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CLINICAL REPORT

A Repeat Validated Population Questionnaire of a Defined Swedish Population Verifies Reduction in Leg Ulcer Prevalence Over Time

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This study was performed to measure if the introduced interventions in leg ulcer care in a selected Swedish county yield a detectable reduction in leg ulcer prevalence in the population. A validated postal questionnaire sent to 10,000 (9,868) randomly selected 30–89-year-olds in the Skaraborg county (255,042 inhabitants). All positive responders were telephone-interviewed and verified ulcer patients were clinically examined including assessment of arterial/venous circulation with hand-held Doppler and, where indicated, duplex ultrasound scanning. All results were compared with numbers from 1990 (initial study). The response rate was 82% (8,070/9,868), 200 active ulcers and 290 previous ulcers. The calculated prevalence was 0.75% for 30–89 years and 1.05% for 50–89 years (2.1% in 1990). The leg ulcer prevalence was reduced by 32% (0.52% compared to 0.77% in 1990), and the relative risk was reduced by 50% (95% CI 0.36–0.69). The study shows a true reduction in leg ulcer prevalence detectable in the population supporting a successful care of leg ulcer patients. ***Key words: leg ulcer; prevalence study; epidemiology.***

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Leg ulcer is a common condition (prevalence 0.06–0.36%) causing significant patient suffering such as pain and deterioration of quality of life (1–3). The patients are dependent on healthcare staff for often frequent dressing changes. The tendency of long duration of an active ulcer (>1 year in 50%) and the high recurrence rate (~60% recurrent ulcers) means that the patients often suffer long periods and therefore the condition is unfortunately often referred to as chronic condition (2, 4–6). Studying the underlying causes of leg ulcers is therefore of importance as it enables the possibility of even curing the patient from the condition. Primarily, this is important for the patient but also has a great socioeconomic impact as the annual cost for treating a leg ulcer has been calculated to up to €10,000 (7).

Increasing age is the single most important risk factor for developing any leg ulcers (1, 5). It is thus expected that the leg ulcer prevalence will increase with ageing populations. The 2 main causes of leg ulcers are arterial and venous insufficiency (4–6). Studies indicate that peripheral artery disease is a growing pandemic problem, and with growing age and obesity, which are 2 of the main risk factors for varicose veins, it is expected that the 2 main groups of leg ulcer will become an increasing problem (8, 9).

In Skaraborg County several epidemiological studies concerning leg ulcer prevalence and aetiology have been performed from the late 1980s onward. The purpose of the earlier studies was to define the size of the problem and the burden on the health care resources in the treatment of leg ulcer patients (4, 10, 11). The results from these studies have been valuable in developing treatment guidelines, organised care pathways, education and multidisciplinary care for the leg ulcer patients (12). Early field diagnosis of leg ulcers primarily by the use of hand-held Doppler (HHD) has been an important issue. The hospital clinics have gained easy access to duplex ultrasound scanning (DUS) in ulcer diagnosis and increased liberal use of early vascular surgical interventions that have emerged as key elements (6, 12, 13).

The initial Skaraborg study in 1988 registering the leg ulcers known in the health care system was followed by a population study in 1990 based on a validated questionnaire including 12,000 randomly selected inhabitants of Skaraborg County (6,000) and the city of Malmö (6,000) aged 50–89 years (10, 11). The results indicated that there was a high rate of self-treatment among leg ulcer patients as the observed point prevalence of active leg ulcers in Skaraborg was 0.77%, more than twice as much as expected (calculated from the healthcare study in 1988) (10, 11). To ascertain that the observation of decreased leg ulcer prevalence in the study of 2002 (registering the patients with active ulcers known to health care) was reliable, this repeated population study using the same questionnaire as in 1990 was performed (6, 11, 13). The follow-up studies including this study were performed to evaluate the effectiveness of the new strategies of leg ulcer care (6, 12–14). This study aims to measure if there is a detectable reduction in leg ulcers in the total population as indicated pre-

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viously within health care and if the extent of self-care of leg ulcers has changed.

