching all the

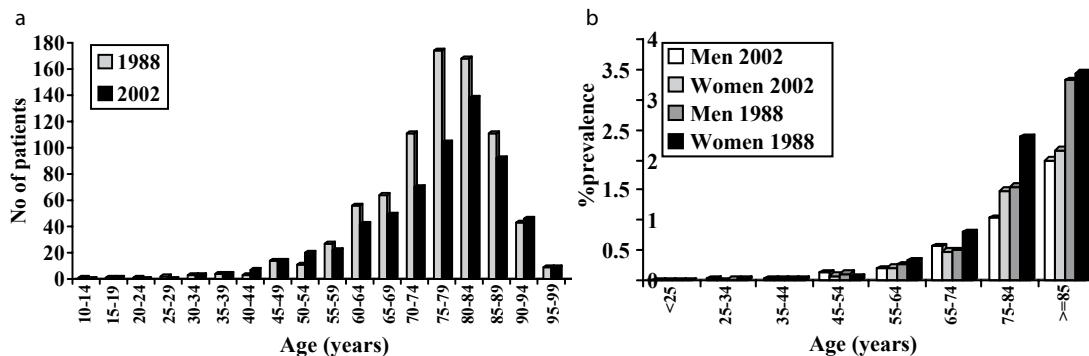


Fig. 3. (a) Age distribution of leg ulcer patients in 1988\* (n=803) and in 2002 (n=621). (b) Distribution of age- and sex-specific prevalence among leg ulcer patients in 1988 and 2002. \*Data from reference (4).

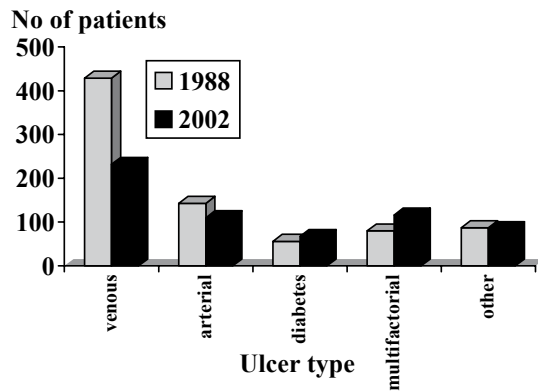


Fig 4. Leg ulcer aetiology 1988 (795 patients)\* (ref 10) and 2002 (609 patients). \*number adjusted for change of catchment area

different caregivers in order to obtain a high response rate. This is illustrated by the initial report, revealing only 361 patients from 79 units, a figure which after extensive reminders by e-mail and personal telephone calls increased to 802 patients reported from 250 units.

Since the main purpose of this study was to evaluate the effect of a changed management strategy for leg ulcer patients it was important to use the same methodology as in 1988. The response rate in 1988 from district nurses, hospital wards and outpatient clinics was comparable to that in 2002 (100%). Community nurses were, however, new and the dominating providers of care in 2002. A total response rate could therefore not be calculated to compare with the 92% response rate achieved in 1988 (4).

Compared with other leg ulcer prevalence studies in the world (2, 5–8) there is a relatively high leg ulcer point prevalence in Skaraborg. It is thought that this is mainly because both studies (1988 and 2002) were thorough, identifying most ulcer patients, and not because the Skaraborg population is more susceptible to leg ulceration. In our studies we had a clear definition of a leg ulcer and we validated the ulcer disease through examination of random samples. Others have claimed a decrease in leg ulcer point prevalence over time but without defining the results of earlier studies (7). Such reports are therefore not fully reliable. There is unfortunately no follow-up study available performed in a geographical area where no interventions in the care of leg ulcer patients have been made, which would be very interesting to compare the natural variations in leg ulcer prevalence.

