

Title: Improving access to digital ulcer care through nurse-led clinic: a service evaluation.

Short running title: Nurse-led digital ulcer clinic

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Abstract

Objective: Digital ulcers (DU) remain one of the most burdensome co-morbidities in systemic sclerosis. The objectives of the study were to describe patient-level stratification and to evaluate a nurse-led DU clinic service development.

Methods: A nurse-led digital ulcer clinic was established to identify patients with DU and manage them. Patients were recruited through scleroderma clinics, GP referrals and self-referrals. The clinic involved patients being treated with appropriate treatment. Patients were stratified according to their DU risk level based on number and severity of ulcers. Among these, 22 patients were asked to complete a patient satisfaction survey. Data were analysed descriptively.

Results: 75 patients were seen in the clinic, 46 (61%) were 56 years of age and above. Patients were identified as high (23%), medium (51%) or low risk (26%) for development of DU. The duration of DU history was from 7 months to 40 years. Prior to attending the nurse-led DU clinic, 90% of patients had received up to six courses of antibiotics for their DU, 76% had attended A&E, and 90% had unscheduled appointments. 90% had been seen by the GP due to DU and subsequently required hospital admissions. During the nurse-led clinic follow-up, only 2 patients had emergency admission. All patients reported that their needs in personal care of DU were met.

Conclusion: There are a significant number of people with SSc who have DUs affecting their quality of life as well as needing more healthcare services. A dedicated specialist nurse-led DU clinic may improve overall care of patients.

Background

Systemic sclerosis (SSc), also called scleroderma, is a complex multifaceted autoimmune rheumatic disease characterised by vascular damage, immune activation and fibrosis (Johnson et al., 2002; Geyer & Muller-Ladner, 2011). Its clinical presentation varies, with symptoms presenting in the skin, cardiovascular, gastrointestinal, musculoskeletal and pulmonary systems and in vasculopathy.

While SSc is considered a rare disease based on its prevalence (82 per 1,000,000 adjusted for the UK population) (Allcock et al, 2004), it has a very substantial disease burden and one of the highest mortality risks among any of the connective tissue diseases. A meta-analysis of cohort studies conducted by Elhai et al (2012) has estimated a pooled standardised mortality ratio of 3.53 (95% CI 3.03 to 4.11). Due to its multisystem involvement, the disease has severe physical and psychosocial impact affecting patients' quality of life (Frantz et al, 2016).

Among the most frequent SSc complications are digital ulcers (DUs), which are an external manifestation of systemic vasculopathy. These ulcers can be persistent and debilitating, as well as challenging to manage (Ennis et al., 2013; Mouthon et al., 2014; Mouthon et al., 2010; Guillevin et al, 2013). Up to 50% of patients with SSc will experience DUs at some point in the course of their disease and around a third of all SSc patients present with recurrent DUs, defined as persistent or recurrent ulcers for at least 6 months (Khimdas et al., 2011; Hachulla et al., 2007; Walker et al., 2007). When DUs develop, they can be very painful, difficult to treat and usually take a long time to heal especially if they are associated with calcinosis and osteomyelitis (Ennis et al., 2013; Hughes & Herrick, 2017; Zhou et al., 2014). DU may develop on any parts of the digits in particular over the tips and digital contractures (Mouthon et al., 2014; Mouthon et al., 2010; Hachulla et al., 2007; Amanzi et al., 2010). Regardless of the sites, they can lead to hand impairment and functional loss, and their impact can be disabling physically (Ennis et al., 2013; Guillevin et al., 2013) and mentally (Mouthon et al., 2010).

In severe cases, DUs lead to complications such as osteomyelitis, permanent tissue loss, ischaemia, gangrene and amputations. This is in addition to the deleterious effects on patients, resulting in loss of work productivity, loss of quality of life and significant impact on healthcare costs to society (Hachulla et al., 2007; Matucci-Cerinic et al., 2015; Nihtyanova et al., 2007; Steen et al., 2009; NHS England, 2015).