MATERIAL AND METHODS

In February 2005 a simple questionnaire, identical to the one used in 1990 was sent to 10,000 randomly selected 30–89 year old individuals in Skaraborg (11). The study was approved by the local ethics committee of Gothenburg University, Sweden.

The extended age range including subjects 30–49 years was chosen due to results from a study of industrial workers indicating an unexpected high prevalence of leg ulcers in younger age groups (15). The randomisation was made through a computer company using official population registers (VM-data Skaraborg). At the time there were 164,367 individuals within the age range 30–89 years in Skaraborg with a total population of 255,042. The randomised selection represented 6% of the population within that age range. Reminders were sent out to 3,209 non-responders 6 weeks after the initial inquiry. All answers were registered by the end of March.

In the selection of 10,000 individuals, 132 were actually only 29 years old (about to turn 30 during the year of the investigation) at the time of the questionnaire. Eighty-eight of the individuals who were wrongly included responded to the questionnaire, 87 had no ulcer and 1 had a previous ulcer. All 132 individuals were disregarded making 9,868 questionnaires evaluable.

Just as in the previous studies a leg ulcer was defined as an ulcer below the knee (including foot ulcers) that has not healed or is not expected to heal within 6 weeks after onset regardless of the cause (4, 5, 10, 11, 14, 16). The study form (identical to the initial study in 1990) consisted of a short definition of leg ulcers and 2 questions: 1) Do you have an active ulcer on your lower leg/feet? 2) Have you previously had one? If the answer was yes in either question we asked that the subject marked out the location of the ulcer on a drawing of 2 lower legs (11). All positive responses were primarily regarded as possible active ulcers regardless if they had marked on the drawing or not. All individuals with an active leg ulcer according to the questionnaire were contacted by telephone for further interview. The subjects were asked to describe the ulcer by signs, symptoms, location, duration, treatment and any contact with the health care system. After the telephone interview the subjects that still filled the criteria for active leg ulcers or that presented any uncertainties about the diagnosis were invited for a medical examination and non-invasive assessment of venous and arterial circulation with HHD in the same manner as previous studies (4, 6). All legs were graded according to Venous Clinical Severity Score (VCSS) and further investigation with DUS was offered when signs of venous insufficiency was detected (17). The ulcers were classified in the same manner as in previous studies in the main groups venous, arterial, diabetic, multifactorial and other, all with underlying subgroups (4, 6). All healed ulcers at the time of examination were considered as on-going ulcer at the initial inquiry rather than previous as it in many cases was difficult to obtain the exact date of healing. All examinations were finalised within 3 months after the initial survey.

Statistics

All the data from the questionnaire and the examinations were recorded and processed in Statistical Package for the Social Science (SPSS) version 18–21 (SPSS Chicago, IL, USA).

Official statistics were used to acquire data about the population size, age and sex distribution at the time of the study (from Statistics Sweden). The statistical testing of prevalence changes between 1990 and 2005 was done by χ^2- test. Relative risk (RR) with 95% confidence intervals was calculated to compare the prevalence levels and to quantify the difference. $p < 0.05$ was considered as statistically significant.

RESULTS

The initial response rate was 68% and rose to total response rate of 82% after one reminder. The flowchart of the study is shown in Fig. 1. The age-specific response rate was 74% for 30–49 years and 87% for 50–89 years. The 8,070 evaluable responders represented 5% of the total population of 30–89-year-olds in Skaraborg County. The age range of the examined leg ulcer patients was 36–87, median 69 years. There was an equal number of women and men among the 34 leg ulcer patients verified by clinical examination. Men were however overrepresented among the positive responders in the survey and thus also among false positive responders (Table I).

The aetiological distribution after clinical examination is shown in Table II.

Venous ulcers dominated as expected but the low number of ulcers makes any further analysis and conclusions regarding the distribution of ulcer types not possible.

