Neuropathic diabetic foot ulcers in the elderly: clinical outcomes and healing

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Abstract
There is little evidence on healing outcomes of neuropathic foot ulcers in elderly patients.

Aims: To determine the healing rates of neuropathic diabetic foot ulcers at 12 and 24 weeks achieved by standard care provided at an established multidisciplinary diabetes foot clinic in patients aged 65 years and above. Data on the incidence of falls and hypoglycaemia were also collected due to their perceived clinical risk in the group studied.

Methods: This was a retrospective observational study looking at clinical outcomes of neuropathic foot ulcers. Patients aged 65 years or more presenting with a non-infected neuropathic ulcer at the time of their initial review were identified and classified into two groups: Group E patients were aged above 80 years and Group Y patients 65-80 years.

Results: A total of 97 patients, presenting with 106 ulcer episodes, were identified. Mean HbA₁c was 60 mmol/mol in Group Y and 55 mmol/mol in Group E. Healing rates of all ulcers at 12 and 24 weeks in the elderly group lagged behind rates in the younger group (67.6% at 12 weeks and 73% at 24 weeks in Group E vs. 78.2% at both intervals in Group Y).

The elderly group had more falls, 11% vs. 2% in Group Y. In all, 50% of the falls in Group E were attributed to their prescribed pressure relief (off-loading) devices.

Conclusions: With standard foot care given in a multi-disciplinary foot service, neuropathic diabetic foot ulcers can heal in the elderly despite their age-related skin changes.

The rate of healing of neuropathic ulcers noted in our study provides a benchmark for healing outcomes and enables comparison with other age groups and centres. Our study identifies a risk of falls associated with off-loading devices and highlights the need for structured falls risk and mobility assessments in this group.

Key words: elderly, diabetes foot ulcer, healing outcomes

Background
Care of the elderly has been an evidence-poor area of medicine. This means that most physicians extrapolate from the evidence base of other specialties knowing that there is very little, if any, representation of their patient group in the research. As more and better quality research is being carried out with elderly patients, confidence is improving that the care being provided is optimum for this patient group. Diabetic care guidelines now treat frail patients within the elderly group as a separate category, with different targets for medical treatment such as a higher HbA₁c to reduce the risk of hypoglycaemia. However, evidence on management of diabetic foot ulcers in the elderly remains very limited.

Usual clinical management for neuropathic ulcers relies on regular debridement to remove surrounding callus, combined with pressure relief (off-loading). The principle of off-loading of both plantar and non-plantar ulcers is to adjust footwear to ensure that continued trauma to the ulcerated area is minimized, but the method adopted has to be both safe and acceptable to the individual patient.¹

One review into management of diabetes foot ulcers in the elderly specifically highlighted the lack of evidence regarding off-loading in elderly patients.² It was the authors’ impression that elderly patients develop fewer plantar ulcers than their younger counterparts but there are few data to support this. They also suggested that elderly patients need special consideration in this area: they are the group most likely to suffer from gait and balance disturbances and therefore are least likely to be able to tolerate this treatment.

This review discusses diabetic foot care with relation to elderly patients specifically.

In conclusion, there is still little evidence concentrating on outcomes of neuropathic diabetic foot ulcers in the elderly patient.

Aim
The aim of our study was to determine the healing rates of neuropathic diabetic foot ulcers at 12 and 24 weeks achieved by routine care provided at an established multidisciplinary diabetes foot clinic in patients aged 65 years and above. Data
on the incidence of falls and hypoglycaemia were also collected due to the perceived clinical risk in the group studied.

**Methods**
This was an observational retrospective study of routine care of patients with diabetic foot disease managed at the Diabetes Limb Salvage Service (DLSS), a multidisciplinary foot clinic at our hospital. Use of the electronic clinical database was approved by the Leeds Teaching Hospitals NHS Trust and analysis of routine care did not require local research ethics committee approval. The Mann-Whitney U test was used to look at ulcer healing and falls data.

