Digital Ulcers in Systemic Sclerosis
Studies of Pathogenesis, Epidemiology, Functional Impact and Treatment Response

This is an update from the 18th month report dated 16-8-10. Ideally by this time we should have completed our analysis, but progress has been slower than planned because of having to reconfigure the different responsibilities of the study as a result of Adrienne Taylor's sickness absence. We aim to have all aspects of the study analysed by the end of May 2011, and to submit abstracts describing the work to the American College of Rheumatology (abstract deadline May 2011).

Study aim

The overall aim of the study is to increase understanding of pathogenesis (cause), epidemiology, functional impact and treatment response of digital ulcers in patients with systemic sclerosis (SSc). These ulcers can be extremely painful and disabling.

Progress and achievements since August 2010

Prevalence of digital ulcers and their functional impact

Study design

Patients attending specialist scleroderma clinics for annual review between January and December 2010 were asked to participate in the study. On signing informed consent, each patient completed the following measures of manual dexterity: the Cochin hand function index and the Michigan Hand Outcomes questionnaire. A full assessment of the hands, including the Hand Mobility in Scleroderma Test (HAMIS), was carried out, and all digital ulcers were documented and assessed. Clinical and demographic data, including data on physical function from the Scleroderma Health Assessment Questionnaire (SHAQ) and the Scleroderma Functional Index, were recorded.

The data files from all patients have been reviewed, and data extracted for analysis. Most of the data have now been summarised, and analysis will soon be complete. Some summary results which are already available are as follows:

Recruitment

During the 12 month recruitment period, a total of 199 patients were approached and 148 (74%) agreed to participate in the study.

Sample characteristics

Demographic and clinical characteristics are shown in Table 1 for the sample as a whole.

Table 1.

Variable	**Total study population (n=148)**
Gender	Female 125, Male 23
Age (mean [standard deviation])	58.9 (10.8)

in years	
Disease duration (mean [standard deviation]) in years	13.9 (8.17)
Smoking	Current 17, Ex-smokers 52, Never 72, Unknown 7

Prevalence of digital ulcers

The number of patients presenting with digital ulcers at the time of their clinic visit was 15 (10%).

Characteristics of digital ulcers

Of the 15 found with digital ulcers, 8 had a single ulcer and 7 had multiple ulcers.

Physical function

Scores for the Scleroderma Functional Index, the HAQ and the HAQ Visual Analogue Scales (VAS) are shown in Table 2 for the sample as a whole.

Hand function

Scores for the HAMIS, Cochin and Michigan are shown in Table 2 for the sample as a whole.

Table 2. Results are mean (standard deviation)

Variable	**Total study population (n=148)**
Physical function	
Scleroderma Functional Index*	10 (7.6) *Range 0-33*
HAQ overall score**	1.40 (0.96) *Range 0-3*
Pain VAS	0.91 (0.79) *Range 0-3*
Raynaud's VAS	0.93 (0.82) *Range 0-3*
Finger Ulcer VAS	0.52 (0.78) *Range 0-3*
Overall VAS***	0.98 (0.75) *Range 0-3*
Hand function	

HAMIS Right	9.61 (8.6)
HAMIS Left	9.29 (8.51)
Cochin Hand Function Scale	20.72 (19.10) *Range 0-90*
Michigan – Hand Function	68.7 (9.7) *Range 0-100*
Michigan – Daily Life	65.77 (27.6) *Range 0-100*
Michigan – Work	52.67 (31.8) *Range 0-100*
Michigan – Pain	47.33 (27.7) *Range 0-100*
Michigan – Aesthetics	45.88 (25.3) *Range 0-100*
Michigan – Satisfaction	58.87 (28.8) *Range 0-100*
Michigan – Overall score	56.55 (14.1) *Range 0-100*

* 4 missing

** 4 missing

*** 6 missing

Incidence and pathophysiology of digital ulcers

Sixteen patients developed new digital ulcers during the 12 month follow-up period and were agreeable to attending for further studies. All patients underwent a detailed assessment, including X-rays, thermography, laser Doppler imaging and skin autofluorescence, which will provide unique insights into the pathophysiology of systemic sclerosis-related digital ulcers. The imaging is in the process of being analysed. We do not wish to present an incomplete analysis, and so will forward this as soon as available.

Summary and future plans

1. All data collection is complete. Fifteen of 148 patients (10%) in the prevalence study had digital ulcers at the time of their annual review clinic visit and 16 patients agreed to participate in the studies of pathophysiology of incident ulcers.
2. The analysis of the prevalence study should be completed by the end of April 2011.
3. All images from the pathophysiology study should be analysed by the end of April 2011, and results analysed by the end of May 2011.
4. Abstracts describing both studies will be submitted to the American College of Rheumatology meeting.
5. First drafts of the two papers (prevalence and pathophysiology) to be completed by July 2011.

Professor Ariane Herrick, March 2011