

# The evolution of a hospital based leg ulcer clinic

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## Abstract

The objective was to determine whether there was a change over time in referral patterns, as well as clinical and demographic features, of patients attending a hospital based outpatient leg ulcer clinic based at a tertiary referral hospital servicing a total population of 473,500. This prospective clinical audit involved the collection of comprehensive clinical data of all patients referred to the ulcer clinic over an 8 year study period.

The referral source, patients' demographic and clinical features, as well as the type of management instituted were recorded. Six hundred and twenty seven patients attended the clinic. The mean age of patients at admission was 72.3 years. General practitioners (GPs) referred approximately 80% of these patients and there was no significant change in patients' demographic features.

Over time, there was a statistically significant increase in the number of patients who presented with an ulcer which had been present for less than 3 months and there was a significant decrease in the proportion of subjects who presented with multiple ulcers. The proportion of venous ulcers treated at the clinic decreased from 53.7% during the first two year period to 35.9% in the final two year period, whilst there was a 6% increase in the proportion of ulcers caused by combined arteriovenous insufficiency over this time. In conclusion, although there was only minimal change in patients' demographic features or referral source, there was a significant change in the clinical features of patients over time.

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## Introduction

Chronic lower limb ulceration is a common and often recurrent condition in the elderly population. An epidemiological study conducted in Western Australia reported that approximately 15% of the people over 80 years of age had a leg ulcer<sup>1</sup>.

Effective management of a leg ulcer requires active follow-up and frequently places considerable demand on hospital, as well as community, medical and nursing resources<sup>2</sup>. Though it is difficult to accurately calculate the total costs of treating leg ulcers, Baker *et al.* estimated that the cost of treating venous leg ulceration in Australia ranged between \$A365 million and \$A431 million<sup>1</sup>.

It has previously been shown that community and hospital based leg ulcer clinics can dramatically improve patients' quality of life, decrease ulcer healing times and are cost effective<sup>3,4</sup>. Though much is known about establishing leg ulcer clinics<sup>5,6</sup>, considerably less is known about how these clinics change over time.

This audit reviews a hospital based leg ulcer clinic which has been operating since 1994. This clinic is based at the Royal Hobart Hospital, a tertiary referral hospital in Tasmania, and services a population of 473,500<sup>7</sup>.

A formal review of this leg ulcer clinic was conducted in 1997, 40 months after its opening <sup>6</sup>. However, as highlighted by Lambourne *et al.* <sup>8</sup>, the clinical audit is a continuous process of evaluation, change in practice and re-evaluation which must not be seen in isolation. This present audit assesses the transformation in wound care, describing the pattern of clinic referrals, patients' demographics as well as the change patients' clinical features. Through investigating the change in referral patterns and patient characteristics it is anticipated that further improvements in wound care management could be made.

## Method

### Patient selection

This study was conducted at the leg ulcer clinic of the Royal Hobart Hospital. All patients who were referred to the clinic between March 1994 and March 2002 were included in this study. Once a patient had been admitted to the clinic they were reviewed until either their ulcer had healed, it was deemed that their ulcer was likely to heal with no further intervention, or an appropriate referral for further management had been made; at which point they were discharged from the clinic.

Given that clinical characteristics change over time, patients who had been discharged and were later referred back to the ulcer clinic were classified as a new admission. When a patient who had been admitted to the clinic developed another ulcer prior to being discharged, they were not treated as a new patient or separate admission; however, a record of the new ulcer was made.

Patients were excluded from this study if their ulcer had healed prior to admission, provided that they did not develop another ulcer before discharge from the clinic. Patients who presented with no ulcer and who had no prior history of limb ulceration were classified as being inappropriately referred and were also excluded from analysis.

### Data collection

Clinical and demographic information were collected prospectively through the regular operation of the clinic. A detailed medical history was obtained from each patient at initial presentation. The duration of the ulcer prior to attending the clinic was classified categorically as being: less than 3 months; between 3-6 months; between 7-12 months; longer than 12 months; or recurrent. Recurrent ulceration was defined as an ulcer which had healed yet had subsequently broken down again.