All patients attending the DLSS with neuropathic diabetic foot ulcers between 2016-2020 who were aged 65 and above at the time of their initial presentation were identified using the hospital electronic patient record. Presence of neuropathy in patients was determined by partial or total loss of protective sensation on 10 g monofilament testing. All patients with evidence of neuropathy and a foot ulcer were included. Patients with evidence of ischaemia or infection at their initial presentation were excluded in an effort to reduce the number of variable factors. For the purpose of this study, peripheral vascular disease was excluded if at least one peripheral pulse was palpable. Ulcer healing outcomes were assessed at 12 and 24 weeks as other foot ulcer studies in the literature have measured ulcer healing at similar intervals.

A total of 97 patients were identified using the Trust electronic patient database, giving 106 ulcer episodes. The 106 ulcer episodes were classified into two groups: Group E (elderly group) were ulcer episodes in patients above 80 years at the time of their initial clinical assessment and Group Y (younger group) were ulcer episodes in patients aged 65-80 at the time of assessment. 80 years of age was used as the definition of elderly patients, as this is the cut-off used in many Trusts for elderly services. Elderly patients were compared to a group aged 65-80 because we felt this group of patients were most likely also to be retired and to have similar lifestyles and commitments, although this was not measured and is likely to be variable.

Individual patient records were examined for the site and time to healing of index ulcers. Electronic records of their first diabetes review at DLSS were looked at to ascertain their glycaemic control and episodes of documented hypoglycaemia were identified. A hypoglycaemic event was defined as documentation of either a capillary blood glucose below 4 mmol/L recorded on the patient’s glucometer or noted on diary review by a clinician during their diabetes reviews.

**Results**
In total, 45 patients and 51 ulcer episodes in Group E and 52 patients and 55 ulcer episodes in Group Y were included (Table 1). At their initial review the two groups had comparable glycaemic control, with a mean glycated haemoglobin (HbA₁c) of 60 mmol/mol in the younger group and 55 mmol/mol in the elderly. There were five hypoglycaemic events documented in the elderly group at their initial appointment, compared with none in the younger group. Ten percent of the elderly group had their diabetes treatment reduced as a result whereas the younger group were more likely to get a treatment increase for poor control. The incidence of events is likely to be much higher as patients did not have their diabetes reviewed at every individual foot appointment within the DLSS.

Off-loading footwear was offered to 91% of patients in Group Y and 78% of patients in Group E. The off-loading devices prescribed included rebound boots, Heel Pros, temporary orthotic shoes and made-to-measure footwear. Patients were deemed to be non-adherent with the prescribed footwear if clinical notes suggested this was an issue or if the patients reported it. Non-adherence was noted to be a factor in 13.3% of the elderly group and 11% of the younger group.

We also looked at the incidence of falls recorded or reported in these patient groups. A fall was defined as a documented event that resulted in a person coming to a rest unintentionally on the ground or another level. Clinical records revealed that 11% of Group E and 2% of Group Y had documented falls whilst under DLSS review. However, this was dependent on patients volunteering history of falls: there was no formal falls risk assessments during the study.

Clinical annotations on electronic patient records showed that 50% of the falls in the elderly group were attributed to the use of their prescribed off-loading devices. The most common reasons reported were getting up in the night and mobilising with devices not intended for this use or designed to offload the heel when lying in bed like the Heel Pros.

**Data on ulcer types and healing**
In Group E, five patients were lost to follow-up, four patients died with active ulceration and there were incomplete data on four more. In Group Y, four patients were lost to follow-up, one died with an active ulcer and there were incomplete data on five more. These patients were excluded from further analysis on ulcer healing. Thus, a total of 32 patients (37 ulcers) in Group E and 42 patients (46 ulcers) in Group Y were analysed.

There were more plantar ulcers than dorsal ulcers in both groups. The majority of the ulcers in both groups had a SINBAD score of 2 or less (Table 2).

