The impact of diabetic foot ulcer pain on patient quality of life

Sarah Bradbury, Patricia Price

Abstract

Aims: This cross-sectional, exploratory study investigated the presence and characteristics of diabetic foot ulcer (DFU) pain and its impact on quality of life (QoL). Methods: A two-phase approach was adopted using audit to determine the extent of the problem within one specialist clinic population, followed by a qualitative design using semi-structured interviews to explore the effect on QoL from the patients' perspective. Results: Twenty-eight patients were included in the audit. Pain was assessed using a modified Short-Form McGill Pain Questionnaire. 86% of patients (n=24) reported some degree of DFU pain. Aching was the most common sensory pain (n=14). Tiring/exhausting was the most common affective descriptor (n=10). Three patients were recruited into the interview phase. Content analysis identified four themes: experience of pain; physical effects of pain; coping, support and social impact; psychological impact Conclusions: DFU pain can occur frequently and intensely despite peripheral neuropathy, and is not necessarily limited to the presence of DFU-related complications. It can affect patients physically and psychologically. Further qualitative work into the patient's perspective on DFU pain would help clinicians to understand the relevance to diabetic foot care, and aid in the provision of holistic care. Conflict of interest: None.

KEY WORDS

Diabetic foot ulcer Quality of life Pain Patient's perspective

ecognition of the presence and impact of wound-related pain for patients with various wound types is growing (Dallam et al, 1995; Lindholm et al, 1999; Hollinworth and Collier; 2000; European Wound Management Association [EWMA], 2002; World Union of Wound Healing Societies [WUWHS], 2004), yet a lack of evidence still remains in some areas, such as pain outside of dressing changes or for wound aetiologies other than venous leg ulcers (VLU). Diabetic foot ulcer (DFU) pain is a particular area which has been underresearched, yet two recent studies have

Sarah Bradbury is Research Nurse, Department of Dermatology and Wound Healing, Cardiff University; Patricia Price is Professor and Dean of Healthcare Studies, Cardiff University suggested that specific ulcer pain from DFU is more prevalent than expected and can impact on quality of life (QoL) (Ribu et al, 2006; Bengtsson et al 2008).

Neuropathic pain is often assumed to be the only type of pain experienced by DFU patients (Freedman et al, 2004; Driver et al, 2007), except as a symptom of complications such as infection, Charcot arthropathy or osteomyelitis (Sibbald et al, 2006). UK clinical guidelines (National Institute of Health and Clinical Excellence [NICE], 2004) and advisory literature offered by the International Diabetes Federation (IDF) for the assessment and management of DFU do not consider pain at all, except as an indicator of infection. Although it is well-documented that these factors often cause pain in an insensate foot, there still appears to be no evidence to suggest that patients with DFU do not experience nociceptive pain, procedural pain or other experiences of non-cyclic or cyclic acute pain as described by Krasner's Chronic Wound Pain Model (Krasner, 1995).

It is known from previous qualitative studies (Carrington et al, 1996; Brod, 1998; Meijer et al, 2001) that both DFUs and pain generally can negatively

affect QoL through such influences as reduced mobility, loss of independence, increased amputation risk and multiple, prolonged clinic visits (Goodridge et al, 2005). Many patients reported that ulcer pain affected sleep and that they had to avoid pressure on the ulcer, even from bedclothes. Pain was reported when walking even short distances and during dressing changes (Ribu and Wahl, 2004; Ashford et al, 2000). Despite this, there is relatively little research in this area. Although pain is often raised as an issue in studies on DFU and QoL, none have looked specifically at DFU pain and QoL from the patient's perspective.

This lack of evidence, along with the outcomes of the previous studies into DFU pain, suggest it is an area worthy of further consideration in order for patient's to be appropriately assessed and managed. This led to the formulation of a cross-sectional, exploratory study to investigate the presence and characteristics of DFU pain and the potential effect on QoL. The study aimed to gain information on the number of patients attending one specialist diabetic foot clinic who experienced DFU pain, determine if a relationship existed between ulcer pain and specific aetiologies of DFU, explore the type and

Clinical RESEARCH/AUDIT

intensity of pain experienced, and current management strategies being utilised. The final aim was to investigate how ulcer pain impacts on QoL.

Methods

The study was performed in two phases due to the need to collect quantitative and qualitative data.

A local audit was used in the first phase to collect data on the number of patients experiencing DFU pain and to gather data on their DFU history and characteristics of the pain at a single time point, providing a 'snapshot' of occurrences within the sample (Greenhalgh, 2001).

Consecutive patients attending over an eight-week period were assessed for inclusion (see Table 1 for inclusion/ exclusion criteria). This time period was with consideration to the average number of patients seen within the clinic that could provide an idea of the scope of the problem from which to draw reasonable conclusions. Patients with active infection, osteomyelitis or Charcot arthropathy were included to determine if a specific correlation between DFU pain and these complications existed. This provided a more representative sample as large numbers of patients seen in specialist diabetic foot clinics regularly encounter these problems, thus reflecting the realities of clinical practice.

A clinical assessment tool was devised for data collection of simple demographics and a thorough clinical history of patients' diabetes and foot ulcer(s). The tool was positively reviewed by colleagues before starting the audit to obtain feedback on its ease of use in the clinic setting.

Diagnosis of aetiology was made following full vascular and neurological assessment and foot inspection, guided by the recommendations of the International Working Group on the Diabetic Foot (IWGDF, 2007). A wound assessment was performed using standardised criteria, and classified using the University of Texas Classification System (UTCS) (Lavery et al, 1996). Type of footwear, frequency of podiatry visits and referrals made to a specialist pain practitioner were recorded.