Clinical examination findings of each patient's lower limbs and specific details of the ulcer were recorded. Importantly, the ulcer site on the leg (where Zone 1 referred to the region below the medial malleolus, Zone 2 the region between the medial malleolus and the widest part of the patient's calf and Zone 3 being above the widest section of the calf) <sup>9</sup>, the surface area of the ulcer and ankle brachial pressure index were recorded.

Investigation results performed immediately prior to admission or undertaken as a part of the clinical assessment were also recorded. Laboratory tests, plain x-rays, arterial or venous duplex scans, and tissue biopsies were performed only when clinically indicated.

The clinical information obtained allowed each patient's ulcer to be classified according to aetiology. The aetiology of each

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ulcer was categorised by a medical specialist who oversaw the clinic for the duration of the study period. Patients' clinical details were updated when their clinical information changed or became available. The aetiology of ulcer formation assigned to each patient was regularly reviewed.

The type of treatment for each patient initiated at the clinic was noted. Importantly, the type of dressings and the type of bandage was recorded. The dressings were subdivided to include:

- Alginates and hydrofibres – Aquacel, Algoderm, Kaltostat, Sorbsan.
- Cadexomer iodines – Iodoflex.
- Films.
- Polyurethane foam – Allevyn, Cutinova foam, Biatain, Lyofoam.
- Hydrocolloids – Comfeel, Cutinova, Duoderm.
- Hydrogels – Clearsite, Intrasite.
- Other dressings not previously categorised.

Bandages were classified as being:

- High pressure compression bandage – Charing Cross 4-layer.
- Low pressure compression bandage – Charing Cross 3 layer.
- Protective, retention bandage.

All clinical information and action taken during each appointment at the clinic was recorded on specially prepared clinical data sheets.

### Data analysis and management

Data collected during each clinic were entered into a Filemaker Pro® database on a personal computer. At the conclusion of the study all data were reviewed and the database was 'cleaned' of duplication and typographic errors. The process of data review was undertaken using Microsoft Excel®. Statistical analysis was undertaken using the Stata® version 7 program. Missing data identified when cleaning the database were obtained, where possible, from previous medical notes or directly by phone consultation with the patient.

The primary endpoint for this study was the number of new admissions and frequency of follow-up attendances made to the clinic over the 8 years. The state of healing of each patient's ulcer and the type of treatment initiated was assessed as important functional indicators of the clinic.

The outcome measures for this study were subdivided into the change in referral patterns and patient demographic features, as well as the change in new patients' clinical features. Patients were grouped according to the date at which they were first admitted to the leg ulcer clinic. To determine the temporal relationship of the clinic referrals and patient characteristics the study period was subdivided into

four 2 year periods. An assessment of wound healing was made at the conclusion of each 2 year period. Patients whose ulcer had not healed were then carried into the next subdivided period. However, they were not classified as a new admission to the clinic in that following period.

The Chi-squared test of trend was performed to measure the correlation over time between variables which had categorical outcomes. A one-way analysis of variance was used to determine difference between variables which had a continuous outcome. Age at admission, follow-up times and number of reviews conducted were analysed using a one-way analysis of variance. Statistical significance was set at  $p=0.05$ .

### Ethics approval

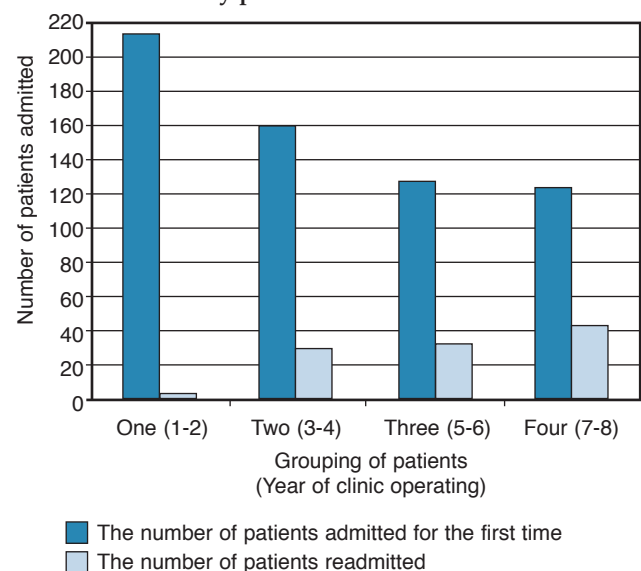
Ethics approval was obtained from the Southern Tasmania Health & Medical Human Research Ethics Committee.