Healing outcomes achieved at 12 and 24 weeks for all ulcers are shown in Table 3 and individual healing rates for plantar and dorsal ulcers are shown in Table 4.

**Table 1. Patient characteristics**

<table>
<thead>
<tr>
<th></th>
<th>Group E</th>
<th>Group Y</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (ulcer episodes)</td>
<td>45 (51)</td>
<td>52 (55)</td>
<td></td>
</tr>
<tr>
<td>Male:Female</td>
<td>27:18</td>
<td>37:15</td>
<td></td>
</tr>
<tr>
<td>HbA₁c in mmol/mol (IQR)</td>
<td>51 (46-66)</td>
<td>60 (48-74)</td>
<td>0.12*</td>
</tr>
<tr>
<td>No. of hypoglycaemia events</td>
<td>5</td>
<td>0</td>
<td>0.016*</td>
</tr>
<tr>
<td>Falls</td>
<td>5 (11%)</td>
<td>1 (2%)</td>
<td>0</td>
</tr>
</tbody>
</table>

* Mann Whitney U test; IQR, Interquartile range
Table 2. Ulcer characteristics

<table>
<thead>
<tr>
<th></th>
<th>Group E</th>
<th>Group Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site of ulcers</td>
<td>Plantar</td>
<td>32</td>
</tr>
<tr>
<td></td>
<td>Dorsal</td>
<td>5</td>
</tr>
<tr>
<td>SINBAD score</td>
<td>≥3</td>
<td>3</td>
</tr>
<tr>
<td>Presence of Charcot foot deformity</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 3. Healing rate of all ulcers at 12 + 24 weeks

<table>
<thead>
<tr>
<th></th>
<th>Group E (n=37)</th>
<th>Group Y (n=46)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healed @</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 weeks</td>
<td>no. %</td>
<td>no. %</td>
</tr>
<tr>
<td>24 weeks</td>
<td>25 66.7%</td>
<td>36 78.2%</td>
</tr>
</tbody>
</table>

Table 4. Healing rate of plantar and dorsal ulcers at 12 + 24 weeks

<table>
<thead>
<tr>
<th></th>
<th>Elderly</th>
<th>Young</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Plantar ulcers (32)</td>
<td>Dorsal ulcers (5)</td>
</tr>
<tr>
<td>Ulcer healing</td>
<td>no. %</td>
<td>no. %</td>
</tr>
<tr>
<td>At 12 weeks</td>
<td>20 62.5%</td>
<td>4 80%</td>
</tr>
<tr>
<td>At 24 weeks</td>
<td>22 68.8%</td>
<td>4 80%</td>
</tr>
</tbody>
</table>

Discussion

Although populations around the world are ageing, the evidence that increasing longevity is accompanied by an extended period of good health is scarce. Ageing is the predominant risk factor for chronic wounds, skin fragility, infections, co-morbidities and decreased quality of life. There is also much research to show that age-related changes in the epidermis and dermis change the skin’s ability to resist injury. Although most wounds do heal in the elderly, the healing process is slower, and all phases of wound healing are affected. Thus, elderly patients are particularly burdened by diabetic foot disease. However, very little is known about diabetic foot ulcer healing outcomes in this population.

Ince et al. looked at outcomes of the routine management of neuropathic ulcers in a single specialist centre in the UK. The rates of healing in this cohort provide a benchmark for comparison with other centres in the UK. The reported proportions of ulcer healing at 12, 20 and 52 weeks in this study were 59.3%, 70.5% and 86.6%, respectively. However, their study population was markedly younger than both the groups included in this study, with a mean age of 57.4 ± 12.0 years (mean ± SD). Despite this difference, healing rates of 67.6% at 12 weeks and 73% at 24 weeks for all ulcers in the current study are comparable to those achieved in the Ince et al group.