The most important finding of the present study was the 23% reduction in leg ulcer point prevalence over a 14-year period. The validating study indicates that it was the groups of leg ulcers with curable circulatory diseases (venous and arterial) that have shown reductions in numbers. The distribution of major causes of leg ulcers showed a 46% reduction in venous ulcers

and a 23% reduction in arterial ulcers. There is reliable evidence that superficial venous surgery significantly reduces 12- and 48-month recurrence rates in limbs with chronic venous ulceration (12, 13). Earlier studies have shown that venous ulceration was by far the most common type of leg ulcer in Skaraborg County (10) and the increased use of venous surgery since then might have had an influence. Documented evidence of very low ulcer recurrence rates following subfascial endoscopic perforator surgery and superficial venous surgery has been published recently from Skaraborg, validating the observed marked reduction in venous ulcers in the present study (14). As seen in Fig. 4 the venous and arterial ulcers still dominate (54%), indicating that a further reduction can probably be made. The results from 2002 also indicate that ulcers with multi-factorial causes have increased by 46% and diabetic ulcers have increased by 20%. The fact that the group of diabetic-related ulcers had increased is in correlation with the increasing number of diabetic patients in Skaraborg. Patients with leg ulcers with multi-factorial causes are usually elderly and suffering from multiple associated diseases. Since no single treatable cause of the multi-factorial ulcers can be identified, these are the most difficult to treat. The fact that patients with chronic diseases today have longer life expectancy in addition to limited treatment options probably explains why the multifactorial group has increased. These data are, however, in need of further evaluation.

In view of the fact that the current population is slightly older than in 1988 (see method) one would have expected an increase in leg ulcer prevalence rather than the opposite, if management is unchanged, since increasing age is reported to be the single most important risk factor for developing leg ulcers (2, 5, 6, 8, 9). The 23% decrease in leg ulcer point prevalence might therefore be an underestimation of the effect of the changed management strategy. To this could be added the fact that the population in Skaraborg lives in an area where there has traditionally been a high interest in the care of leg ulcers, which has resulted in increased media attention and probably more awareness among the population. It is therefore possible that there are more patients who seek healthcare for their leg ulcers today than in 1988.

Our methodology in 2002 may underestimate the prevalence of leg ulcers, since data is based on reports from many more healthcare providers than in 1988. We have not taken into account the patients who cared for their ulcers themselves, either in this or the previous study. An earlier similar study in 1990 (9) using a validated population questionnaire presented a prevalence of 0.63%, indicating that half of all patients with leg ulcers were unknown to healthcare providers. Preliminary results from a similar population study in 2005 indicate that there were no more self-carers in 2002 than in 1988.

There was a possible risk of overestimating the number of patients through double registration of the 70 patients who chose to be registered only by birth year and sex. These patients were, however, compared by area of registration, sex and age and only 4 possible matching individuals were found and, in addition, the validation of the material through examination of 203 patients showed only 2% wrong inclusions. We therefore find that the risk of overestimating leg ulcer prevalence is very low.

In the previous study in 1988 the gender proportions were 1.7 females for every male (1.4:1 after age adjustment). By tradition most other reports show that women outnumber men by 2 to 1 (2, 5), without adjusting for age. In the present study the female:male ratio was 1.4:1 and only 1.1:1 after age adjustments. The relative decrease in leg ulcer prevalence was smaller for men than for women. Possible explanations might be that women adhere better to treatment advice than men do and that men might consult healthcare more frequently today.

Previous studies have defined the high costs of leg ulcer treatment (2, 3). A 23% reduction in the number of leg ulcer patients saves a lot of healthcare resources. One year of treatment for a leg ulcer patient has been estimated to cost 79,500–110,800 SEK (3). Using these figures a rough estimate of the yearly cost saving leads to an annual sum of 15–23 million SEK in Skaraborg, corresponding to 1.7–2.5 million Euros.

In conclusion, this is a unique study of a kind not previously reported in the literature. The point prevalence of leg ulcers has been reduced by 23% within our population and we believe that this is likely to have been the result of the changes implemented in leg ulcer management. The fact that the groups of leg ulcer patients with curable and treatable circulatory disturbances showed lowered prevalence figures indicates that our strategy is appropriate and effective. There is a great need for repeated educational efforts and open communication, which we continuously try to develop. That this is of great importance has been indicated in a UK study, which showed declining healing rates when the involvement of leg ulcer nurse specialists was discontinued (15).

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