## Results

### Referral and admission patterns of the clinic

During the study period 627 patients were referred to the clinic. After discharge, 77 (12.3%) of these patients were later referred back to the clinic. As shown in Figure 1, the number of new patients admitted to the clinic decreased during the study period, whilst the number of patients who were referred back to the clinic increased. Fifty four (8.6%) patients were referred back to the clinic for a third time. During the study period no patient was referred more than five times to the clinic. All patients were grouped according to year of admission, Group 1 (years 1 and 2), Group 2 (years 3 and 4), Group 3 (5 and 6) and Group 4 (7 and 8).

**Figure 1. Pattern of patients admitted to the clinic over the study period.**



**Table 1. Referral sources of patients admitted to the clinic.**

Referral source	Group 1		Group 2		Group 3		Group 4		Overall	
	n	%	n	%	n	%	n	%	n	%
GP	194	89.8	164	86.7	141	87.0	144	84.7	643	87.2
Surgeon*	11	5.1	14	7.4	8	4.9	8	4.7	41	5.6
Physician †	6	2.7	7	3.7	7	4.3	5	2.9	25	3.4
Accident and Emergency	3	1.3	3	1.6	5	3.1	8	4.7	19	2.6
District Hospital	0	0.0	1	0.5	1	0.6	4	2.4	6	0.8
Allied health professional ‡	2	0.9	0	0.0	0	0.0	1	0.6	3	0.4
<b>Total</b>	<b>216</b>		<b>189</b>		<b>162</b>		<b>170</b>		<b>737</b>	

\* General, vascular and orthopaedic surgeons

† Rheumatologists, oncologists, nephrologists and general physicians

‡ Diabetic coordinators, podiatrists, occupational therapists and physiotherapists

The number of patients who were treated for secondary ulceration, which was not present at admission, decreased – from 35 in Group 1, to 17 in Groups 2 and 3, whilst 23 patients from Group 4 developed a new ulcer whilst under the care of the clinic. Ninety two patients developed another ulcer prior to being discharged from the clinic.

There were a total of 10 inappropriate referrals to the clinic during the study period. These patients were either referred to the clinic due to dermatitis, chronic venous disease or peripheral arterial disease. A further 21 patients were excluded from analysis because they had a past history of leg ulceration, yet when reviewed at the clinic had no signs of an active ulcer. There was no association between the date when these referrals were made and the length of the clinic operating.

Table 1 presents the referral source of patients to the clinic. General practitioners (GPs) referred the majority of patients.

