### Bibliographic reference


### Study type
Observational, prospective study

### Summary

**Location:** Italy, a diabetological unit for foot ulcer, single centre.

**Intervention:** Patients were admitted to hospital if they had a full thickness gangrene or abscess. Subjects with superficial ulcer were also admitted if the ulcer was large, infected and showed a defective healing in 30 days of outpatient treatment.

 Comprehensive protocol combined with a multidisciplinary approach in a dedicated centre. Patients were referred from outpatient centre, casualty department and from other hospitals. Protocol involved aggressive and radical debridement, abscesses were drained and toe amputation and ray resection carried out when required, antibiotic therapy, optimized metabolic control sought, vascular status checked and arteriography performed as required to evaluate the opportunity for vascular intervention. During hospitalisation all patients received orthopaedic devices for offloading. Patients also received hyperbaric oxygen therapy. (see paper for more details)

**Comparison:** Rates of amputation were compared with the previous two periods before criteria for admission to hospital and therapeutic-diagnostic protocol were established.

**Population:** 115 diabetic patients consecutively hospitalised for foot ulcer.

**Outcome:** Amputation.

For study quality please see GRADE tables

### Number of patients

- Total n = 115 diabetic patients
- Division of General Surgery period= 42
- Diabetology centre, processing stage of the multidisciplinary protocol period= 78
- Standardised application of the multidisciplinary protocol= 115

### Patient characteristics

Patients taken from:

- Inclusion:
  - Diabetic patients consecutively hospitalised for foot ulcer
  - Admitted if either full-thickness gangrene or abscess
  - Subjects with superficial ulcer were admitted if the ulcer was large, infected and showed a defective healing in 30 days of outpatient treatment
Appendix G: Diabetic foot problems - full evidence tables – review questions 11 - 16


Exclusion: Non mentioned

Baseline characteristics:

<table>
<thead>
<tr>
<th></th>
<th>1986-1989 (n=78)</th>
<th>1990-1993 (n=115)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wagner grade 2</td>
<td>18</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Wagner grade 3</td>
<td>8</td>
<td>32</td>
<td></td>
</tr>
<tr>
<td>Wagner grade 4</td>
<td>52</td>
<td>70</td>
<td>0.03</td>
</tr>
<tr>
<td>Ankle brachial pressure index</td>
<td>0.80 ± 0.27</td>
<td>0.64 ± 0.25</td>
<td>0.01</td>
</tr>
<tr>
<td>Angiography</td>
<td>44</td>
<td>98</td>
<td>0.00</td>
</tr>
<tr>
<td>Vascular Procedures</td>
<td>10</td>
<td>29</td>
<td>0.05</td>
</tr>
<tr>
<td>Infection</td>
<td>57</td>
<td>105</td>
<td>0.01</td>
</tr>
</tbody>
</table>

Overall:
age = 63.4 ± 9.9
Requiring insulin= 60.9%
Oral hypoglycaemics alone= 39.1%
Male: 73%
Cause of foot lesion: not reported
Peripheral neuropathy: not reported
Wagner grade
2= 11.3%
3= 27.8%
4= 60.9%
Hypertension: 51.3%
Smoking: 35.5%
Coronary disease: 47.8%
Chronic renal insufficiency: 20%
End stage renal failure: not reported
Prior wound= 28.7%

**Intervention**

Patients were admitted to hospital if they had a full thickness gangrene or abscess. Subjects with superficial ulcer were also
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### Comparison

- Rates of amputation were compared with the previous two periods before criteria for admission to hospital and therapeutic-diagnostic protocol were established.

### Length of follow up

- Observation period 8 years total

### Location

- Italy

### Outcomes measures and effect size

- Rates (and recurrent rates) of foot ulceration, infection and gangrene resulting from diabetes
  - Not reported

- Resource use and costs (including referral rates)
  - Not reported

- Rates of hospital admission for foot problems resulting from diabetes
  - Not reported (cohort taken from hospitalised patients)

- Length of hospital stay
  - Not reported

- Rates and extent of amputation

  - Major amputations (above or below the knee)
    - Period from 1979 to 1981, patients admitted to general surgical department (n=42)= 17 major amputations 40.5%
    - Period from 1986 to 1989, patients admitted to diabetology centre, processing stage of multidisciplinary protocol (n=78)= 26 major amputations 33.3%
    - Period from 1990 to 1993, standardised application of multidisciplinary protocol (n=115)= 27 major amputations 23.5%
  - Odds ratio (95% CI)= 0.66 (0.46-0.96) i.e. significant difference
### Appendix G: Diabetic foot problems - full evidence tables – review questions 11 - 16

**Bibliographic reference**

**Source of funding**
Not reported

**Comments**
This study showed significantly fewer major amputations in the period in which a comprehensive diagnostic and treatment protocol as well as a multidisciplinary approach in a dedicated centre was employed.