Table I

Phase one: inclusion/exclusion criteria

Inclusion criteria	Exclusion criteria		
Over 18 years of age	Dementia or learning/communication difficu		
Diagnosis of diabetes mellitus	Problems with vision making questionnaire completion difficult		
One or more foot ulcers below the malleolus	Surgical or amputation wounds		
Willing and able to complete a simple pain questionnaire			

Table 2

Phase two: inclusion/exclusion criteria

Inclusion criteria	Exclusion criteria		
Over 18 years of age	Dementia or learning/communication difficulties		
Experience of specific DFU pain			
Willing to participate in an interview			
Able to fully understand and give informed consent			

Pain was assessed using a modified version of the Short-Form McGill Pain Questionnaire (SF-MPQ) (Melzack, 1987) which captures the nature and intensity of pain, assisting in identifying if certain pain characteristics are associated with DFU. The patient was asked to give specific consideration to any pain in, or immediately surrounding, the ulcer only. The aim was to ascertain if the pain was specifically ulcer-related and not primarily of neuropathic origin.

Verbal informed consent was obtained from each patient before completion of the SF-MPQ. As the information being gathered was for audit purposes and within the realms of normal clinical practice, formal ethical approval was not required.

The audit data was summarised, classified according to ulcer aetiology, and analysed using appropriate statistics. The

results of the SF-MPQ were analysed as outlined in the original articles on the full MPQ and the SF-MPQ (Melzack, 1975; 1987).

After the first phase was completed and it had been determined that DFU pain was being experienced in sufficient numbers within the authors' patient population, an exploratory research design was continued in the second phase using qualitative methods.

Participants were chosen using purposive sampling from the same local specialist diabetic foot clinic as phase one. Basic inclusion/exclusion criteria were used to assess if a participant was suitable (*Table 2*).

Face-to-face semi-structured interviews were considered an appropriate method to collect qualitative data on the effect of DFU pain on

everyday life. An interview schedule was developed to guide the conversation onto relevant topics based on the study aims and issues identified within the literature, but with a particular focus on pain. The first interview acted as a pilot of the schedule to determine if the questions were valid and easy to understand, and to gain insight into how the questions were interpreted by patients to try to improve reliability. Following this, the interview schedule was shortened and revised to include broader topic areas.

The interviews were recorded and manually transcribed. Reflective notes were also made shortly after completing the interview, recording any nonverbal communication, the researcher's thoughts on the topics covered and the response of the participant to ensure that the best quality information was assembled for analysis.

The study protocol for the second phase was approved by the Local Research Ethics Committee. Confidentiality and anonymity were maintained throughout the research process, and written informed consent was taken. Identification of suitable participants and completion of the interviews occurred over a six-month period. All participants chose to be interviewed at home, and each interview lasted approximately 30 minutes.

The taped conversations were transcribed by the researcher and verified by a second researcher not involved with the interviews. A copy was sent to the appropriate participant for verification and to make any required changes or additions. These processes were performed to improve reliability and minimise bias within the study findings. The transcribed and verified data was analysed using thematic content analysis, guided by elements of the method published by Burnand (1991).

In an effort to demonstrate methodological rigour and reduce researcher bias, the identified data categories were checked by a second researcher to ensure the primary interpretation fairly represented the data. The themes were examined to identify any associated relationships, which were discussed and compared.

Results Phase one

Twenty-eight patients were recruited into the audit from March–May 2007. The majority of the patients were male (n=22). The overall sample was aged 43–92 years (mean 67.5, sd 13.56). *Table* 3 indicates the diabetes history.

Diabetic foot ulcer history

50% of patients presented with an ulcer(s) of neuropathic aetiology (n=14), and 46% with neuroischaemic aetiology (n=13). Only one patient had a purely ischaemic ulcer. Mean ulcer duration of 48 weeks (sd 66.21, range 1–234 weeks). Ulcers were classified using UTCS and indicated a range of scores from A1 to D3, the most common

being A1 (29%). Some problems with clinician understanding of the UTCS were identified when results were compiled, making analysis of any correlation between DFU pain and increasing DFU severity using the Texas scores unreliable.

Analgesia

Sixteen patients (57%) were taking regular oral analgesia, including drugs for neuropathic pain. 43% (n=6) of patients with neuropathic foot ulcers (NFU) were taking analgesia compared with 69% (n=9) with neuroischaemic ulcers (NIU).

Analgesia was not always taken specifically for ulcer-related pain. 63% (n=15) of patients reporting some degree of DFU pain were taking analgesia, while nine patients (38%) who recorded DFU pain took no analgesia. Two patients had previously seen a pain specialist due to pain related to diabetic foot problems.

Table 3
Diabetes characteristics by aetiology

	N (n=14)	NI (n=13)	 (n=1)	Total (n=28)
Type of diabetes				
Type I	2	0	0	2
Type 2	12	13	1	26
Mean duration of diabetes (years)	14.3	24.6	5	18.8
Number of diabetes-related complications				
0	3	0	0	3
T. Control of the con	6	0	0	6
2	5	6	ı	12
3	0	3	0	3
4	0	3	0	3
5	0	ı	0	ı
Type of diabetes-related complication				
Cardiovascular disease	6	- II	ı	18
Peripheral vascular disease	0	13	ı	14
Retinopathy	5	7	0	12
Nephropathy	2	4	0	6
Minor amputation	2	3	0	5

N= neuropathic; NI=neuroischaemic; I=ischaemic

Presence of DFU pain

86% of patients (n=24) reported some degree of DFU pain on the SF-MPQ. The overall possible score obtainable using the SF-MPQ is 142. Higher scores indicate higher pain levels. The range of scores obtained across the sample was 0–91.

Of the patients reporting DFU pain, 39% (n=11) had NFUs and 50% (n=12) had NIUs. The patient with a purely ischaemic ulcer also reported pain. For comparative purposes only, the neuropathic and neuroischaemic groups will be used. The results of the ischaemic patient will be considered as part of the overall group.