False positive responders

There were a total of 140 (70%) false positive responders, 24 that misunderstood the questionnaire, 26 with previous ulcer and 90 patients with other diagnoses (72 according to telephone interview and 18 additional after examination) (Fig. 1). The causes of the 72 false positive responses according to telephone interview were 47 with eczema (65%), 5 with athlete's foot and 20 with other skin diseases. Among the 18 false po-

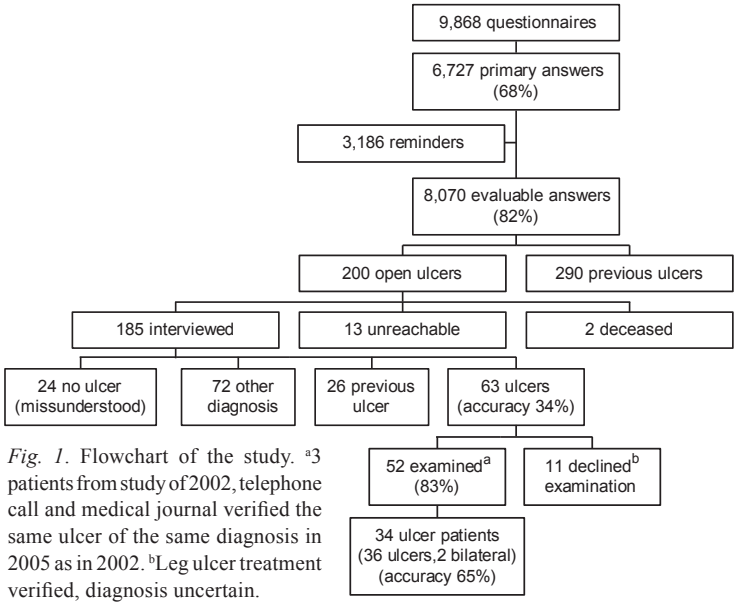

Fig. 1. Flowchart of the study. [a]3 patients from study of 2002, telephone call and medical journal verified the same ulcer of the same diagnosis in 2005 as in 2002. [b]Leg ulcer treatment verified, diagnosis uncertain.

Table I. *Sex distribution of positive responses in the survey and verified ulcers after clinical examination*

	Survey	Examination[a]
Men, *n* (%)	112	17 (21)
Women, *n* (%)	88	17 (24)
Total, *n* (%)	200	34 (45)

[a]Including 11 non-attenders, 4 men and 7 women verified by clinical records.

sitive examined patients, 8 had eczema (44%) and 10 had other skin diseases. In all 61% (55/90) of the false positive responses were caused by eczema.

Self-carers

Twelve patients had not previously been in contact with the health care system for their leg ulcer. Nine of these had no wound dressing (8 were not active ulcers at the time of examination) and 3 cared for the ulcer themselves or by a family member. Another 2 patients had previously contacted health care but cared for their current ulcer themselves. All 14 leg ulcer patients were unknown to the health care system and were regarded as self-carers.

Calculation of number of leg ulcers

The number of leg ulcers were calculated by excluding the false positive responses (96) and previous leg ulcers (26) according to telephone interview and the false positive responses after clinical examination (18) from the initial positive responses ("yes leg ulcer") in the survey (200). This resulted in 60 leg ulcers.

Leg ulcer prevalence

According to the earlier study in 2002 of ulcer prevalence in the health care system, 91% of leg ulcers were within age group 30–89 years old (55/621 [9%] were older than 90 years and 1/621 [0.2%] younger than 30) (13). These numbers were used in estimating the total number of leg ulcers in the population (1,332) resulting in a total prevalence of 0.52% (Table III).

The expected prevalence based on the study of the leg ulcer patients known to health care in 2002 and the observed prevalence in the population are presented in Table III (13). Comparisons with the results from 1990 are also presented in Table III. The observed prevalence was still more than double than expected. However, the detectable prevalence reduction within the population was 32% compared with the reduction of 23% within healthcare 3 years earlier (13).