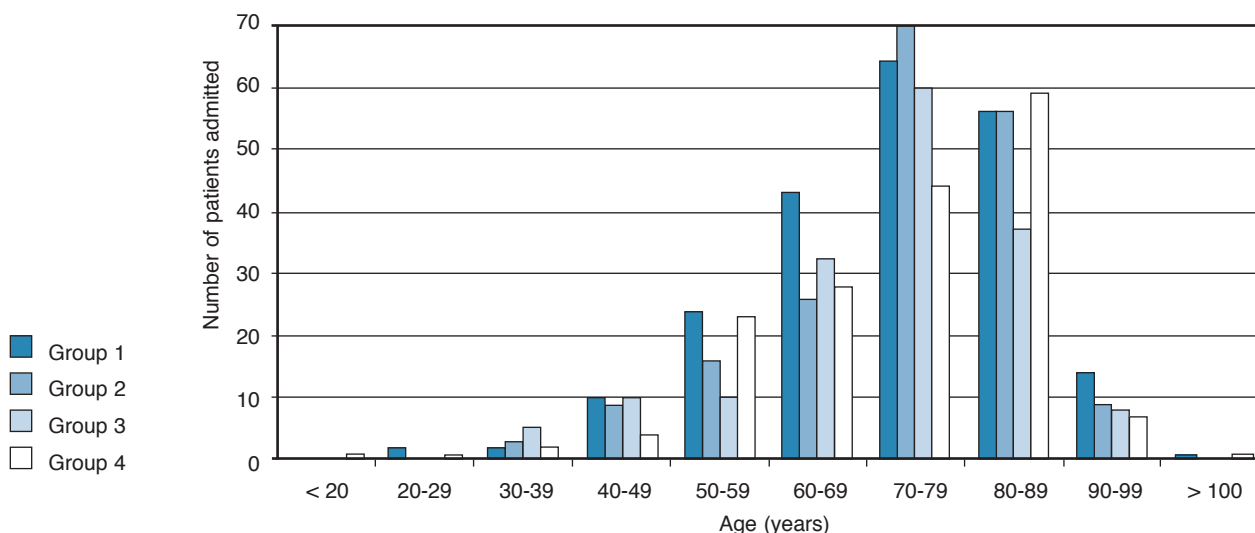
There was no statistical difference in the number of patients referred from GPs over time. A higher proportion of patients in Groups 3 and 4 were referred from the Emergency Department; however, this was not statistically significant.

### Patients’ demographic features

Overall, the mean age at the time of admission to the clinic was 72.3 years (interquartile range 65-82 years). The age distribution of patients admitted to the clinic was similar across each of the groups (Figure 2).

The proportion of females admitted to the clinic increased over the study period. Fifty five percent of patients in Group 1 were female, as compared to 58.7% in Group 2, 59.3% in Group 3 and 59.4% Group 4, yet this change was not statistically significant. The mean age of the patients excluded from analysis was 72.7 years and 61.3% (19 of 31) of these patients were female.

**Figure 2. Age distribution of leg ulcer patients in each group.**



The distance patients had to travel to the clinic was found to be similar between Groups 1, 2 and 4. In these groups approximately 66.8% of patients lived within 10kms of the clinic, 9.6% lived 10-20kms away, 15.9% lived 20-50kms away and a further 7.7% lived more than 50kms from the clinic. A higher proportion of patients in Group 3 lived further than 20kms from the clinic than in any of the other groups.

### Follow-up at the clinic

Following admission to the clinic, there were a total of 1712 follow-up reviews made at the clinic. The number of follow-up attendances conducted in Group 2 and Group 4 was equivalent (456 and 453 respectively). The greatest number of patients reviewed after admission was in Group 1 (489) and 314 follow-up reviews of patients were made in Group 3.

Over the study period the mean time between reviews at the clinic was 64 days (interquartile range of 35-75 days). The number of days between follow-up reviews differed significantly between the groups ( $p<0.001$ ). The mean time between reviews in Group 1 was 47 days; however, this increased to 68 and 76 days in Groups 2 and 3 respectively, whilst the mean time between reviews was only 58 days in Group 4. There was no statistical difference in the number of follow-up appointments conducted between the groups. The mean number of follow-up reviews performed per patient was 2.9.

### Patients' clinical features

Over time there was a statistically significant ( $p<0.05$ ,  $\chi^2=9.2$ ,  $df=2$ ) increase in the proportion of patients who presented with an ulcer which had been present for less than 3 months. However, this increase was not matched by a statistically significant increase in the proportion of patients who presented with recurrent ulceration.

The number of patients with multiple ulcers when admitted to the clinic decreased significantly over time ( $p<0.05$ ,  $\chi^2=7.2$ ,  $df=2$ ). During the first 2 years of the clinic's operation, approximately 42% patients admitted had more than one ulcer; however, this number decreased over time. During the final 2 year period of the study only 32% of patients admitted had multiple ulcers.