14% of patients (n=4) reported no ulcer pain on the SF-MPQ, scoring 0 on both the pain descriptors and visual analogue scale (VAS) elements. Of these, three had NFU and one NIU. A further six patients (25%) reported pain in the bottom 10% of overall recorded scores (=9), four NFU and two NIU.

Characteristics of DFU pain

Figure 1 shows all types of pain on the SF-MPQ recorded by the sample. The first ten descriptors indicate the sensory component of the pain sensation, and the final four, the affective component. Aching was the most commonly reported sensory type of DFU pain (n=14), with tiring/exhausting the most common affective descriptor (n=10).

Figure 2 compares pain descriptors used by patients with neuropathic and neuroischaemic aetiology. Despite reporting similar types of pain, there tended to be a higher frequency for the neuroischaemic patients across both the sensory and affective components.

Pain intensity

VAS scores obtained across the whole sample were from 0–73, with an average score of 26.4 (sd 24.3). 46% (n=13) recorded pain levels >40mm using the VAS, a level indicating moderate to severe pain intensity requiring immediate review and intervention (WUWHS, 2004).

For the neuropathic group, the mean VAS score was 21.6 (sd 24.6, range 0–73). Seven patients recorded scores

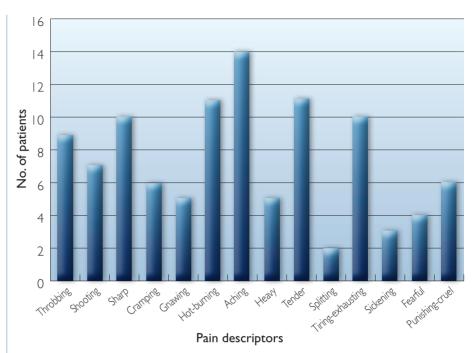


Figure I. SF-MPQ pain descriptors.

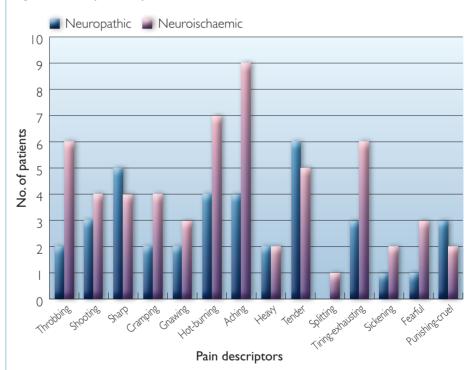


Figure 2. SF-MPQ pain descriptors by aetiology.

in the bottom 10% (=7). For the neuro-ischaemic group, the mean score was 32.2 (sd 24.6, range 0–67). Three patients recorded scores in the bottom 10%. The patient with an ischaemic ulcer recorded a VAS score of 27.

Figures 3 and 4 indicate the reported pain intensity for each pain descriptor using the SF-MPQ by aetiology. Across the sample, mild pain was reported 84

times, moderate pain 44 times and severe pain 12 times.

Pain and DFU-related complications

64% (n=18) presented with one or more DFU-related complications (*Table 4*). Eight patients with clinical signs of ulcer infection were taking systemic antibiotics. Five patients with suspected osteomyelitis were referred for further investigations, five had confirmed osteomyelitis, three of

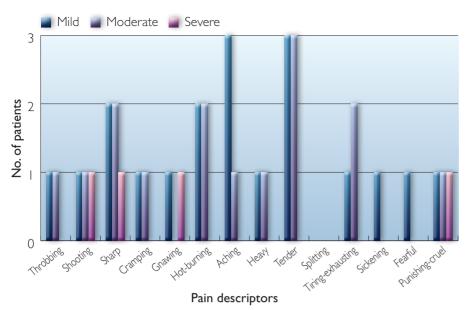


Figure 3. SF-MPQ pain intensity for neuropathic aetiology.

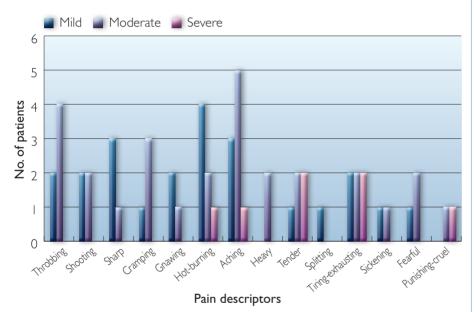


Figure 4. SF-MPQ pain intensity for neuroischaemic aetiology.

which were chronic. One patient of the eight with Charcot arthropathy had an active Charcot during assessment.

Fourteen of these patients reported some degree of DFU pain, and four recorded an overall score of zero on the SF-MPQ. The mean VAS score for patients with one or more DFU-related complications was 26.1 (sd 24.4), compared with 26.9 (sd 25.4) for the comparative group with no DFU-related complications. For the overall SF-MPQ score, the group with complications had a mean score of 31.9 (sd 28.5), compared with 33.3 (sd 31.9) for those without. Figure 5 compares the pain descriptors

used by patients with and without DFU-related complications and *Figures 6* and 7 compare pain intensity.

Pain and pressure-relieving footwear

18 patients (64%) wore some form of pressure-relieving footwear, resulting in an average VAS score of 26.9 (sd 23.9) and overall SF-MPQ score of 33.2 (sd 28.2) versus 25.4 (sd 26.3) and 31.0 (sd 32.3) for those who wore normal shop-bought footwear.

Pain and podiatry input

20 patients (71%) regularly attended a podiatrist for DFU assessment, review and management. The average VAS score

for these patients was 25.0 (sd 23.8), with an average overall SF-MPQ score of 31.1 (sd 28.4), versus 29.9 (sd 26.9) and 35.9 (sd 33.0) for those who received no regular podiatric input.

Phase two

Three patients were recruited between September 2007 and January 2008. The intended sample was five patients but, mainly due to the time delay while waiting for ethics approval, a number of patients achieved ulcer healing and were discharged, or no longer had pain in their ulcer. Some patients refused to participate.