Table II. *The distribution of major causative factors among the examined patients (*n = *52) excluding the false positive (*n = *18)*

Aetiologic group	Legs, *n* (%)	Expected %
Venous	13 (36)	38
Arterial	4 (11)	17
Diabetes	3 (8)	12
Multifactorial	4 (11)	19
Other[a]	12 (33)	14
Total[b]	36	

[a]Pressure ulcer, hydrostatic ulcer, skin disease, traumatic ulcer, skin tumour, artefact. [b]Two patients with bilateral ulcers (1 venous and 1 arterial).

Table III. *Expected and observed leg ulcer prevalence (*n = *60) in Skaraborg County 1990 and 2005*

	1990		2005	
	Expected[a]	Observed prevalens[b]	Expected[c]	Observed prevalens[d]
Age group				
30–39 years			0.02	0.3
40–49 years			0.1	0.2
50–59 years	0.1	1.4	0.1	0.6
60–69 years	0.4	1.8	0.3	1.2
70–79 years	1.3	1.9	0.8	1.2
80–89 years	2.8	5.1	1.8	1.9
30–89 years			0.35	0.75
50–89 years		2.1	0.55	1.05
Total population	0.30	0.77	0.23	0.52

[a]Prevalence of leg ulcers known to health care 1988 (10). [b]Prevalence of leg ulcers according to postal survey 1990 (11). [c]Prevalence of leg ulcers known to health care 2002 (13). [d]Calculated of leg ulcers prevalens 2005 (see Method), 60 leg ulcers.

Previous leg ulcer

Assuming an identical overall response accuracy (30%) among the initial 290 individuals responding yes to a previous leg ulcer and adding the 26 verified by telephone (assuming an accuracy of 100%) resulted in a total of 2,508 previous leg ulcer patients in the population, representing a prevalence of 1.5% compared to 1.8% in 1990 (11). The ratio of previous leg ulcer to current active leg ulcer was 2:1, comparable to earlier results (11). The total prevalence of previous ulcers in the age group 50–89 years was 1.8%.

Relative risk

Comparison of the prevalence and calculation of the relative risk of an active leg ulcer with the results from 1990 are seen in Table IV.

Table IV. *Comparison of prevalence and relative risk (RR) of leg ulcer in Skaraborg in 1990 and 2005*

	Prevalence per 1,000			
	1990[a]	2005 (*n* = 60)[b]	RR[c]	95% CI
Age group				
50–59 years	14.4	5.6	0.38*	0.18–0.79
60–69 years	17.7	12.2	0.69	0.39–1.20
70–79 years	18.5	11.7	0.63	0.33–1.21
80–89 years	50.6	18.6	0.37*	0.19–0.72
Total 50–89 years	21.0	10.5	0.50*	0.36–0.69

[a]Prevalence of leg ulcers according to postal survey 1990 (11). [b]Representing the maximum calculated number of leg ulcers registered in the postal survey of 2005 (see Method). [c]RR for year 2005 compared to 1990.
*Statistically significant.

There was in all a 50% less risk of developing an active leg ulcer in the age group 50–89 years ($p < 0.001$). The largest significant risk reduction of over 60% was observed for the age groups 50–59 ($p = 0.007$) and 80–89 ($p = 0.002$). In the age groups 60–69 and 70–79 the risk reduction was 31% and 37%, respectively, which was not statistically significant ($p = 0.186$ and $p = 0.158$, respectively). There is no obvious factor found that explains the difference between the age groups. The total risk of an active leg ulcer is clearly increasing by increasing age as seen on the prevalence numbers in Table III.

DISCUSSION

This study was important to perform in order to evaluate the introduction of a new strategy in the care taking of leg ulcer patients and to certify that the leg ulcer prevalence in the Skaraborg county population truly has decreased as indicated by the study of the prevalence in the health care system in 2002 (6, 12, 13). This verification was important to ascertain whether the detected decrease in leg ulcers known in the health care system was not due to fewer patients seeking health care professionals, i.e. more self-carers.