Zone 2 of the leg was the most common site of ulceration. Although the proportion of patients presenting with an ulcer in this zone was similar in each of the first three groups (73.2%, 76.7% and 74.7% respectively), only 59% of patients in Group 4 presented with an ulcer in this zone. This statistically significant difference ( $p<0.05$ ,  $\chi^2=8.9$ ,  $df=2$ ) was accounted for by an equally significant ( $p<0.001$ ,  $\chi^2=15.2$ ,  $df=2$ ) increase in the proportion of patients presenting with ulceration in Zone 1. There was no other significant inter-group variation.

The proportion of patients with a total ulcer surface area of greater than 10cm<sup>2</sup> at the time of admission decreased over the study period. The proportion of patients with a total ulcer surface area less than 10cm<sup>2</sup> at the time of admission increased in each consecutive group.

During the study period, chronic venous disease was the most common cause of lower limb ulceration. However, the proportion of patients with venous ulcers decreased significantly over time ( $p<0.05$ ,  $\chi^2=8.1$ ,  $df=2$ ). Table 2 lists the various aetiologies assigned to each patient's ulcer. The diagnosis of venous disease was confirmed in 68 patients using Duplex ultrasound and in a further two patients through venography.

### Management and outcomes of ulcers

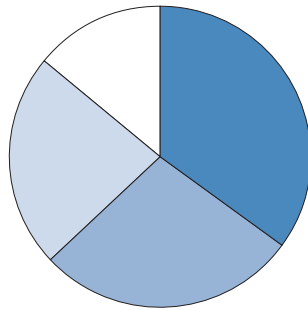
Between groups there was considerable variation in the type of dressing prescribed. There was a decrease in the amount of foam – Group 1 (18.2%), Group 2 (16.7%), Group 3 (6.5%),

**Table 2. Aetiology assigned to each patient's ulcer.**

Aetiology	Group 1		Group 2		Group 3		Group 4		Overall	
	n	%	n	%	n	%	n	%	n	%
Vasculitic	3	1.4	3	1.6	2	1.2	5	2.9	13	1.8
Malignant	0	0	3	1.6	5	3.1	8	4.7	16	2.2
Trauma	5	2.3	4	2.1	5	3.1	5	2.9	19	2.6
Pressure	8	3.7	5	2.6	7	4.3	10	5.9	30	4.1
Diabetic	6	2.8	5	2.6	5	3.1	11	6.5	27	3.7
Combined arteriovenous insufficiency	20	9.3	17	9.0	25	15.4	26	15.3	88	11.9
Arterial	42	19.4	31	16.5	14	8.6	28	16.5	115	15.6
Venous	116	53.7	108	57.1	86	53.1	61	35.9	371	50.3
Other	3	1.4	4	2.1	4	2.5	3	1.8	14	1.9
Not known	13	6.0	9	4.8	9	5.6	13	7.6	44	5.9



Figure 3. Type of bandages used.



Over the whole study period:

- 871 high pressure compression bandages
- 694 low pressure compression bandages
- 559 retention bandages
- No bandage

Group 4 (4.5%) – and hydrogel dressings prescribed – Group 1 (7.94%), Group 2 (5.1%), Group 3 (1.9%), Group 4 (2.1%).

The amount of hydrocolloid dressings prescribed was lowest in Group 4 (24.6%) than in any other group – 37.7%, 44.2% and 37% in Groups 1, 2 and 3 respectively. The use of alginates dressings increased from 125 (17.7%) and 127 (19.7%) in Groups 1 and 2 to 169 (36%) and 160 (25.7%) in Groups 3 and 4 respectively. Cadexomer iodine, which was only available during last two study periods, was prescribed at 103 (9.4%) appointments. The proportion of film dressings prescribed was statistically equivalent in each group.

On the other hand, the proportion of each bandage type prescribed did not differ significantly between the groups. High-pressure compression bandages were the most common

type of bandaging used (Figure 3). Of all the 2449 consultations, a dressing was not required on 216 (8.8%) occasions, as the ulcer had healed. In 325 (13.3%) appointments, bandages were not required.