Historically, patients with more severe DUs are admitted for intravenous infusions of prostacyclin analogues (e.g. iloprost) and other expensive therapies. These high-risk patients are also more likely to require frequent hospitalisation for treatment of their severe DU disease (Zhou et al., 2014; Amanzi et al., 2010; Matucci-Cerinic et al., 2015; Nihtyanova et al., 2007; Steen et al., 2009; NHS England, 2015; Denton et al., 2016). During 2011, the Royal Free Hospital had 64 patients with DUs requiring non-elective admissions resulting in 1,487 bed days and of those 40 required iloprost infusions. Not all these patients would have been admitted because of DU, but a considerable number of these admissions arose from complications of DU rather than simply their presence. It was assumed that if these high-risk patients could be identified and a proactive approach to disease prevention adopted, there would be a reduction in hospital resource use associated with admission for treatment of digital vasculopathy.

The aim of this study was to evaluate the impact of the adoption of a DU disease prevention strategy according to the Royal Free Hospital treatment algorithm for high-risk SSc patients. The objective being a reduction of hospital admissions for treatment of digital vasculopathy over a 12-month period compared with the preceding 12-month period. A nurse-led clinic was set up to improve access and service for patients with DU, so that they could be reviewed in a timely manner thereby reducing hospital admissions and reducing complications.

Methods

This was an evaluation of a new nurse-led clinic for DU in one hospital in London. As a service evaluation, ethical approval was not required. An innovative nurse-led digital ulcer clinic was set up in June 2012 to identify adult patients with a diagnosis of SSc and digital ulcers who needed proactive disease management. Information was gathered through the nurse-led clinic notes into the local DU database.

Identification and recruitment

New and old patients were alerted to the existence of the DU clinic through patient education sessions and patient newsletters. Seventy-five patients were identified with ulcers from the SSc clinics, GP referrals, patient self-referrals, via the Emergency Department (A&E) or from the inpatient ward. Thirteen patients had other ulcers such as elbows, wrist, toes, shin, calf and the rest had finger ulcers. Patients were classified according to the diagnosis that was documented in their medical notes. There were 26 diffuse cutaneous systemic sclerosis patients, 45 with limited cutaneous systemic sclerosis and one patient each with mixed connective tissue disease, undifferentiated connective tissue disease, severe vasculopathy and secondary Raynaud's.

Measures

Among all the patients seen in the digital ulcer clinic, a subset of 22 unselected patients was asked to complete a service satisfaction questionnaire. The questionnaire consisted of a baseline and an exit questionnaire. The baseline questionnaire explored DU complication history, management of DU and access to medical services including frequency of A&E attendances, GP attendances and unscheduled appointments. Unscheduled appointments were defined as appointments arisen as a consequence of unexpected needs or emergency at the request of the patients or GPs. The exit questionnaire enquired about patient experience related to DU clinic attendance such as waiting times, duration of consultation, feedback on quality of service provided and treatments offered for DUs. These patients were followed up over variable periods (at least once a month) when their DU was actively managed in the clinic.

Results

A majority of the respondents (61%) who attended the DU clinic were 56 years old and above, and 76% of these were women. The DU disease duration was variable ranging from 7 months to 40 years.