A weakness of the study is the limited number of clinically examined patients which was the result of choosing a method of a preceding telephone selection before offering clinical examination. This choice of method was based on earlier findings of 34% false positive responses among the patients that accepted to be clinically examined in the study from 1990 (11). The method was thus thought to be able to define more easily the false positive responses by telephone interview to limit the number of unnecessary clinical examinations. An advantage of this method was that 93% (185/200) positive responders were contacted and further interviewed compared to in 1990, where clinical examination (83/179; 46%) was the only further patient contact (11). In this study 86% of patients offered examination were actually examined.

The important strengths of the study is that it clearly defines the population, includes a large number of individuals without selection bias, has a clear definition of leg ulcers and includes clinical confirmation of the presence and a thorough diagnosis of the ulcers. All these are important parameters in establishing true leg ulcers prevalence (1)

The total false response rate of 70% illustrates that self-report of leg ulcers is an uncertain method if it is used without validation (11, 18). The finding of 61% of eczema among the false positive responses is comparable to the 75% of eczema found in 1990 (11). It is thus very important in all epidemiological leg ulcer studies to verify the presence of a leg ulcer through interview and/or preferably clinical examination.

The small number of clinically examined patients limits any deeper analysis of the aetiological groups of leg ulcers. The distribution is however in the larger groups, arterial and venous, similar to that expected, whereas the group of multifactorial leg ulcers was smaller than expected (6). This could possibly be explained by the median age of 69 in the group of examined patients in this study compared to the median of 76 years (age range 30–98) in 2002 (6) in the health care system. In that study the median age of the multifactorial ulcers was 78 (age range 59–92 years) (unpublished data from 2002).

There was still a group of patients that cared for their ulcer by themselves. In our study 23% (14/60) were self-carers compared to 44% (82/181) in 1990 (11). There were up to 50% self-carers among the patients younger than 50 years. The less extent of self-carers supports that the prevalence reduction of leg ulcers known within health care in Skaraborg is a true reduction and indicates that more patients seek health care for their ulcers (13). There is thus a more patient and health care awareness in diagnosing and treating leg ulcers. Patients seem to be more prone to seek healthcare for their ulcers since good publicity and reputation probably gives patients better hope in healing their leg ulcers.

It is important to perform epidemiological studies in order to define the patient burden of specific medical conditions to enable development of new ways of caretaking and to evaluate new strategies. To our knowledge this type of studies are seldom performed and no other study has presented a detectable decrease in leg ulcer prevalence over time although a 20-year follow-up study in Newcastle showed an unchanged leg ulcer prevalence (19).

The epidemiological studies in Skaraborg in 1988 and 1990 created a base line before the onset of structured broad-scale interventions of leg ulcer care. The follow-up study in health care (13) and this population study clearly indicate the success of the Skaraborg model by a detectable decrease of total leg ulcer prevalence of 23% registering the patients known in health care and 32% registering all leg ulcer patients in the population (13). As other studies indicate that there is an increasing number of patients suffering from peripheral artery disease and at least unchanged prevalence of venous stasis syndrome and ulcers in combination with an ageing population which in itself is the most important risk factor for leg ulcers, it is expected that leg ulcer prevalence would naturally increase (1, 5, 8, 10–13, 20, 21). This supports the fact that it is the interventions in Skaraborg that has led to a substantial decrease in leg ulcer prevalence which is unique and inspires to further improvements. In this study a careful approach in calculating the number of leg ulcers was chosen in order not to underestimate the problem and overestimate the positive results. There are however some indications that the numbers could be far more positive.

The work is continuous and these data have served as the ground for further development of the leg ulcer care. To limit the expected increasing number of leg ulcer patients is of upmost importance both for economic incentives and for the patients' wellbeing.

