**Table 71: Rerkasem 2008**

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Study type</td>
<td>Observational, prospective study</td>
</tr>
<tr>
<td>Study quality</td>
<td>Summary</td>
</tr>
<tr>
<td></td>
<td>Location: Chiang Mai University Hospital in Thailand</td>
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<tr>
<td></td>
<td>Intervention: a foot care team consisting of endocrinologists, a rehabilitation physician, a family doctor, nurses, and plastic and vascular surgeons. Flow sheets based on diabetic foot protection algorithms were developed. Preventive services were provided routinely according to the flow chart including self-care education, a routine palliative foot service, and the provision of protective footwear. The consultation between specialists was carried out in flow sheets directly without any formal consultation form.</td>
</tr>
<tr>
<td></td>
<td>Comparison: Standard care prior to the development of the protocol was undertaken using the interdepartmental consultation form for cases with ischaemia and neuropathy. Preventive measures were taken at the discretion of the physician and there were no detailed guidelines or flow sheets for these specific services.</td>
</tr>
<tr>
<td></td>
<td>Population: 183 patients with diabetic foot ulcer</td>
</tr>
<tr>
<td></td>
<td>Outcome: amputations, hospitalisation, length of hospitalisation</td>
</tr>
<tr>
<td></td>
<td>1. The method of allocation to intervention groups was unrelated to potential confounding factors (the reason for participant allocation to intervention is not expected to affect the outcome under study)? Controls were taken from before the period that the service was established. Unclear if any other confounding factors may</td>
</tr>
<tr>
<td>Bibliographic reference</td>
<td></td>
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<td>--------------------------</td>
<td></td>
</tr>
</tbody>
</table>

have affected the results during this time.
2. Attempts were made with the design or analysis to balance the comparison groups for potential confounders?
There were no attempts to balance groups for confounders
3. The groups were comparable at baseline, including all major confounding factors?
Groups were comparable at baseline including major confounding factors reported
4. The comparison groups received the same care and support apart from the interventions studied?
Unclear if comparison groups received comparable care other than due to the changes implemented by the protocol.
5. Participants receiving care and support were kept blind to intervention allocation?
Participants were not blinded to intervention allocation
6. Individuals administering care and support were kept blind to intervention allocation?
Individuals administering care were not blinded to intervention allocation
7. All groups were followed for an equal length of time, or analysis was adjusted to allow for differences in length of follow up?
Observational period was over 4 years. Unclear if participants were observed for an equal length of follow up.
8. Groups were comparable for intervention completion?
Unclear if groups were comparable for compliance or intervention completion or for general adherence to treatment.
9. The groups were comparable with respect to the availability of outcome data?
There was no loss to follow up reported.
10. The study had an appropriate length of follow up?
Observation period was appropriate 4 years, length of follow up was most likely variable and may not have been appropriate in all cases.
11. The study used a precise definition of outcome?
The study used a clear definition of amputation
12. A valid and reliable method was used to determine the outcome?
Unclear if a valid and reliable method was used to determine outcome.
13. Investigators were kept blind to participant’s exposure to the intervention?
Investigators were not kept blinded to exposure to the intervention
14. Investigators were kept blind to other important confounding factors?
Investigators were not kept blinded to other important confounding factors
Appendix G: Diabetic foot problems - full evidence tables – review questions 11 - 16

### Bibliographic reference

|-----------------------------------------------------------|

Authors state that technology and facilities in the past may not have been as good as they are now. Also some data in the historical cohort group was sometimes unavailable.

### Number of patients

<table>
<thead>
<tr>
<th>Total n= 183 patients with diabetic foot ulcer</th>
</tr>
</thead>
<tbody>
<tr>
<td>73 received diabetic foot protection</td>
</tr>
<tr>
<td>110 received standard care</td>
</tr>
</tbody>
</table>

### Patient characteristics

- **Patients taken from:** Thailand
- **Inclusion:** Patients with diabetic foot ulcer
- **Exclusion:** Not defined

Baseline characteristics:

No significant differences for the confounding factors below (p values provided)

<table>
<thead>
<tr>
<th></th>
<th>Diabetic foot protection (n=73)</th>
<th>Standard care (n=110)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males</td>
<td>25</td>
<td>37</td>
</tr>
<tr>
<td>Age, mean (SD)</td>
<td>58.8 (11.9)</td>
<td>60.6 (10.5)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>50</td>
<td>49</td>
</tr>
<tr>
<td>History of smoking</td>
<td>31</td>
<td>55</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>33</td>
<td>73</td>
</tr>
</tbody>
</table>

### Intervention

Care provided by a foot care team consisting of endocrinologists, a rehabilitation physician, a family doctor, nurses, and plastic and vascular surgeons. Flow sheets based on diabetic foot protection algorithms were developed. Preventive services were provided routinely according to the flow chart including self-care education, a routine palliative foot service, and the provision of


protected footwear. The consultation between specialists was carried out in flow sheets directly without any formal consultation form.

Comparison

Standard care prior to the development of the protocol was undertaken using the interdepartmental consultation form for cases with ischaemia and neuropathy. Preventive measures were taken at the discretion of the physician and there were no detailed guidelines or flow sheets for these specific services.

Length of follow up

4 years observation period, unclear individual length of follow up

Location

Thailand

Outcomes measures and effect size

Rates (and recurrent rates) of foot ulceration, infection and gangrene resulting from diabetes

Not reported

Rates of hospital admission for foot problems resulting from diabetes

Not reported

Rates and extent of amputation

Number of major amputations

Defined as either a below knee or above knee amputation

Under diabetic foot protection period= 0 above knee amputations

Control period= 3 above knee amputations

P=0.28 i.e. not significant

Under diabetic foot protection period= 3 below knee amputations

Control period= 12 below knee amputations

P=0.1 i.e. not significant

Minor amputations
### Bibliographic reference

|---|

### The loss of any part of a lower limb (not including major amputations)

**Under diabetic foot protection period**
- Toe- 4 amputations
- Transmetatarsal- 0 amputations
- Syme- 0 amputations

**Control period**
- Toe- 10 amputations
- Transmetatarsal- 4 amputations
- Syme- 1 amputations

The incidence of major amputations in the protocol and standard care groups was 4.1% and 13.6% respectively (P=0.03)

### Health related quality of life

In the second study 56 participants who received diabetic foot protection and 40 patients who received standard care respectively were recruited to provide information about quality of life using the short-form 36 questionnaire.

Patients who had been seen under the diabetic foot protection service had significantly higher scores on the SF-36 questionnaire for both physical and mental health dimensions than standard care patients.

- **Total SF-26 score**
  - Under diabetic foot protection period= 54.7 ± 21.6
  - Control period= 46.0 ± 16.5
  - P=0.03 i.e. significant

### Source of funding

Unclear source of funding

### Comments

Protocol and facilitated interdisciplinary care amongst patients with diabetic foot ulcer was associated with significantly fewer major amputations and improving quality of life.