Table 3 presents the outcome of patients' ulcers managed in the clinic. The proportion of ulcers, which had healed in each group, was similar. Although not statistically significant, the proportion of ulcers which had not healed increased over the study period.

## Discussion

This study describes the change in referral patterns and patient characteristics of a lower limb ulcer clinic over an 8 year period. Although conducted prospectively, as an observational audit, the potential for bias in this investigation must be considered. Recall bias, specifically relating to the duration of patients' ulcers, was introduced into this study. A double data entry system was not used and so errors may have occurred when patients' information was entered into the database. However, this quality assurance bias should have been reduced through the frequent review and cleaning of the data.

Misclassification bias may have also been incorporated into this study. Patients who had been referred back to the clinic, after previously being discharged from it, were classified and managed as a new admission. Potentially, however, a small number of these patients may have been managed as though they had never been discharged from the clinic, not as a new admission.

In addition to the bias introduced, this study is limited by the amount of missing data. During and on completion of the

Table 3. The outcomes of all ulcers managed in the clinic.

Outcome	Group 1		Group 2		Group 3		Group 4		Overall	
	n	%	n	%	n	%	n	%	n	%
Lost to follow-up*	19	7.1	21	7.9	18	8.0	20	7.9	78	7.7
Deceased	34	12.8	17	6.4	8	3.5	9	3.6	68	6.7
Not adherent <sup>†</sup>	1	0.4	3	1.1	0	0	2	0.8	6	0.1
Amputation <sup>‡</sup>	2	0.8	7	2.6	2	0.8	7	2.8	18	0.2
Excision ± skin graft	1	0.4	3	1.1	7	3.1	4	1.6	15	0.2
Referred to dermatologist	2	0.8	4	1.5	1	0.4	3	1.2	10	0.1
Referred to vascular surgeon <sup>Δ</sup>	12	4.5	15	5.7	7	3.1	15	6.0	49	4.9
Received hyperbaric therapy	1	0.4	4	1.5	3	1.3	3	1.2	11	0.1
Not healed <sup>Ω</sup>	36	13.5	35	13.2	37	16.4	41	16.3	149	14.7
Healed	158	59.4	156	58.9	142	63.1	147	58.6	603	59.9

\* All patients who were due to be reviewed in the clinic, however failed to attend, excluding those who were deceased.

† Patients who were frequently reviewed in the clinic, yet were found to be non-compliant with therapy.

‡ Primary outcome for patients who had their ulcer-affected region amputated.

Δ Referred for further intervention in arterial or combined arteriovenous disease.

Ω The outcome of a patient's ulcer which had not healed at the conclusion of a time period; the patient was then also included for analysis in the next chronological group.

study, endeavours were made to locate missing information. Overall, the amount of data missing was equivalent across each group. Additional information was sought regarding 17 patients in Group 1, 19 patients in Group 2, 15 patients in Group 3 and 16 patients in Group 4. The attrition rates of 8.1%, 7.2%, 8.3% and 9.2% in each chronological group were similar.

The clinic operated for an average of one and a half days per week. A consultant surgeon accompanied by at least one medical officer attended a weekly morning clinic, whilst a wound care nurse facilitated the second, day-long, follow-up clinic. On average, three appointments were allocated for admitting new patients and seven appointments reserved for follow-up and review. A vascular surgery clinic ran concurrently with the half-day clinic, whilst a diabetic clinic and a separate dermatology clinic operated on the day of the follow-up clinic. The diabetic clinic offered a range of limb care advice, receiving considerable input from a podiatrist. As supported by Gottrup *et al.*<sup>5</sup>, concurrently run multidisciplinary clinics make inter-clinic reviews or referrals convenient and efficient.

As expected, over the study period there was a decrease in the number of new admissions to the clinic and an increase in the number of patients readmitted to the clinic. It would appear that, with time, a steady state between the proportion of new patients and those who had previously been discharged would be reached.