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REFERENCES

1. Graham ID, Harrison MB, Nelson EA, Lorimer K, Fisher A. Prevalence of lower-limb ulceration: a systematic review of prevalence studies. Adv Skin Wound Care 2003; 16: 305–316.
2. Briggs M, Flemming K. Living with leg ulceration: a synthesis of qualitative research. J Adv Nurs 2007; 59: 319–328.
3. Herber OR, Schnepp W, Rieger MA. A systematic review on the impact of leg ulceration on patients' quality of life. Health Qual Life Outcomes 2007; 5: 44.
4. Nelzén O, Bergqvist D, Lindhagen A. Leg ulcer etiology – a cross-sectional population study. J Vasc Surg 1991; 14: 557–564.
5. Cornwall JV, Dore CJ, Lewis JD. Leg ulcers: epidemiology and aetiology. Br J Surg 1986; 73: 693–696.
6. Forssgren A, Nelzén O. Changes in the aetiological spectrum of leg ulcers after a broad-scale intervention in a defined geographical population in Sweden. Eur J Vasc Endovasc Surg 2012; 44: 498–503.
7. Nelzén O. Leg ulcers: Economic aspects. Phlebology 2000; 15: 110–114.
8. Fowkes FG, Rudan D, Rudan I, Aboyans V, Denenberg JO, McDermott MM, et al. Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. Lancet 2013; 382: 1329–1340.
9. Robertson L, Lee AJ, Gallagher K, Carmichael SJ, Evans CJ, McKinstry BH, et al. Risk factors for chronic ulceration in patients with varicose veins: A case control study. J Vasc Surg 2009; 49: 1490–1498.
10. Nelzén O, Bergqvist D, Hallböök T, Lindhagen A. Chronic leg ulcers: an underestimated problem in health care among elderly patients. J Epidemiol Community Health 1991; 45: 184–187.
11. Nelzén O, Bergqvist D, Lindhagen A. The prevalence of chronic lower-limb ulceration has been underestimated: results of a validated population questionnaire. Br J Surg 1996; 83: 255–258.
12. Nelzén O. Fifty percent reduction in venous ulcer prevalence is achievable – Swedish experience. J Vasc Surg 2010; 52 5 Suppl 5: 39–44.
13. Forssgren A, Fransson I, Nelzén O. Leg ulcer point prevalence can be decreased by broad-scale intervention: a follow-up cross-sectional study of a defined geographical population. Acta Derm Venereol 2008; 88: 252–256.
14. Nelzén O, Fransson I. True long-term healing and recurrence of venous leg ulcers following SEPS combined with superficial venous surgery: a prospective study. Eur J Vasc Endovasc Surg 2007; 34: 605–612.
15. Nelzén O, Bergqvist D, Fransson I, Lindhagen A. Prevalence and aetiology of leg ulcers in a defined population of industrial worker. Phlebology 1996; 11: 50–54.
16. Nelzén O, Bergqvist D, Lindhagen A. Long-term prognosis for patients with chronic leg ulcers: a prospective cohort study. Eur J Vasc Endovasc Surg 1997; 13: 500–508.
17. Rutherford RB, Padberg FT Jr, Comerota AJ, Kistner RL, Meissner MH, Moneta GL. Venous severity scoring: An adjunct to venous outcome assessment. J Vasc Surg 2000; 31: 1307–1312.
18. Firth J, Nelson EA, Hale C, Hill J, Helliwell PJ. A review of design and reporting issues in self-reported prevalence studies of leg ulceration. Clin Epidemiol 2010; 63: 907–913.
19. Sala Tenna A, Stevens H, Lees T. Have we reduced the prevalence of leg ulcers? A repeat audit after 20 years in an urban health district (Abstract). Br J Surgery 2013; 100 (S2): 1–8.
20. Heit JA, Rooke TW, Silverstein MD, Mohr DN, Lohse CM, Petterson TM, et al. Trends in the incidence of venous stasis syndrome and venous ulcer: A 25-year population based study. J Vasc Surg 2001; 33: 1022–1027.
21. Pannier-Fischer F, Rabe E. Epidemiology of chronic venous diseases. Hautarzt 2003; 54: 1037–1044.