More comparable in age to our cohort is a recent sub-analysis by Gershater et al. of consecutively presenting patients aged ≥75 years (n=1,008) from a previous study on 2,480 patients with diabetic foot ulcer treated in a multidisciplinary system until healing. In their study primary healing was achieved in 54% of patients. The authors found that healing without major amputation was achieved in 84% of surviving patients ≥75 years, despite extensive co-morbidity and dependency.

We did not assess mobility rigorously in our group of patients but clinical annotations on our diabetes database support the fact that the elderly group had reduced mobility. A potential protective effect provided by their reduced mobility might aid ulcer healing in an elderly group. This is supported by the Gershater et al study, who note that 56% of patients who were living in institutions or dependent on home nursing healed without amputation, compared to 44% of patients living in their own home without any support from social services or home nursing. At 24 weeks both dorsal and plantar ulcer healing in the elderly group lagged behind their younger counterparts, suggesting that age-related changes were impacting ulcer outcomes. However, numbers are too small to confirm this.

Compliance with the prescribed footwear was gleaned from the clinical notes at the time of patients’ DLSS review. Acceptance of prescribed off-loading footwear and non-adherence were noted to be an issue in our study. However, it was difficult to measure. As a result, we could not conclude that this contributed significantly to the healing outcomes noted.

Falls are the most common cause of death from injury in the over 65s: they cost the NHS over £2bn and more than 4 million bed days a year. This case series confirms the higher incidence of falls in the elderly and suggests the need for a more considered approach to use of these off-loading devices in the elderly population. However, more rigorous research is needed.

NICE guidance recommends that patients above 65 who are at risk of falling due to cognitive or visual impairment or who have a condition that affects mobility or balance, such as diabetes, need assessment of their gait and balance. The NHS website (2018) provides a self-assessment of falls risk based on the Falls Risk Assessment Tool (FRAT Tool).

This is a validated screening tool that needs little in the way of extra resources or time. Since carrying out this study, we have incorporated use of the FRAT tool as a risk screening tool for patients above 65 years attending our multidisciplinary diabetes foot clinic. This can guide health professionals in making an informed choice about off-loading footwear for this vulnerable group.

Data on incidence of hypoglycaemia were limited to patients’ diabetes review at their initial appointment within the DLSS. It is likely that the incidence of hypoglycaemia would be much higher in both groups if they had a diabetes review at every appointment within the DLSS. Thus, whilst hypoglycaemia risk in this study mirrors that seen in larger studies in this area, research with larger study groups is needed to confirm the patterns seen in our series.

To summarise, our study provides useful insight into healing
outcomes of neuropathic foot ulcers in the elderly, a poorly researched group. The rates of ulcer healing demonstrated in this study provide a benchmark for healing outcomes in the elderly and can enable comparison with other age groups and other diabetes foot services. Neuropathic foot ulcers can heal in the elderly, despite age-related skin changes, with standard foot care given in a multidisciplinary foot service. The study also outlines the risks of treatments we prescribe for elderly patients and highlights the need for a more considered discussion with patients and their carers to be incorporated within the diabetes foot services.

Limitations
Numbers of patients are relatively small and further studies with larger numbers would be needed to confirm our findings. Our study uses age as marker of elderly patients rather than frailty scores as it predated the use of frailty score at the trust for risk of stratifying vulnerable patients. We also do not have data around duration of diabetes for individual patients. A further limitation of our study is likely to be the incidence of reported falls in our groups. Our service at the time of study did not regularly screen patients for falls risks and it is likely that there were many falls which were unidentified. Adherence to footwear was difficult to measure and we had to rely on clinical notes by the podiatrists, patient self-reporting as well as direct observation at their clinical review. Data on incidence of hypoglycaemia was limited to their diabetes review at their initial appointment within the DLSS.

Conflict of interest None.
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References
7. NICE Clinical guideline (CG161). Falls in older people: assessing risk and prevention. Published date: 12 June 2013.