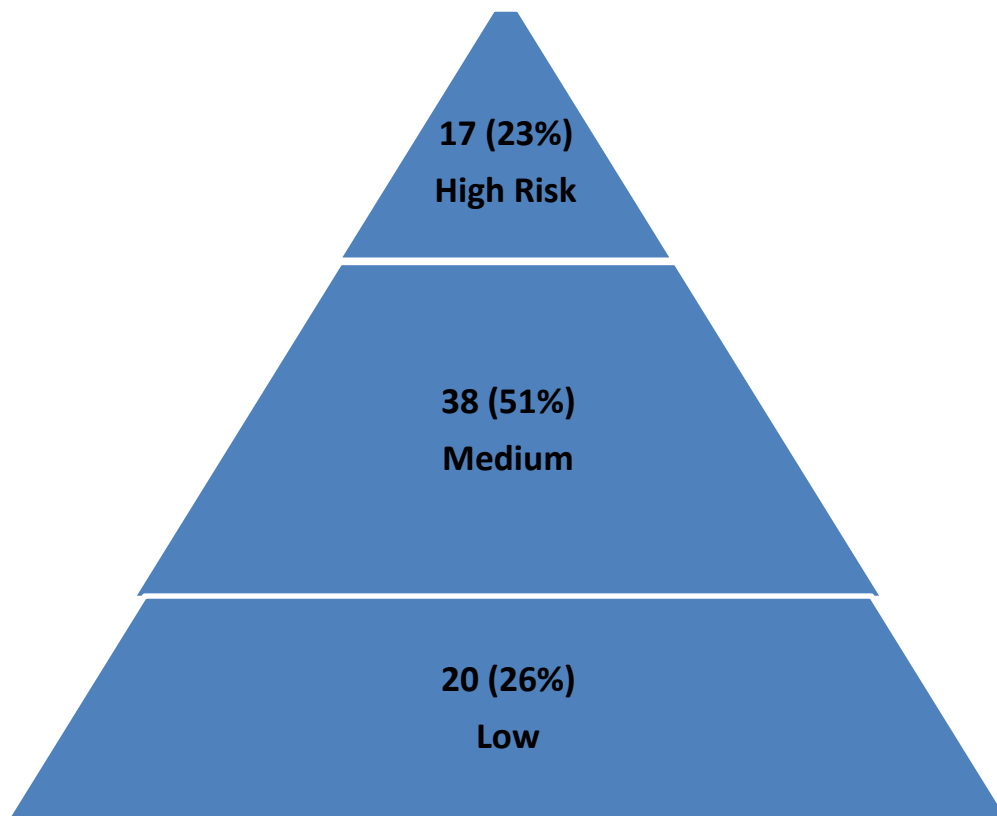


Figure 1: Risk of developing DUs for patients enrolled into the DU Clinic

Figure 1 above demonstrates the classification of the patient groups who were seen in the clinic from June 2012 to June 2014. Patients were seen within 1–3 weeks of referral. Follow-ups were mostly after 2–3 weeks. Patients who were identified to be high risk had multiple ulcers at the time of being enrolled into the DU clinic. Tables 1 & 2 reveal the complications and interventions experienced by this group.

Complications	Jun 2012- Jun 2013	Jun 2013- Jun2014
Gangrene	4	1
Digital Ischemia	3	1
Soft tissue infection	10	6
Auto-amputation	0	0
Osteomyelitis	3	1

Table 1: Complications in high-risk group

Interventions	Jun2012- Jun 2013	Jun 2013- Jun 2014
Emergency admissions	5	0
Sympathectomy	1	0
Debridement	3	1
Angioplasty	1	0

Table 2: Interventions in high-risk group

During the 2 years between 2012 and 2014 the high-risk group received different advanced therapies to assist with the digital ulcers. Ten patients received sildenafil, bosentan was prescribed for 10 patients, and 5 patients had unscheduled iloprost. The table below (Table 3) indicates the number of patients per advanced therapy each year. Interestingly, the second year indicates a reduction of unscheduled iloprost in this group by 75%.

Advanced Therapy	Jun 2012-Jun 2013	Jun 2013-June 2014
Sildenafil	4	6
Bosentan	4	6
Unscheduled Iloprost	4	1

Table 3: Advanced Therapy in high-risk group

In the high-risk group, one patient was offered bosentan but refused therapy due to fear of side effects. Another patient had to discontinue bosentan because of side effects. Three patients were lost to follow-up due to lengthy travel times between homes to hospital. Five patients were discharged from the clinic as their ulcers completely healed as a result of the management they received in the clinic. In this group of patients, it should be noted that in June 2013–2014 there were no interventions received by the patients, which could be as a result of receiving more advanced therapies, i.e. bosentan and sildenafil. Additionally, there was a significant reduction of unscheduled iloprost from 4 to 1 from 2013–2014. This may reflect better outcomes from more prompt initiation of advanced therapies.