The study sample, again although small, presented views from a male and female perspective (*Table 5*). The type and duration of diabetes and ulcer aetiology and duration were similar across the group. All the patients had complex medical histories consisting of independent diseases and diabetes-related complications, which could impact on QoL. The interview data will be presented using the four themes generated during analysis.

Experience of pain

This theme was generated from the patients' descriptions of their pain, when it occurred, the factors that caused it or made it worse and how they managed it.

Participants described their pain in various ways — sharp, unexpected, variable in occurrence but of severe intensity, intermittent, spontaneous, continuous and unrelenting. One described it '... as if my foot were in a bed of stinging nettles', while another stated it was the worst he had ever had.

None of the patients seemed surprised to be experiencing pain, despite having peripheral neuropathy. One felt that pain could even be a good sign, while another was more surprised at its severity.

The main issue consistently raised relating to factors that increased or worsened pain was application of pressure on the wound, especially during dressing changes and from footwear.

All patients described pain occurring in

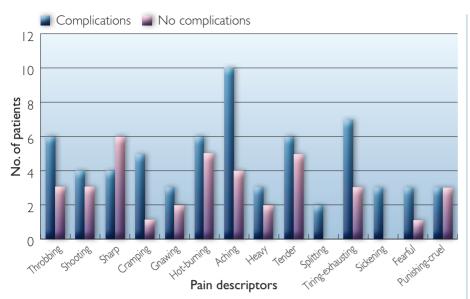


Figure 5. Comparison of pain descriptors used by patients with and without DFU-related complications.

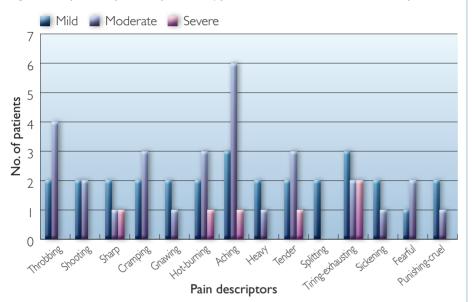


Figure 6. SF-MPQ pain intensity for patients with DFU-related complications.

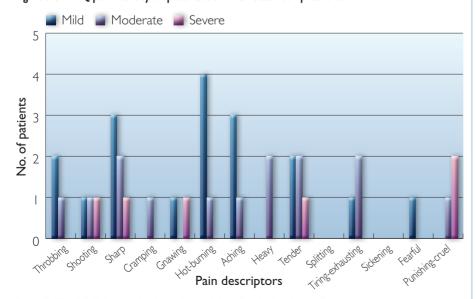


Figure 7. SF-MPQ Pain intensity for patients without DFU-related complications.

bed due to pressure from bedclothes or moving to lie on the ulcer:

... I can't sleep in bed, I can't stand blankets or anything on the foot.

Two patients having dressings changed by family members stated it was not terribly painful, except during cleansing and if the dressing had 'dried out'.

The patient having dressings changed by district nurses remarked that cleansing could be painful, but felt the pain was more dependent on the individual performing it, describing some as 'rough-handed'. He also experienced pain during dressing application and for some time afterwards: 'If anybody touches it, it's hell'.

Difficulty finding footwear that did not exert pressure and cause pain was expressed by two patients. Both had bought their own shoes or found solutions, but not always ideal ones, such as wearing sandals throughout the winter. One was particularly frustrated with the service provided by the hospital as she did not feel listened to, finding the shoes too heavy, bruising the feet and aggravating the toe ulcer:

Analgesia was used by all three participants for pain management. Two took a codeine-based preparation which helped decrease their pain most of the time, although one felt the pain never went away entirely. This patient was reluctant to take increased or further analgesia due to polypharmacy. The third patient was taking multiple forms of analgesia, including morphine tablets and liquid, an anti-epileptic for neuropathic pain and paracetamol, but still experienced uncontrolled ulcer pain:

...the medicine I'm taking is not touching me...; ... If I could find a tablet or a medicine that could take it away just for a few hours, I'd be more than happy.

He had previously overdosed on Oramorph® (Boehringer Ingelheim) in desperation to get rid of the pain, leaving him feeling ill for several days. When discussing a previous possibility of having the leg amputated due to a back

Table 4
DFU-related complications

DFU-related complication	Number of patients		
Infection	2 (neuroischaemic = 2)		
Infection and osteomyelitis	4 (neuropathic = 1, neuroischaemic = 3)		
Infection and non-active Charcot	3 (neuropathic = 2, neuroischaemic = 1)		
Infection and osteomyelitis and non-active Charcot	2 (neuropathic = I, neuroischaemic = I)		
Osteomyelitis	4 (neuropathic = 1, neuroischaemic = 3)		
Non-active Charcot	2 (neuropathic = I, neuroischaemic = I)		
Active Charcot	I (neuropathic = I)		

Table 5
Phase two sample demographs

Study number	PI	P2	P3
Gender	M	F	М
Age	72	86	71
Type of diabetes	2	2	2
Duration of diabetes (years)	30	21	10
DFU aetiology	NI	NI	NI
Duration of DFU (months)	17	16	6
Number of diabetes-related complications	2	12	

condition and reduced circulation, he felt that at times amputation would be preferable to continuing in such pain from his ulcer:

I suppose that's the worst I can look forward to, but if it can get rid of that (pointing at the ulcer)...I know it sounds stupid....

He described restlessness at not getting any relief from the pain, describing himself as 'an animal in a cage', stating he'd try anything to decrease the pain.

Physical effects of pain

This theme was identified from patient

comments regarding the effects of DFU pain on physical aspects of their daily life.

Problems with mobility due to pain were discussed by all participants, leading to feelings of loss of independence. One felt his pain was improving as his ulcer was beginning to heal and commented that feelings of loss of control in his life had diminished as his mobility improved.

Another felt decreased mobility had the biggest effect on QoL. Already experiencing limited mobility, the ulcer pain now forced her to use a wheelchair. Footwear problems highlighted previously also had adverse effects.