Over time, the referral patterns of patients to outpatient clinics can change<sup>10</sup>. As information about the clinic spread, it was expected that there would be a decrease in the number of inappropriate referrals made. However, this was found not to be the case. GPs were found to be the largest referral source of patients to the clinic. Though small in number, over time, there was an increase in the number of referrals from the Emergency Department. This may reflect a decrease in the number of hospital admissions required.

It is well known that increasing age is associated with the development of leg ulcers and the age distribution recorded was similar to that observed in previous publications<sup>1,11,12</sup>.

During the study period few changes in patients' demographic features were observed. Nonetheless, the clinical characteristics of these patients did differ with time. There was a decrease in the proportion of venous ulcers managed at the clinic over the study period. However, this study supports the notion that venous disease is the most common cause for lower limb ulceration in the elderly population. The diagnostic importance of considering malignancy as a cause for chronic lower limb ulceration is reflected by the increase over time in the number of malignant ulcers diagnosed.

Lower limb arterial insufficiency is an often-overlooked cause for chronic ulceration. The static proportion of healing ulcers between the groups may be accounted for by lack of emphasis on arterial disease. Nonetheless, a vascular surgeon reviewed all patients who were diagnosed with arterial or combined arteriovenous disease. This consultation process was facilitated by having the leg ulcer clinic and the vascular clinic functioning simultaneously. Formal consultations were made when surgical intervention was required.

Whilst it is important to note that it is difficult to directly compare the aetiology for lower limb ulceration between studies due to differing sampling biases, the proportion of venous ulcers managed at this clinic is higher than that reviewed by McMullin<sup>13</sup>, and lower than reported by Colgan *et al.*<sup>14</sup>. The low incidence of diabetic, vasculitic or arterial ulceration reported here may not truly reflect that of the reference population and is possibly a result of other local services available.

A high proportion of patients (27%; 169 from 627) admitted to the clinic developed a second ulcer. Although there were a large number of patients who developed their second ulcer prior to discharge from the clinic, this number decreased over time. However, this change may be accounted for by the relative increase in the number of patients readmitted to the clinic. In general, the reason for patients developing a second ulcer is not clear, but does support the notion that, for elderly people, lower limb ulceration is a chronic disease.

The dispersion of knowledge relating to the presence and function of the clinic may have accounted for the decrease in length of time that patients had had their ulcer for prior to being referred to the clinic. Over the study period there was a significant increase in the proportion of patients admitted to the clinic who had had their ulcer for less than 3 months. Regular wound management workshops, in conjunction with close liaison between ulcer clinic staff and GPs or community nurses, fostered appropriate community ulcer management. Over time, the active education of local health professionals may have accounted for the patients presenting earlier.

The change in prevalence of specific aetiology was mirrored by a decrease in the proportion of ulcers in Zone 2. The decrease in the proportion of patients presenting with multiple ulcers or ulcers greater than 10cm<sup>2</sup> in surface area, may also be a reflection of the shorter time that patients had had their ulcer prior to admission or, alternatively, it may also indicate a change in aetiology of the ulcers managed by the clinic.

The most common type of bandaging system employed for high-pressure compression countering chronic venous disease was the Charing Cross 4-layer bandage<sup>15</sup>, whilst a retention bandage, exerting negligible pressure, was used for patients

with peripheral arterial disease. It is the policy of the clinic to advise all patients with venous disease to wear compression stockings (Class 2 or 3); however, an accurate record of this was not made and hence was excluded from the present audit.

The impact ulcer clinics have on wound healing and patients' quality of life has been well documented<sup>3-5, 16</sup>. In the present investigation, the proportion of ulcers which had healed was similar across each of the study groups.

Although community and hospital outpatient clinics provide cost efficient measures of managing chronic ulcers<sup>2</sup>, a prospective study investigating the long-term change in the costs of running a community clinic would be useful. Fluctuations in the price of dressing, bandage and other consumable resources could, over time, dramatically alter economic management and planning of leg ulcer clinics. Any future prospective studies would do best to concurrently map trends in best clinical practice.

### Acknowledgments

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