The medium-risk patients had at least one DU at enrolment in clinic. Their vasodilation therapy was maximised. Tables 4 & 5 below show the complications they encountered and the interventions they received. Table 4 shows 1 individual who had gangrene in 2012–2013 who continued to have the same problem in the following year 2013–2014; this shows that these complications can persist for a long time.

Complications	Jun 2012 – Jun 2013	Jun 2013– Jun 2014
Gangrene	1	1
Digital ischemia	1	1
Soft tissue infection	9	11
Auto-amputation	1	0
Osteomyelitis	0	2

Table 4: Complications in the medium-risk patients

Interventions	Jun 2012 – Jun 2013	Jun 2013 – Jun 2014
Emergency admissions	2	0
Sympathectomy	0	0
Debridement	0	1
Angioplasty	0	0
Advanced Therapies		
Bosentan	1	3
Sildenafil	2	0
Unscheduled iloprost	0	0

Table 5: Interventions in the medium-risk patients

Table 5 indicates the reduction of interventions between June 2012 and June 2014 and the advanced therapies received. 3 patients were prescribed bosentan but none had sildenafil or unscheduled iloprost. Twenty-four patients in this group were able to be discharged during the period of June 2012 to June 2014 and 1 patient passed away from scleroderma heart involvement.

Patients considered low risk presented to clinic with solely xeroderma, cracked skin, digital pits or paronychia. For all these patients, face to face education was given including an information leaflet as shown in Figure 2. In this group, most patients were seen once in clinic and discharged.

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Skin care

Skin care is essential for everyone, especially for people who suffer from dry, chapped, itchy and irritated skin. Moisturising makes the skin softer and looks healthy & supple. Every one is different and it is about looking for emollients and moisturisers that gets on with one's skin.

Here are some examples and where to obtain them.

Bathing & Showering

Product	Use	Where to obtain
Aveeno Bath & Shower	Emollient	Any supermarket or pharmacy
Hydromol Bath & Shower	Emollient	GP
Double base Bath	Emollient	GP
Double base Wash	Emollient	GP
Epiderm Cream/Ointment	Emollient	GP
Oilatum	Emollient	Any supermarket/pharmacy
Eucerin Bath & Shower oil 20% omega	For itchy skin	Pharmacy/ GP
Bath E45	Emollient	Pharmacy
QV Gentle Wash	Emollient	GP

Moisturisers

Product	Where to obtain
Hydromol Ointment/ Cream	GP
Aveeno Lotion/ Cream	Supermarket/ Over the counter
QV Skin Lotion/ Cream	GP
Flexitol Hydrating skin Lotion	GP/Over the counter
Double base Gel	GP
Cetaben	GP
Dermol Lotion	GP
Double base Dayleve Gel	GP
Epiderm Cream/ Ointment	GP
Diprobase	GP
E45	Over the counter/GP

Chapped or extra dry skin Moisturisers

Product	Where to Obtain
Hydromol intensive	GP
Eucerin Soothing Skin Balm	GP/over the counter
Calmurid	GP
QV Intensive Cream	GP
Aveeno Skin Relief Moisturising Lotion	Over the counter/Supermarket

Itchy Skin

Product	Where to Obtain
Flexitol Very Dry Skin	Over the counter/GP
Eucerin Dry Skin Intensive 10%	GP/Over the counter
Balneum Plus Cream	GP/ over the counter
E45 Itch Relief	Over the counter/GP
Dermol Cream	GP

Dry Hands

Product	Where to Obtain
Eucerin Intensive hand Cream 5%	Pharmacy
Urea	Pharmacy
Neutrogena hand cream	Pharmacy
Flexitol Hand Balm	Pharmacy

Dry Feet

Product	Where to obtain
Flexitol Heel Balm	Over the counter/GP
Eucerin Intensive Foot Cream 10%	Over the counter/GP
Flexitol Moisturising Foot cream	Over the counter/GP