Another participant identified walking as a dominant factor in increasing his ulcer pain, requiring an electric scooter outside the house and leaving him unable to drive.

Sleep was also altered due to DFU pain, particularly for one. He slept in a chair as he could not tolerate the pressure of the duvet on his foot while in bed, but was awake for long periods during the night. Sleeping tablets were ineffective:

I just move my foot like everybody else does in bed... and that's it, bang, it wakes me up;... about half hour and I wake...; I've gone through the roof with smoking... every time I wake up I've got to have something to do.

He thought lack of sleep made him feel much worse, feeling he could cope much better generally if his sleep improved.

Another commented that pain affected her sleep, finding she needed daytime naps due to tiredness, but felt that analgesia taken at night helped. One participant felt ulcer pain did not specifically wake him during the night, but took sleeping tablets with his bedtime analgesia.

Pain had also led to the loss of a previously healthy appetite for one participant:

Well, I'm not living, it's as simple as that. I've got no appetite, I eat like a pigeon. I used to love my Sunday dinners, but the look of them makes me feel ill now.

Coping, support and social impact

This theme was derived from the patients' accounts of the impact ulcer pain had on their relationship with family, friends and healthcare professionals, including the support they received and coping strategies they adopted.

All participants remarked that they were unable to perform all their activities of daily living independently. This was also due to other medical conditions which affected their general health, such as cardiovascular disease, haemolytic

anaemia and previous back surgery, in addition to the pain.

Help and support from family members also enabled them to cope. One felt the support received from her daughter made a big difference to her daily life and with coping with the pain. She performed dressing changes, reminded her to take analgesia and did the housework. This, however, made the patient feel she was putting pressure on her daughter's time. Feeling a burden on their family was also identified by the other participants, with one commenting that he and his wife had no retirement. Another also depended greatly on his wife, feeling that DFU pain and the limitations it placed on his mobility was impacting on his family relationships:

I've got a daughter nearby... I hardly see her...; I've got to the stage where I don't want anybody... I mean, I love having the grandkids up here but they can be noisy, and it makes me irritable; ... as kids are, they don't realise. I'm frightened when one of them is behind me.All I need is a tap on that and I'm up in the air; ... it has changed my life, without a doubt.

He also felt unable to perform any household maintenance or previously enjoyed social activities, especially as there were steep steps outside his house:

... I'm not in the mood, I just can't be bothered. I'm sick of being in but I don't want to do anything else.

Another participant stated:

I've just been like a zombie. With no interest. Now I'm beginning to get out a bit, I feel better. I want to go out more.

All participants commented on the care received from various clinicians for their DFU and related pain. Two felt that healthcare professionals had provided them with good care and support, which helped them cope:

There was one nurse... she sat with me and gave me comfort. Now that is something that you cannot get with swallowing a bill. One felt psychological support would not have helped, as she felt she had adapted to living with pain. Neither felt there was anything clinicians could have done better.

Conversely, one participant was unhappy with the support he had received from his general practitioner and district nurses, in particular, feeling there was no encouragement with progress of the wound and they were always in a rush to leave. He did feel more supported by the DFU clinic that had referred him to a pain specialist whose interventions had provided some relief for a short while. He was, however, frustrated with delays in treatment.

Psychological impact

This theme concerns the patients' emotions, including feelings of depression, isolation and loss of independence, which overlapped considerably with the other themes due to the wide impact of the pain overall.

Loss of motivation and feelings of depression due to ulcer pain were expressed by two participants:

... the worst time I've got at the moment is getting out of bed in the morning. I need real willpower to go into the bathroom and dress.

I look out there now and think spring is coming, but what can I do? Nothing.

Feelings of isolation and loss of independence were also raised. One participant felt frustrated with the lack of relief from the pain and that the ulcer controlled his life. Two participants did, however, express trying to cope with things by thinking more positively, especially one whose pain was slowly improving.

Discussion

It is acknowledged that the small sample numbers of this study make it difficult to generalise the findings, especially considering the specialist, complex patient population from which they were chosen — although complex patients could be representative of many populations with diabetic foot disease due to the nature

of the disease process itself. The sample does, however, reflect the documented epidemiology for people with diabetic foot disease (Boulton, 2002).

Within the second phase, a larger, more diverse sample would have provided a richer and more consistent data set and increased expression of views due to achieving data saturation. However, valuable information of the lived experience of DFU pain was gained. It would have been interesting to learn the experience of patients with purely neuropathic ulceration to determine any differences in OoL issues.

Phase one

There were similar numbers with NFU and NIU, concurring with previous work estimating 25–50% of DFU are neuro-ischaemic (Edmonds, 1987;Thomson et al, 1991; Oyibo et al, 2002). Ischaemic aetiology is grossly under-represented within the sample — therefore, no analysis was made of pain experienced by these patients.

Peripheral vascular disease (PVD) in a neuropathic patient leads to an increased risk of ulceration, difficulty in healing, and poorer overall outcomes (Boulton et al, 1999). The increased duration of diabetes and number of complications experienced by the neuroischaemic group compared with the neuropathic group could suggest they were generally in poorer health. One aim of the audit was to see if this led to an increase in DFU pain levels, or a difference in the type of pain experienced. The UTCS would have assisted in determining this as it categorises wounds by severity, but due to classification errors the collected data was unsuitable for analysis.

Presence of DFU pain

The results of both study phases support specifically the findings of Ribu et al (2006) and Bengtsson et al (2008), and also the outcomes of general QoL studies of patients with DFU (McPherson and Binning, 2002; Rich and McLachlan, 2003) that pain is a problem present within this population that can impact on QoL.

Contrary to previous opinion (Laing, 1998; Krasner and Sibbald, 2001) that

NFU are painless, eleven patients with NFU reported pain. Patients with NIU also essentially have an insensate foot due to peripheral neuropathy, albeit with added ischaemia, yet also experienced pain. When comparing the two groups, more patients with NIU reported pain than NFU, which concurs with the findings of Ribu et al (2006) but contrasts with those of Bengtsson et al (2008), who found no difference between the presence of pain and aetiology. Laing (1998) suggests that ischaemic ulcers are usually painful to the touch, so the presence of PVD and associated increase in ulcer severity may contribute to the sensation of specific ulcer pain. A direct relationship cannot be assumed, however, as the two variables do not always coincide. A larger study with a comparable group of patients with purely ischaemic ulcers could help determine the effect of ischaemia on the experience of DFU pain.

Characteristics of DFU pain

Analysis of terms used to describe the nature of DFU pain should be interpreted with caution due to the small sample size and the purely exploratory nature of the study. The results obtained are also difficult to place into context as there is little previous research into the issue, and none at all using a tool like the SF-MPQ.

Certain descriptors are commonly associated with particular types of pain, such as aching and throbbing for nociceptive pain typically related to tissue damage, or shooting and stabbing for neuropathic pain, but none consistently or reliably. The most frequently used descriptors for DFU pain had elements common to both nociceptive and neuropathic pain, as is often the case for patients with chronic wounds (Doughty, 2006). This is in opposition to the common views of DFU as being painless or only associated with neuropathic pain (Dallam et al, 2004; Driver et al, 2007). As nociceptive pain descriptors are often used, it suggests that patients were able to isolate the DFU pain from other pain sources, such as neuropathy or ischaemia, which had been a concern for the authors when determining the best method for assessing DFU pain.

This was also supported by the finding that the neuropathic and neuro-ischaemic groups reported similar types of pain. Patients with NIU reported pain that was more frequent, severe, and varied in type than patients with purely NFU, contrasting to Bengtsson et al (2008), who reported little difference in pain intensity between aetiologies.

Affective descriptors of DFU pain assess the emotional aspects of the pain experience. The neuroischaemic group were more likely to use affective descriptors, suggesting DFU pain associated with neuroischaemia can be more emotionally or psychologically challenging. This is an important factor impacting on QoL, as it is already welldocumented that living with a DFU can lead to depression, anxiety and other psychosocial problems (Carrington et al, 1996; Tennvall and Apelqvist, 2000; Vileikyte, 2001). This highlights the need for increased awareness by clinicians of the potential for such issues to arise when dealing with patients with DFU.

There is inconsistency in the results of some SF-MPQs, possibly bearing upon its internal validity. Two patients reported no pain for any descriptors on the questionnaire, but scored 2 out of 100 on the VAS scale. In the authors' opinion, this is due to the accepted margin of error which occurs when using VAS scales. Their scores could not be discounted, but could have led to a slightly larger number being reported as experiencing DFU pain than is actually the case, but also an underestimate of pain on a mean basis. Another patient reported moderate or severe pain for four descriptors, yet recorded a VAS score of 1, suggesting a lack of understanding by the patient and/ or a poor explanation from the clinician on VAS completion. Although the SF-MPO has been demonstrated as valid, reliable and easy to use (Helme et al, 1989; McDonald and Weiskopf, 2001), it has never been used for assessment of DFU pain and therefore its validity cannot be absolutely certain.

Pain and DFU-related complications

The results could potentially be skewed as there were more patients with complications than without. It proved

beyond the scope of this audit to detect any correlation between specific complications and DFU pain, as they rarely occurred independently and the group numbers were too small.

It should be acknowledged that five patients only had a suspected diagnosis of osteomyelitis, highlighting a problem with the audit's cross-sectional methodology, as collecting data at a single time point meant that there was no follow-up of the patients to determine if osteomyelitis was confirmed. The results of further investigations would have been preferential when determining which comparative group the patient was included in for analysis.

Interestingly, the four patients in the sample reporting no pain had one or more DFU-related complications, indicating that the absence of DFU pain was not associated with an absence of complications. It also highlights the complexity of assessing DFU, as normal clinical signs, such as pain and tenderness due to wound infection, are often absent (Edmonds and Foster, 2004).

There is little difference in the mean VAS scores between those with and without complications, contrasting with commonly presented views within the literature indicating DFU pain is only associated with complications (Sibbald et al. 2006). This supports the work of Ribu et al (2006) and Bengtsson et al (2008), as the latter study excluded patients with complications. There was no difference in the number of times severe pain was reported by each group, although patients with complications reported moderate and mild intensity more often. When considering overall SF-MPQ scores, patients without complications actually recorded slightly higher mean scores than those with complications, again contrary to previous views. In the authors' opinion, it is therefore clinically inappropriate to assume DFU pain does not exist except in the presence of complications or advancing disease, although the intensity of the pain might differ.

Patients with complications used more affective descriptors for their pain than those without, indicating the emotional effect of pain and complications combined is more intense. This could be due to the anxiety such patients may feel when told that they have an infection, osteomyelitis or Charcot arthropathy. These issues are an added complication to the existing DFU, presenting a further risk of future problems, such as foot deformity, reduced mobility or amputation.

Management of DFU pain

Findings regarding analgesic use are similar to those of Ribu et al (2006), showing a higher percentage of patients reporting DFU pain were taking analgesia than those without. It is difficult to draw implications for analgesic use in DFU pain here as many patients were taking analgesia for other problems. As 57% were taking analgesia at assessment, it is possible that concomitant analgesic use could lead to underestimation of DFU pain.

As found with studies looking at VLU and use of analgesics, there were patients experiencing DFU pain that took no form of pain relief, as with the Ribu et al (2006) study, suggesting that DFU pain management requires attention from clinicians.