Patient Information
Created June 2011

1

Patient Information
Created June 2011

2

Figure 2: Skin Care Leaflet

Service development

Of the 22 patients who were invited to complete the satisfaction questionnaires, in the baseline questionnaire 71% of the patients admitted that prior to attending the clinic their DU was primarily managed by their rheumatologist while 10% indicated only minimal input by a healthcare professional to medical treatment of the DU. Management of DU was variable with systemic approaches with antibiotics, topical treatments and surgical interventions. Prior to DU clinic attendance, 90% reported having received up to six courses of antibiotics in the past one year.

The patients who completed the 14-question exit questionnaire were those being discharged because their ulcers had healed. These patients had been reviewed at variable intervals as judged on clinical need, with a majority reviewed monthly. They reported having received variable treatments throughout the time they were being seen in the digital ulcer clinic. All patients were advised on medication optimisation, wound management, skin care and self-management. Only 2 patients in this group needed emergency admission during follow-up. All patients were satisfied with the

services provided in the digital ulcer clinic including consultation time, waiting times, patient information regarding DU care and wound dressings.

Discussion

This study indicated the feasibility of a digital ulcer nurse-led clinic and its benefit to affected patients. The burden and complications of DU are well documented in the literature (Frantz et al., 2016; Ennis et al., 2013; Mouthon et al., 2014; Mouthon et al., 2010; Guillevin et al., 2013). When complications occur in DU this can result in unscheduled clinic or hospital visits, with subsequent hospitalisation, surgery and expensive treatments (Korn et al., 2004; Kowal-Bielecka et al., 2009). Most digital ulcers are managed by rheumatologists in specialist centres, or under shared care between rheumatology centres and primary care. Not all healthcare professionals in these areas have an interest or knowledge in managing DUs properly; moreover they do not have a dedicated nurse specialised in DUs. There is an unmet need in that 38% of the patients in our study admitted that they had looked after their own DU without the help or advice from a healthcare professional before the digital ulcer clinic was established.

The DU stratification in our study (high, medium and low risk), was in line with the Digital Ulcer Observational (DUO) Registry (Denton et al., 2011). The DUO stratified patients as no DU, episodic, recurrent, and chronic DU. Despite the stratification, the burden that these patients experience is the same. In our study, 76% of patients had attended accident and emergency units at some point due to their DUs. Prior to the DU clinic establishment, 90% of the patients had unscheduled clinic visits; however, during the follow-up in the nurse-led DU clinic there was a significant reduction in unscheduled appointments with only 2 patients requiring emergency visits.

The results from the two years of patients attending the DU clinic revealed significant drop in complications encountered by the patients in all the groups. Patients required fewer interventions, hospital admissions and unscheduled or emergency clinic visits due to medication optimisation with more patients on advanced therapy.

With the satisfaction survey, it can be seen that the patients found the clinic valuable, as they had a point of contact solely for their DU. There were high levels of satisfaction with the service provided. Additionally, a patient and healthcare professional information sheet was developed following the establishment of this clinic to provide information on how DUs can be cared for.

Conclusion

In summary, despite a major resource challenge involved in devoting time and effort into developing the nurse-led clinic, there was outstanding progress observed in achieving the clinic's objectives and meeting the patients' needs. This clinic gave an insight into future planning in DU management and is in line with the work that was completed by the UK Scleroderma Study Group relating to best practice management of scleroderma digital vasculopathy. Moreover, this project revealed some gaps that need addressing in digital ulcer care such as the need for more DU nurse-led clinics, patient DU self-management schemes, and healthcare professional DU education especially in primary and secondary care. Furthermore, it is assumed that not all patients who developed DUs were seen in this clinic, because they were not aware of the clinic or did not seek help or lived far away from the specialist centre.

Our work suggests that a dedicated digital ulcer nurse specialist may offer a cost-effective approach to digital ulcer management.

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