More patients with NIU taking analgesia than NFU could indicate that presence of ischaemia in the neuro-ischaemic foot is the main factor for the increase in severity of DFU pain, therefore requiring more treatment with analgesics. It could, however, be a coincidence due to the large number within the sample requiring analgesia for other problems. The pilot study by Bengtsson et al (2008) found little difference between analgesic use for the two groups, and as this was using much larger numbers than this audit, suggests any results should be interpreted with caution.

Callus build-up causing raised foot pressures (Young et al, 1992) could potentially cause DFU pain. The average VAS and overall SF-MPQ scores were less for those who attended regular podiatry appointments, suggesting regular debridement could contribute to decreasing pain levels. The groups were however not comparable in terms of size.

Pressure-relieving footwear could provide pain relief due to decreased pressure and contact with the ulcer surface. The results did not support this theory as average VAS and overall SF-MPQ scores for patients wearing some form of pressure-relieving footwear were slightly higher than for those wearing normal shop-bought footwear. However, the difference was very small and again, the groups were not entirely comparable in size.

Phase two Experience of pain

The reported descriptions of pain are varied and intense in nature, similar to the results of the SF-MPQ used in phase one. Despite the common perception that neuropathy leads to painless ulcers, the patients were not surprised to be experiencing pain. Preconceptions often held by patients and clinicians regarding the pain experience need addressing if DFU pain is to be understood and adequately managed.

Causes of pain were similar to those reported by qualitative studies relating to DFU as a whole (Ashford et al, 2000; Ribu and Wahl, 2004), with pressure from footwear or bedding being recurrent themes. Pain at dressing change has been noted by these studies, and is a common finding with studies related to wound pain (Mudge et al, 2006; White, 2008; Price et al. 2008). As with one patient here, leg ulcer studies have reported how individual clinicians' technique and basic understanding can impact on the experience, with patients feeling that they are not listened to or cared about (Charles, 1995).VLU were once considered painless or not as painful as arterial ulcers, which potentially caused increased pain at dressing change due to a poor knowledge base — a similar situation could occur with DFU due to the preconception that the pain sensation is compromised. Although pain at dressing change is becoming a more prominent and researched area, more consideration needs to be given to treatment of DFU with the awareness that they can be painful.

Problems with footwear are commonly cited within the QoL

research relating to both DFU and VLU (Ashford, 2000; Ebbeskog and Ekman, 2001; Ribu and Wahl, 2004; Mudge et al, 2006), although not always necessarily related to pain. The dissatisfaction or difficulties expressed by two patients regarding finding appropriate footwear could be an important issue for future care. Appropriate footwear for patients with DFU is paramount due to the requirement for offloading to improve healing (Krasner, 1998; Frykberg, 2002; Jeffcoate and Harding, 2003). Use of appropriate orthoses can improve physical and mental functioning in diabetic patients (Davies et al, 2000), reinforcing the requirement for efficient and effective orthotic services within diabetic foot clinics to not only improve healing, but also QoL. The adverse effect of footwear on DFU pain is a significant issue for any healthcare professional involved in the management of DFU, which again requires raised awareness and consideration within service provision.

Participants reported varying efficacy of analgesia for controlling DFU pain. Whereas previous literature is mainly concerned with the under-use of analgesia or the fear of dependence by patients (Ribu and Wahl, 2004; Persoon et al, 2004), some findings here suggest DFU pain can be so severe and multifactorial that oral analgesia alone may not be sufficient. The only temporary relief one patient experienced was following referral to a chronic pain specialist, yet until clinicians acknowledge that specific ulcer pain exists and is not necessarily of neuropathic origin, there may be minimal referrals to specialist services. Management of some DFU pain may require treatment such as nerve blocks, psychological support or complementary therapies. Further research into this area alone is necessary if DFU pain assessment and management is to become even adequate.

Physical effects of pain

The majority of research into chronic wounds and QoL suggests that they impact significantly on physical aspects of daily life, consistently highlighting issues with mobility and sleep (Charles, 1995; Brod, 1998; Ashford et al, 2000; Kinmond et al, 2003; Ribu and Wahl, 2004). The

consequences of such issues appear far-reaching in terms of fatigue, loss of independence and social isolation.

Similar reports were found here, particularly with regard to mobility. Standing and walking even short distances was found to increase pain, which concurred with previous findings of both quantitative and qualitative studies (Ashford et al, 2000; Ribu and Wahl, 2004; Ribu et al, 2006; Bengtsson et al, 2008). Some patients with DFU report frustration at the enforced decrease in mobility due to the need to offload the foot, and state that they would rather adopt risk-taking behaviours and accept the possible consequences to their physical health for an increase in their OoL (Ashford et al, 2000; Ribu and Wahl, 2004). If pain, however, is the cause of reduced mobility, this option may not be available, leaving patients feeling completely restricted and isolated and with few coping mechanisms on which to depend. Achieving ulcer healing may be the only way of returning to a more normal physical functioning, as described by one participant.

Sleep was an important issue for patients in this study and previous work, leading to extreme fatigue and changes in mood (Brod, 1998; Douglas, 2001). The patients seem to become trapped in a vicious circle whereby the consequence of one problem exacerbates another: Increased fatigue due to sleep deprivation leads to further decreased mobility, which increases fatigue further due to patients becoming lonely, isolated and lacking in energy and motivation.

The results reinforce that the impact of physical restrictions from DFU pain has the same widespread effect on psychosocial well-being, as other types of chronic wound. This emphasises the need for a holistic approach to facilitate a better understanding of patients' needs.

Coping, support and social impact

The accounts of DFU pain causing increased dependence on others for assistance with simple daily activities is in accordance with general QoL studies into patients with DFU and VLU (Kinmond et al, 2003; Ribu and Wahl, 2004; Watson-

Miller, 2006). This causes feelings of loss of control and loss of self, which can leave patients anxious, depressed and vulnerable. While supportive families are a common theme within this study and others, and recognised as invaluable by patients, it is common for patients to feel burdensome and guilty, placing unwanted restrictions on their loved ones, especially if partners are elderly and may not be in perfect health. These issues can affect relationships whereby patients feel a loss of their previous life and a change in their social role, as reflected by the comments of one subject regarding not being able to play with his grandchildren or wanting to socialise with other family and friends. These comments are again a recurring theme in other OoL literature on patients with chronic wounds, where fear of others knocking their wound and causing pain led to the avoidance of social or public situations (Husband, 2001; McPherson and Binning, 2002; Kinmond et al, 2003; Rich and McLachlan, 2003; Mudge et al, 2006). Again, a perpetual cycle may develop where decreased mobility and increased dependence leads to social isolation, leaving patients depressed and not wanting contact with others. One patient alluded to such feelings, mentioning he could not perform tasks related to the upkeep of his home, a restriction which may have left him with feelings of low self-worth due to his change of role within the family. These issues highlight the extent to which DFU pain can restrict individuals and compromise lives.

Varying positive and negative relationships with healthcare professionals were reported by participants. The literature suggests many patients with chronic wounds become disillusioned with their healthcare professionals, feeling that their personal experience is not being recognised, thus inhibiting freedom of expression (Watson-Miller, 2006), and that they are not provided with enough education or involvement in decisionmaking regarding their care (McPherson and Binning, 2002). Others get frustrated with the inconsistency of treatment and develop a lack of confidence in their healthcare professional (Rich and McLachlan, 2003). It has been suggested that clinicians become focused on treating illnesses rather than people, or on curing rather than helping patients to live and cope with chronic illness (Pott, 1992; Husband, 2001) — this may be the case with the patient who felt ignored and that his clinicians never offered him encouragement or reassurance, but seemed only concerned with completing the task in hand (redressing the ulcer) as guickly as possible. The ulcer and its healing can become the sole focus of all interventions, and the clinician loses sight of the personal experience and caring perspective. This underlines the need for clinicians to develop effective interpersonal skills and consider psychosocial aspects to recognise individual needs. The aim should be to prevent or lessen the psychosocial implications of DFU pain in the same way as physical treatment. Support in the form of allowing patients to talk, providing comfort and information-giving were the factors which participants felt fostered good relationships with their healthcare professional and helped them to cope.

Psychological impact

The psychological impact of DFU pain is a common thread running through all the themes already discussed — the experience of pain, physical restrictions and changes in relationships all led to feelings which created a change in psychosocial well-being. Several comments dealt solely with feelings of depression, loss of motivation and resignation at their situation and the effect it was having on their lives.

Increased anxiety and depression in patients with diabetes and foot ulcers has been documented (Carrington et al, 1996; Brod, 1998; Tennvall and Apelqvist, 2000; Anderson et al, 2001). These feelings can be enhanced due to concern that ulcers will never heal and a fear for the future at the loss of hope over regaining any control over their lives. One patient commented that the ulcer and pain controlled him, leaving him without positive thoughts. Another expressed a loss of motivation to even get up and wash and dress, yet was concerned about being a burden on his carer and frustrated at his lack of independence. Fear of amputation and its link to depression is often mentioned within the

literature (Ribu and Wahl, 2004; Watson-Miller, 2006), yet the desperation and anxiety felt by one patient regarding the lack of relief from his DFU pain had led him to question if amputation would be the more preferable option. These issues underline the importance for clinicians to pay more than lip service to holistic and psychological care, especially with regard to patients experiencing DFU pain, if prevention and management of such severe emotions is to be achieved.

Some patients coped with the feelings surrounding their DFU pain and its impact on their lives by either resigning themselves to its existence and their need to adapt to it, or by trying to think positively rather than succumbing to negative feelings. Husband (2001) suggested that after a period of adaptation and endurance of longterm ulceration patients may learn to shift the focus of their life away from the ulcer in order to cope with it. Small improvements in one patient's ulcer pain may have enabled him to see a future without pain and a return to his old feelings of self. Either way, clinicians need to consider helping the patient to cope and adapt to potentially chronic conditions, while also trying to address physical needs and ulcer healing.

Conclusion

The overall results of this study continue to establish that pain specifically from DFU is a phenomenon that is experienced by patients within normal clinical practice, and is a distinct and individual factor in reduced quality of life. Due to previous assumptions that pain only occurs in relation to DFU complications, this phenomenon is only just becoming recognised but remains underestimated and under-researched. This study highlights that pain from DFU can be severe and affects QoL in similar ways to pain from other wound types.

Further research is required to ascertain the prevalence of DFU pain on a wider scale, and once this has been established, advice for clinicians on the assessment and management of DFU pain would be a welcome addition to clinical guidelines on the diabetic foot, such as those offered by NICE and

the IDF. The need for more accurate and responsive pain assessment is accentuated, as nearly half the patients audited reported pain >40mm on a VAS, which WUWHS (2004) guidelines state requires immediate attention. As with other types of wound pain, inadequate use of analgesia is a problem warranting more investigation. The potential for patients to experience specific pain from DFU is also important for clinicians to be aware of when performing procedures such as sharp debridement, and generally at dressing changes, as it is often assumed that these procedures can be performed without consideration to causing pain due to the presence of neuropathy.

Consideration should also be given to further investigation of the impact of DFU pain on life quality from the patient's perspective. Awareness of the physical and psychosocial impact of such pain should be raised to facilitate clinicians to provide effective holistic care. **W**UK

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Key points

- Specific ulcer pain from DFU can occur despite the presence of sensory peripheral neuropathy.
- Assessment and management strategies for DFU pain need to be improved to ensure a high standard of clinical care for patients.
- DFU pain is not solely linked to the occurrence of related complications, such as infection, osteomyelitis or Charcot arthropathy.
- The potential for, or existence of DFU pain needs to be acknowledged by clinicians before performing potentially painful procedures such as sharp debridement and dressing changes.
- DFU pain can impact on patients' life quality both physically and psychosocially in a similar manner to pain from other wound actiologies

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